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**Department of Health**

National Industrial Chemicals  
Notification and Assessment Scheme

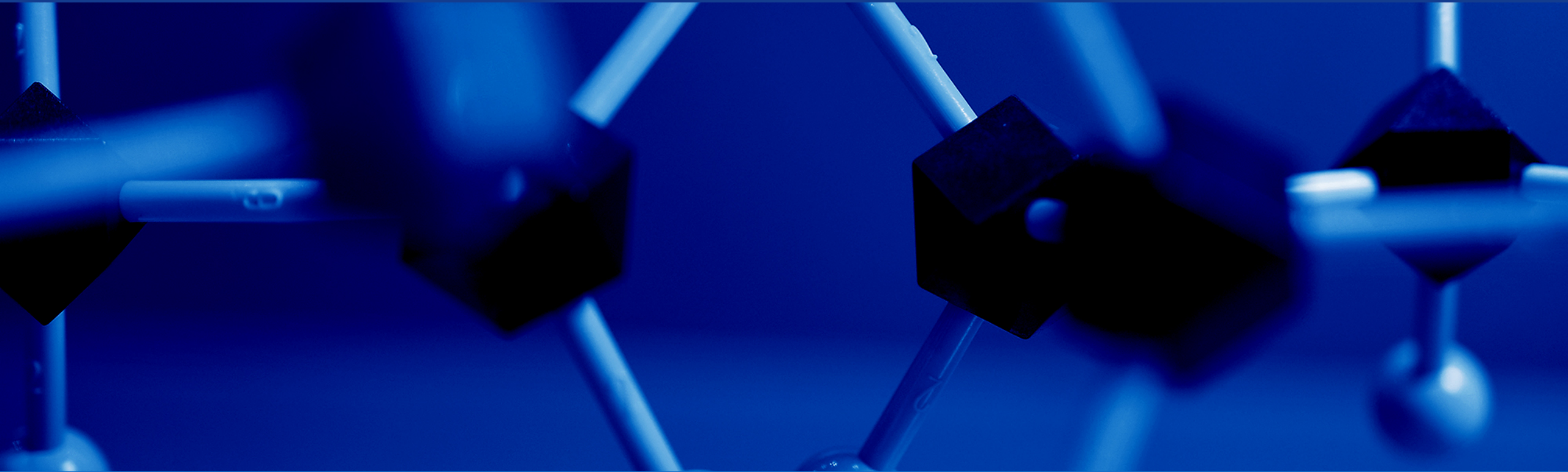
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# **NICNAS ATA Webinar Presentation**



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**Dr Sarah Rumble**  
**Principal Adviser, NICNAS Reforms**

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**Alexander Cubis**  
**Stakeholder Adviser, NICNAS Reforms**



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# About NICNAS

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## About NICNAS

- Statutory scheme administered by the Australian Government Department of Health
- Established in 1990 under the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act)
- Aims to protect human and the environment by assessing the risks to occupational health and safety, public health and to the environment, that could be associated with the importation, manufacture or use of industrial chemicals.



## About NICNAS (cont.)

- Fully cost recovered operations
- Registration charge for importers and manufacturers fund the scheme
- New chemical assessments provided on a fee for service basis
- NICNAS' Director is a statutory office holder with specific functions and powers under the Act

# Why NICNAS was established?

## States and Territories

## Multiple sectors

### Environment



### Public health



### Workers health



- NICNAS avoids duplication of regulatory effort
- Works towards nationally harmonised regulatory controls



# Obligations under the ICNA Act

## NICNAS

- Chemical introducers register
- Maintain the chemical inventory
- Assess new chemicals
- Review existing/assessed chemicals
- International treaties
- Provide human health and environment risk assessment data
- Maintain Cosmetic Standard

## Chemical Introducers

- Maintain a current registration
- Check AICS for existing chemicals listings
- Meet any AICS listing conditions
- Notify new chemicals
- Meet 'exempt from notification' requirements and/or annually report new chemicals.





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# Registration

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## NICNAS registration

- All importers and/or manufacturers of industrial chemicals for commercial purposes must register with NICNAS regardless of the amount of industrial chemicals imported and/or manufactured in that registration year. *The registration year runs from 1 September to 31 August in the following year.*
- NICNAS registration is not the registration of individual industrial chemicals or actual products and should not be confused with the notification and assessment of industrial chemicals. *NICNAS registration is the registration of your business.*
- It is an offence for a person to introduce relevant industrial chemicals without a NICNAS registration in force..



# Registration

- Provides regulatory tools to assist industry with their regulatory obligations under the ICNA Act
- Ensures that chemical information on the safe use of industrial chemicals is widely available to all key stakeholders
- Funds the maintenance of AICS and Register of Chemical Introducers



## What is an industrial chemical?

- 'Industrial chemical' means a chemical that has an 'industrial use', whether or not it also has an 'excluded use'.
- 'Industrial use' in relation to a chemical means a use other than an excluded use.
- Industrial chemicals can include but are not limited to solvents, adhesives, plastics, inks, paints and coatings, household cleaning products, cosmetics and toiletries for commercial use.
- In your industry, this could include art, craft, and hobby supplies, children's cosmetics (e.g. face paints), certain toys (e.g. play doh putties)



## Industrial chemicals – excluded use

- Excluded use means sole use as:
  - an agricultural or veterinary chemical or a constituent of an agvet chemical;
  - therapeutic use, or use as an ingredient or component in the preparation, or manufacture, of goods for therapeutic use; or
  - use as food intended for consumption by humans, or animals, or a constituent of such food, or use as a food additive.
- 'Excluded use' chemicals are regulated by:
  - APVMA: pesticides and veterinary medicines ; FSANZ: food additives and residues; TGA: medicines and medical devices



## Excluded industrial chemicals

- Naturally-occurring chemicals
- Biological material
- Incidentally-produced chemicals
- Reaction intermediate chemicals
- Radioactive chemicals
- Articles are (a) products manufactured for use for a particular purpose, being a purpose that requires that the object have a particular shape, surface or design; and (b) is formed to that shape, surface or design during manufacture; and (c) undergoes no change of chemical composition when used for that purpose except as an intrinsic aspect of that use.

# Relevant industrial chemical

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- Imported and/or manufactured (introduced):
  - for a commercial purpose
  - not an excluded use
  - not naturally occurring
  - not an article
  - relevant tariff classification



# Total value of relevant industrial chemicals

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Manufactured chemicals

Factory cost = cost of labour + cost of materials + factory overheads

Imported chemicals

Customs value + Customs duty + insurance and freight

Imported + manufactured

See NICNAS registration on our website

NB: Relevant commercial documents relating to your introductions must be kept for at least 5 years





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# Introducing existing chemicals under the current scheme

03



# Australian Inventory of Chemical Substances (AICS)

- AICS contains listings for approximately 40,000 'existing chemicals'
- Distinguishes 'new chemicals' from 'existing chemicals' - chemicals not listed on the AICS are regarded as a 'new chemicals'
- Only holds chemical identity data; does not contain information on hazards, toxicity
- Has two sections 'public' (non-confidential) and 'confidential'.



## Introducing 'existing chemicals'

- Business registered with NICNAS can introduce chemicals listed on AICS.
- Chemicals listed on the AICS but introduced other than in accordance with a condition of use on a listing are also new chemicals
- New chemicals must be notified and assessed before being introduced into Australia or be able to be 'exempt from notification' and enjoy an exemption



## Secondary notifications / Conditions of use

- If an chemical is listed on AICS as an existing chemical and has been assessed by NICNAS with 'secondary notification conditions', please email [info@nicnas.gov.au](mailto:info@nicnas.gov.au) with: CAS ID, distinguishing name, concentration, volume, and end use.
- Any other conditions of use must also be met.
- Remember: If a chemical is on the AICS and has no secondary notification or condition of use requirements, then you can introduce this chemical as long as you maintain your registration with NICNAS.



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# Introducing new chemicals under the current scheme

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## New chemicals

- A new industrial chemical is an industrial chemical that is not listed on the AICS; or
- an industrial chemical that is proposed to be introduced other than in accordance with a condition of use to which its listing on AICS is subject.
- Companies introducing a new industrial chemical must notify the chemical to NICNAS or satisfy the requirements for introduction 'exempt from notification'



# New chemicals exempt from notification – “exemptions”

- Available for new chemicals which are
  - Low risk chemicals (low hazard, low introduction volume, and/or low concentration)
  - Require risk assessment by introducer prior to application
  - Most have annual reporting requirements to NICNAS
- For some exemptions you also need to provide us with information before you import and/or manufacture and keep evidence that the chemical poses ‘no unreasonable risk’ to work health and safety, human health and the environment.



## New chemicals under permit or certificate

- If a new chemical does not meet the criteria for an exemption it cannot be introduced into Australia until it has been notified by the introducer and assessed by the NICNAS
- The New Chemicals program will determine if the chemical is to be introduced via a permit or certificate based on its risk profile
- A permit or certificate is issued following a NICNAS assessment to identify potential risks to worker health and safety, public health and the environment; that may be associated with the manufacture, formulation, use, storage and disposal of the new chemical(s).





# New chemicals

## Permits

- Conditions imposed specifying volume and duration
- Time frames 14-28 days
- No reports published
- Chemical not added to the inventory

## Certificates

- More data requirements
- Time frames 28-90 days
- Full public reports published
- First 5 years only certificate holder(s) can introduce the chemical
- Chemical added to the inventory after 5 years unless confidentiality requested



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# Questions and discussion



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# NICNAS Reforms



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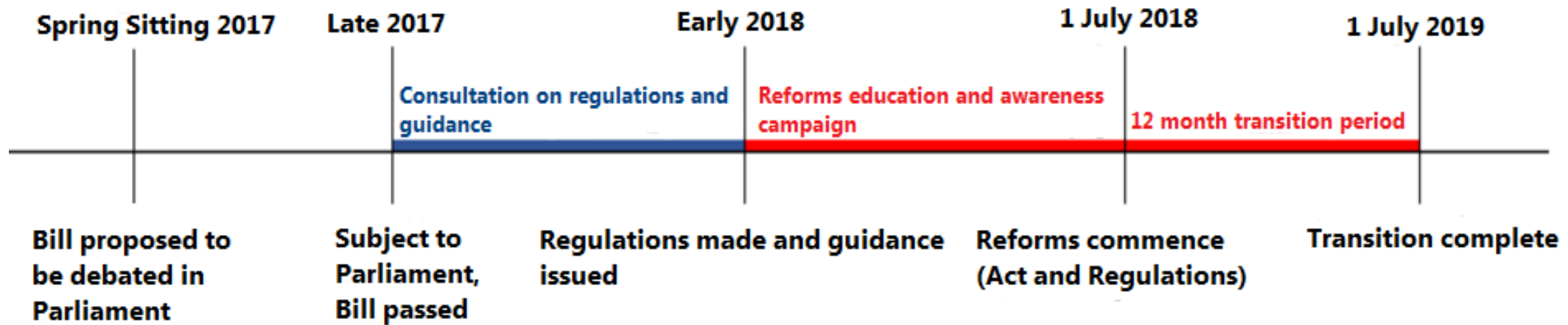
# NICNAS Reforms

- Announced in May 2015 – Implementation on 1 July 2018
- Primary legislation introduced into Parliament Autumn 2017; Passed lower house on 17 October 2017.
- Establishment of the new scheme:
  - Australian Industrial Chemicals Introduction Scheme (AICIS)
  - some changes may take effect before July 2018\*
- The new scheme aims:
  - rebalance pre-and post-introduction regulatory requirements
  - provide greater focus on high-risk chemicals
  - streamline risk assessment processes
  - administer more appropriate monitoring and compliance tools



# NICNAS Reforms

## Proposed implementation timeframe





# NICNAS Reforms

## Implementation detail

- Extensive stakeholder consultation:
  - public consultation papers (5)
  - workshops (10)
  - review of written submissions (~178 to date)
  - consultation with various national and international organisations (>100, more anticipated)
- Proposals adjusted to accommodate stakeholder views when consistent with Government decision (see consultation papers and supporting documents)



# NICNAS Reforms

## The new legislation

- delivers a risk-based and proportionate regulatory approach:
  - low risk chemicals - reduced pre-introduction regulatory intervention balanced by increased post-introduction monitoring
  - faster regulatory pathway to introduction of lower risk new industrial chemicals provides an incentive to introduce safer chemicals
  - requires pre-introduction assessment for higher risk chemicals only
- enables more targeted and effective risk management:
  - greater focus on post-introduction assessment and monitoring – maintaining the protection of consumer health and safety; workers and the environment.



# NICNAS Reforms

## What features of the scheme remain unchanged?

- New legislation will apply to same range of chemicals
- Regulation will remain a shared responsibility between all levels of government (Commonwealth, states/territories, local government)
- The scheme will continue to regulate chemicals at the point of introduction
- Commonwealth standard-setting bodies will continue to set national standards
- State & Territory risk managers will continue to regulate use in accordance with national standards





# NICNAS Reforms

## What will change?

- Changes will address problems/issues with current framework :
  - low risk chemicals are subject to unnecessarily intensive pre-introduction assessments
  - cumbersome, inflexible assessment processes that are not commensurate with risk
  - no capacity to refuse or stop introduction of a chemical if the risk from its proposed use cannot be managed
  - non-transparent post-market obligations on industry
  - current enforcement powers limit our ability to identify and effectively and efficiently address non-compliance



# Registration & Inventory obligations

## Registration

- Businesses must be registered be with AICIS to introduce industrial chemicals**
- Certain introducers will be excluded from having to register e.g. companies that are only transshipping chemicals**
- Annual compliance declarations simplified as part of annual registration**

## Inventory obligations

- All introduced chemicals will still need to be checked against the inventory to determine further regulatory obligations**
- Listing may include terms relating to the chemical's introduction:**
  - defined scope of the assessment/evaluation**
- May also include continuing obligations to provide information:**
  - On new hazards identified since an AICIS assessment/evaluation or in specified circumstances**



## AICIS evaluations

- The Executive Director may initiate evaluations of any listed or unlisted industrial chemical, or group of industrial chemicals
- Triggers may include:
  - international regulatory action
  - adverse events or requests from risk managers/other Government agencies
  - prioritised for evaluation by AICIS
- Flexible evaluation process tailored to address issue(s) of concern
- Able to issue voluntary or mandatory call for information on chemicals subject to evaluation



# Categorisation of chemical introductions

- Introducers will self-categorise their chemical introduction
  - Designed to determine regulatory treatment of that introduction
  - Primary legislation to establish broad framework
  - Detailed guidance material and online tools will assist with categorisation
  - Specific criteria to be detailed in delegated legislation
  - Further stakeholder consultation on delegated legislation and guidance material
  - Stakeholder views will be taken into account in finalising categorisation criteria to be presented to Government



# Categorisation of chemical introductions

All chemical introductions must meet the requirements of an introduction category:

- Listed introduction (chemical on inventory, introduction within terms of listing)
  - Exempted introduction
  - Reported introduction
  - Assessed introduction
  - Commercial evaluation introduction
  - Exceptional circumstances introduction
- } Unlisted chemical introductions



# Key features of the chemical introduction categories

Key features	Introduction category		
	Exempted introductions	Reported introductions	Assessed introductions
<b>Indicative risk</b>	Very low risk	Low risk	Medium to high risk
<b>Pathway to Inventory inclusion</b>	No	No	Yes
<b>Level of interaction with AICIS (pre-market)</b>	None	Report to AICIS	Assessed by AICIS
<b>Record keeping and/or information requirements</b>	Record keeping	Record keeping and information submitted (pre-market)	Specified information submission
<b>Details published</b>	Not published	Limited information published	Assessment statement published and linked to later inventory listing
<b>Continuing obligations</b>	Annual declaration of introducer	Annual declaration of continued compliance	Post-assessment information obligations



# NICNAS Reforms

## Risk matrices

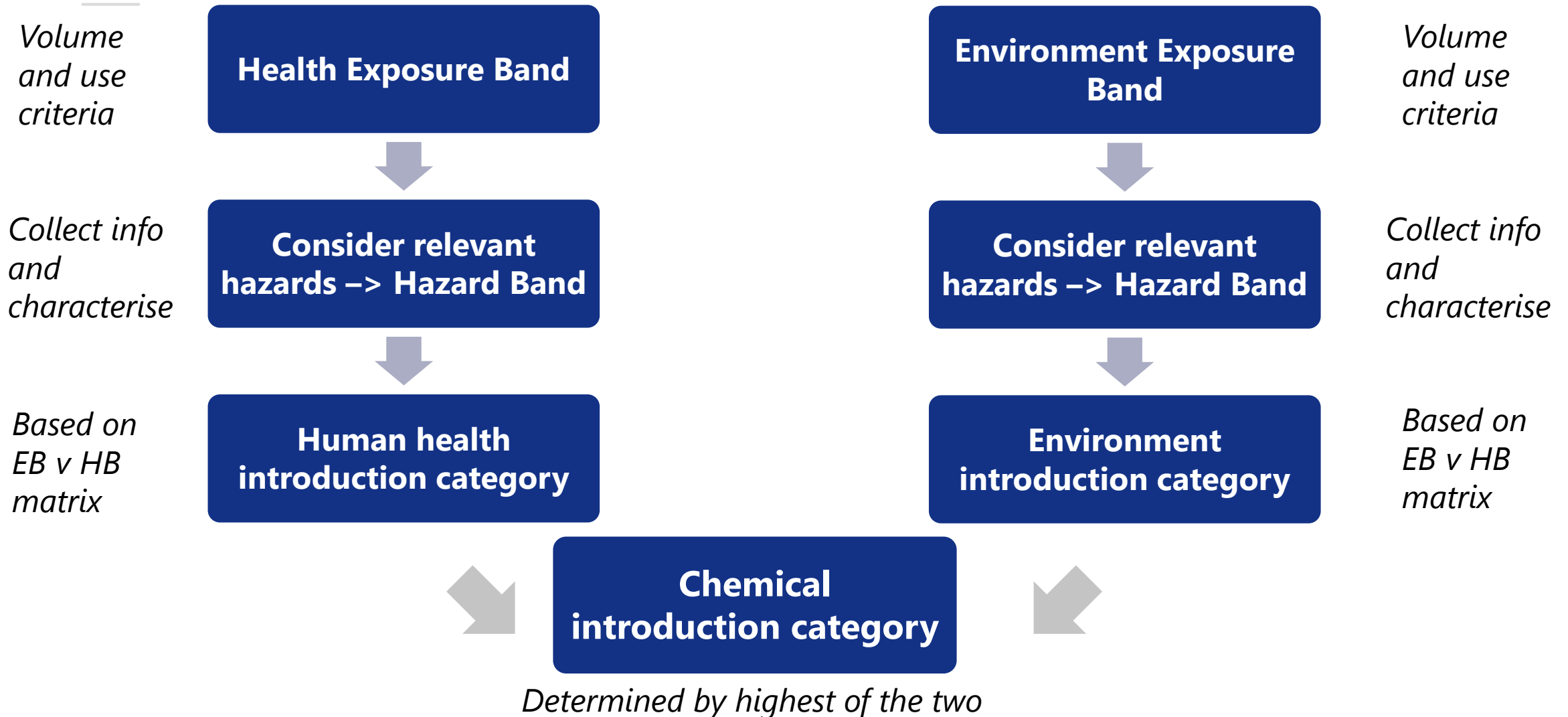
Hazard Band	D				Assessed	
	C					
	B	Exempted		Reported		
	A					
		1	2	3	4	5
Exposure Band						

Human health

Hazard Band	E					
	D				Assessed	
	C			Reported		
	B	Exempted				
	A					
		1	2	3	4	5
Exposure Band						

Environment

# Categorisation process using hazard & exposure







# Categorisation - information requirements

- Introducer must hold or have access to information to support the categorisation
  - if held by a 3<sup>rd</sup> party it must be supplied to AICIS if requested
- Level of information needed increases with potential exposure and/or with increasing category
- Rules will prescribe high-level description of requirement
  - Characterisation Guide and approved forms will describe the detail

*For further details - these requirements are presented in Consultation Paper 5 and its supporting document.*



# Reported introductions – pre-introduction reporting to AICIS

## Required prior to introduction through on-line portal

### Report includes:

**Chemical name**

**Hazard classification/information (commensurate with exposure)**

**Annual introduction volume – within defined bands**

**Proposed maximum introduction and use concentrations – within defined bands**

**Proposed use of the chemical – chosen from high level use descriptors**

**Whether the chemical is introduced on the basis of an international assessment –  
“International Pathway”**

**additional information requirements may apply (eg. details of jurisdiction, end use,  
recommended risk management controls etc)**



## Reported introductions - International pathway

- Introduced under the Reported category based on risk assessment by a trusted international regulator
- Trusted international regulators determined through application of criteria  
(Health portfolio regulators)
- Chemical introduction must have been assessed for:
  - health and environmental risks (or be categorised as “Reported” for missing aspect)
  - same use and same or higher concentration
  - risk assessment assumptions consistent with those relevant to Australia
  - risk management measures specified overseas can be applied in Australia



## Assessed introductions – regulatory treatment

- Electronic lodgement – through portal
- Assessment will focus on area(s) of concern – human health and/or the environment
- Consultation with risk managers, where required
- Results in granting or refusing an assessment certificate
- Pathway to the Inventory
  - listed after 5 years or
  - earlier if requested
- Assessment statement published on AICIS website and linked to subsequent Inventory listing



# Assessment statements

- Assessment statements **will** include:
  - a summary of the risk assessment
  - recommendations to risk managers
  - defined scope of assessment
  - conditions of introduction (if any)
- Assessment statements will **not** include:
  - Trade name
  - Name of introducer
  - Confidential business information



# Commercial evaluation authorisation

- Evaluation must **not** involve:
  - the chemical being made available to the general public on its own, in combination with other chemicals or in an article
  - release of the chemical to the environment without prior treatment
  - uncontrolled use in the workplace.
- Subject to conditions, including volume and site
- No pathway to the Inventory
- Post-authorisation information obligations – consistent with assessed chemicals
- Time limited authorisation (maximum 4 years)



# Ministerial Authorisation

- Used in exceptional circumstances - expected to be used infrequently
- For introduction of unlisted chemical urgently required to protect public health or environment (eg to manage an environmental disaster)
- Time-limited and conditional authorisation
- Similar provision to current s30 permits
- Introducer must be registered with AICIS for the period of introduction
- Not listed on the Inventory – unless subsequently assessed by AICIS



# Monitoring and enforcement powers

- Acknowledged the need to strengthen AICIS's monitoring and enforcement powers to support a framework of risk-based post-market monitoring and enforcement
- Will allow AICIS to more efficiently and effectively identify and address non-compliance with penalties better aligned to the seriousness of the non-compliance
- Derived from *Regulatory Powers (Standard Provisions) Act 2014*, AICIS will be given power to:
  - Issue infringement notices
    - Person can pay or elect to have the matter dealt with in court
    - AICIS would have discretion to issue or not
  - Enter into enforceable undertaking
    - Certain details of these would be published on website for duration of undertaking
  - Apply for the imposition of criminal offences **and** civil penalties





## Other changes

- The Government has agreed that certain functions will be transferred from AICIS to other Commonwealth agencies:
  - Administration of the Rotterdam Convention – to the Department of the Environment and Energy (pending enactment of new legislation)
  - Administration of the Cosmetics Standard – relevant departments are considering options to deliver the policy intent
- Implementation of Government's election commitment to prohibit use of new animal test data for cosmetic ingredients



# Ban on new animal testing data for cosmetic ingredients

- Implementation of Government's election commitment to prohibit new cosmetic ingredients that have been tested on animals
- Vertebrate animal test data produced after 1 July 2018 cannot be used to meet the information requirements for categorisation or assessment of unlisted chemical introductions, where the only end use is cosmetics.
- Limited circumstances where data may need to be considered to protect human health and the environment:
  1. *Human health* – where data generated for other purpose shows adverse effect, introducer can't ignore it.
  2. *Environment* – data on environmental hazards could be used if there is no validated non-animal alternative



## Quick wins for industry (subject to parliamentary approval)

- Changes to the Polymer of Low Concern (PLC) criteria
- Exemption of PLCs from notification requirements
- Removal of annual reporting for permits and self-assessed certificates
- Removal of final statement requirement for registration
- Removal of SDS and label requirement for certain cosmetics exemptions
- Simplification of the annual reporting obligations
- Changes to the definition of a new synthetic polymer (2% rule)
- Reduced timeframes for Approved Foreign Scheme categories



## For details on the reforms

Please see the **NICNAS Reforms webpage** at <https://www.nicnas.gov.au/reforms>

### ■ Primary legislation:

outlines the overarching framework for the reforms

**see Parliament website for details of introduced Bills**

**(link from NICNAS Reforms webpage)**

### ■ Delegated legislation:

details technical matters of the reforms, in particular, relating to the categorisation and assessment of unlisted chemical introductions

(chemicals not included on the Inventory)

**see Consultation Paper 5**

*NB: Not all stakeholders will need to engage in the level of technical detail presented in Paper 5.*



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## Need further information?

On the web: <https://www.nicnas.gov.au/reforms>

NICNAS Reforms staff are available for stakeholder briefings and additional consultation.

Please call: +612 8577 8837

Email: [NICNAS.Reforms@nicnas.gov.au](mailto:NICNAS.Reforms@nicnas.gov.au)



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# Questions and discussion



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**Thank you for attending  
today's seminar**

**Tel: 02 8577 8800**

**Email: [info@nicnas.gov.au](mailto:info@nicnas.gov.au)**

**Freecall: 1800 638 528**

**NICNAS**

**GPO Box 58**

**Sydney NSW 2001**

**[nicnas.gov.au](http://nicnas.gov.au)**



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