



Australian Government

Department of Health

National Industrial Chemicals
Notification and Assessment Scheme

NICNAS to AICIS



March 2020



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Notification and Assessment Scheme

New scheme: same mission



nicnas.gov.au



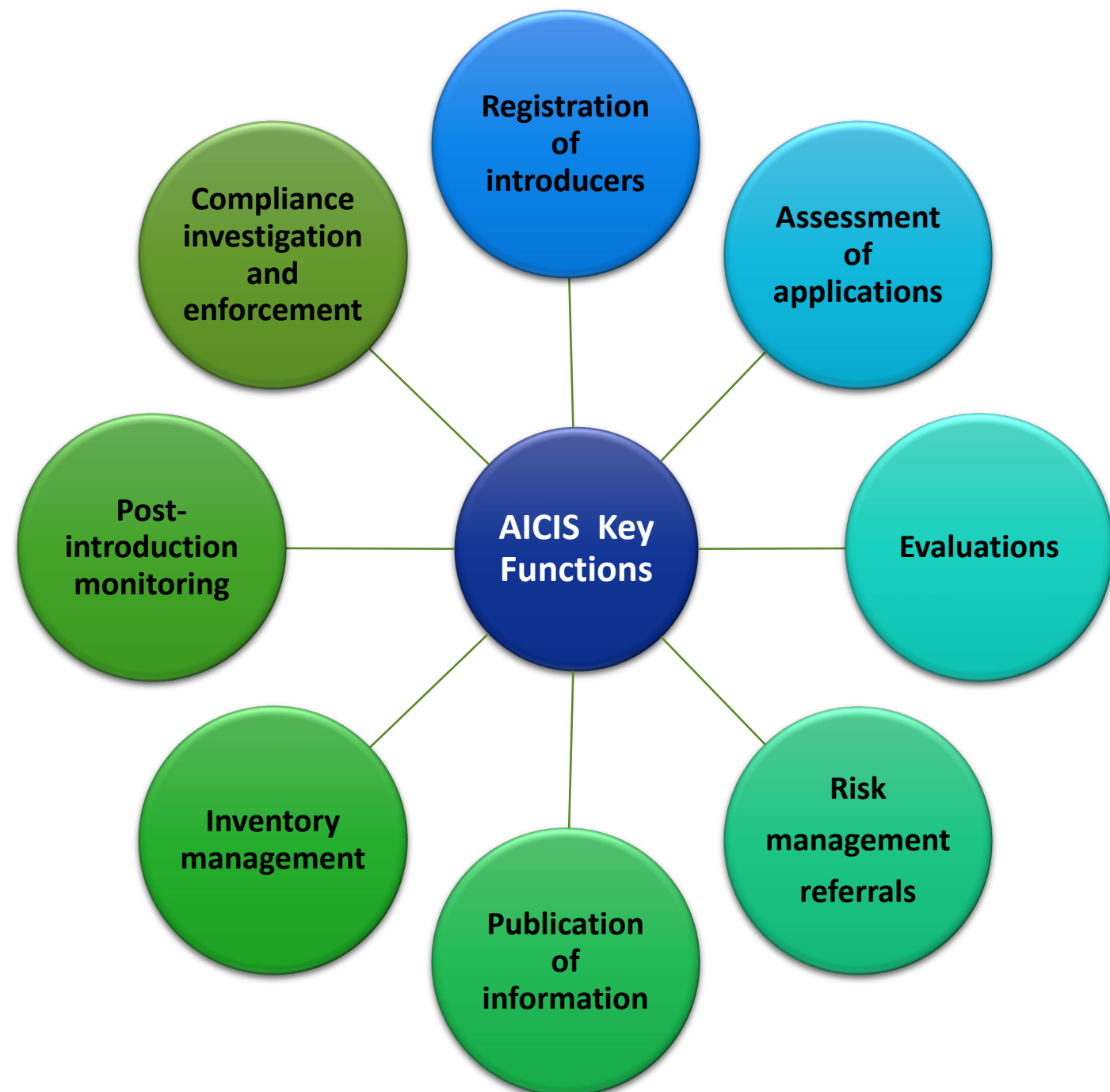
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Key functions of the new scheme





Principles of the new scheme

- Risk-proportionate regulation
- Rebalanced pre-introduction versus post-introduction controls
 - less pre-introduction assessment by focusing on assessing higher risk introductions
 - more post-introduction monitoring and evaluation
- Incentivising lower risk chemical introductions
- Flexible and responsive process for evaluating chemicals on the market



Principles of the new scheme

- 'Risk manager of last resort' powers (where risk can't be managed)
- Graduated compliance powers
- Greater transparency by balancing confidentiality and publication
- Greater use of international assessment materials
- Restrict the use of animal test data for ingredients used in cosmetics



Things that stay the same

- Same range of chemicals
- Same way to define industrial use: by exclusion
- Same point of regulation: at introduction to Australia
- Same regulatory role: risk assessments and recommendations for risk management
- Same primary object of the scheme: help protect human health and the environment



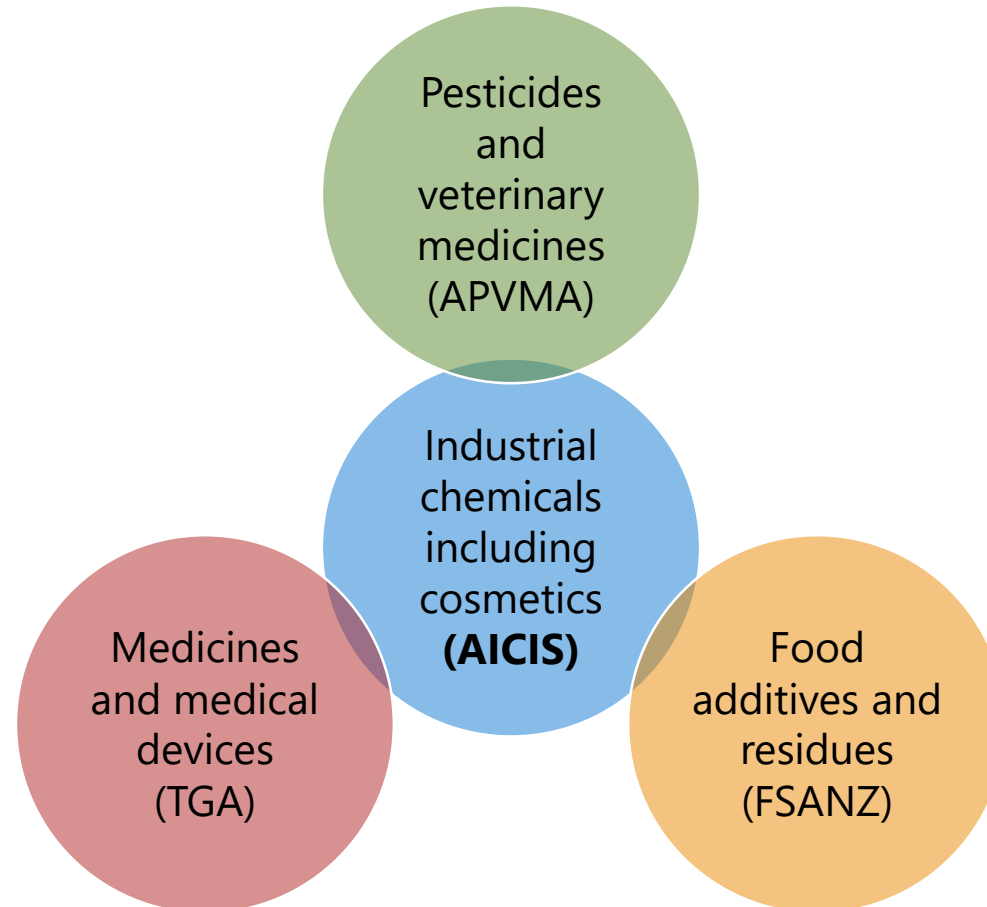
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Regulation of chemicals in Australia





Things that will be different

ICNA Act until 30 June 2019

- Scheme is **NICNAS**
- Led by a **Director**
- The list is the **Australian Inventory of Chemical Substance (AICS)**
- 'Existing chemical'
- 'New chemical'
- 'Exempt information'
- 'Notification' and 'notifier'

Industrial Chemicals Act from 1 July 2020

- New scheme is **AICIS**
- Led by an **Executive Director**
- The list is the **Australian Inventory of Industrial Chemicals (the Inventory)**
- 'Listed introduction'
- 'Unlisted introduction'
- **CBI** and protected information
- 'Application' and 'applicant'



Things that will be different

ICNA Act until 30 June 2019

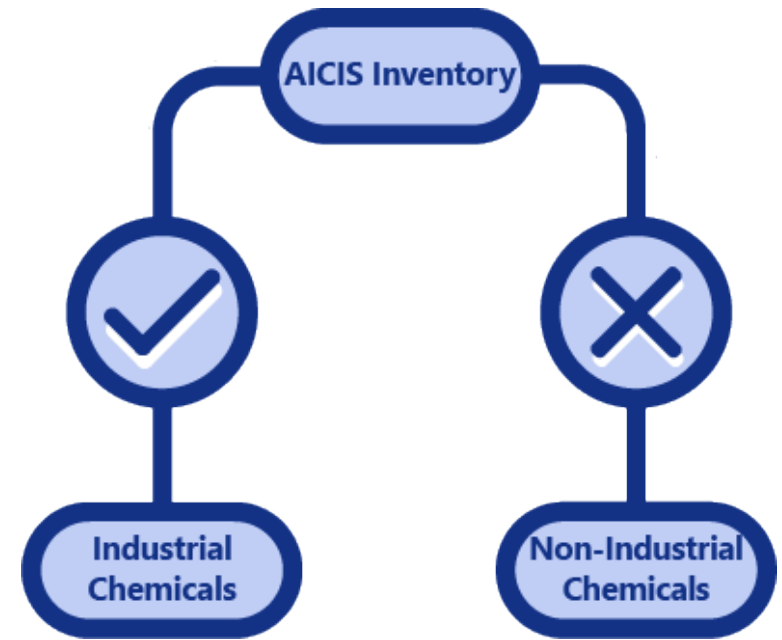
- Permits
- Confidential Inventory
- IMAP
- PEC
- Secondary notification obligations

Industrial Chemicals (IC) Act from 1 July 2020

- Commercial Evaluation Authorisations (CEAs)
- **Inventory** listings with confidential business information
- **Evaluations** – the big umbrella
- **Variation** applications
- **Information** obligations



The same but different: The Inventory



- Australian Inventory of **Industrial** Chemicals
- **Transitional Rules:** non-industrial chemicals on AICIS will not transition
 - All industrial chemicals will
- The AICIS Inventory will have links to assessment statements
- Different treatment of confidentiality



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Introducer obligations





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AICIS registration

Same as NICNAS

- Legal requirement for all introducers (importers or manufacturers) of industrial chemicals in Australia
- Pay a fee and a charge
- Amounts to change – cost recovery consultation

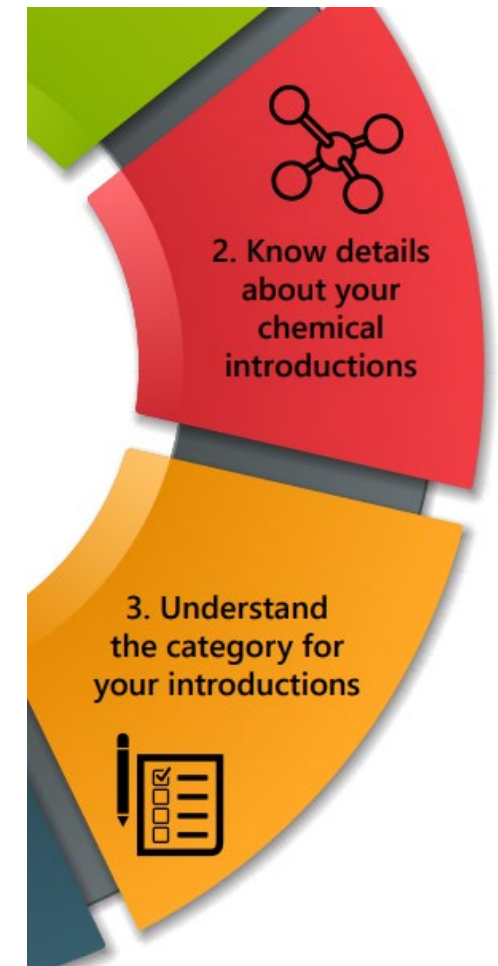




Know what you're introducing

A bit different to NICNAS

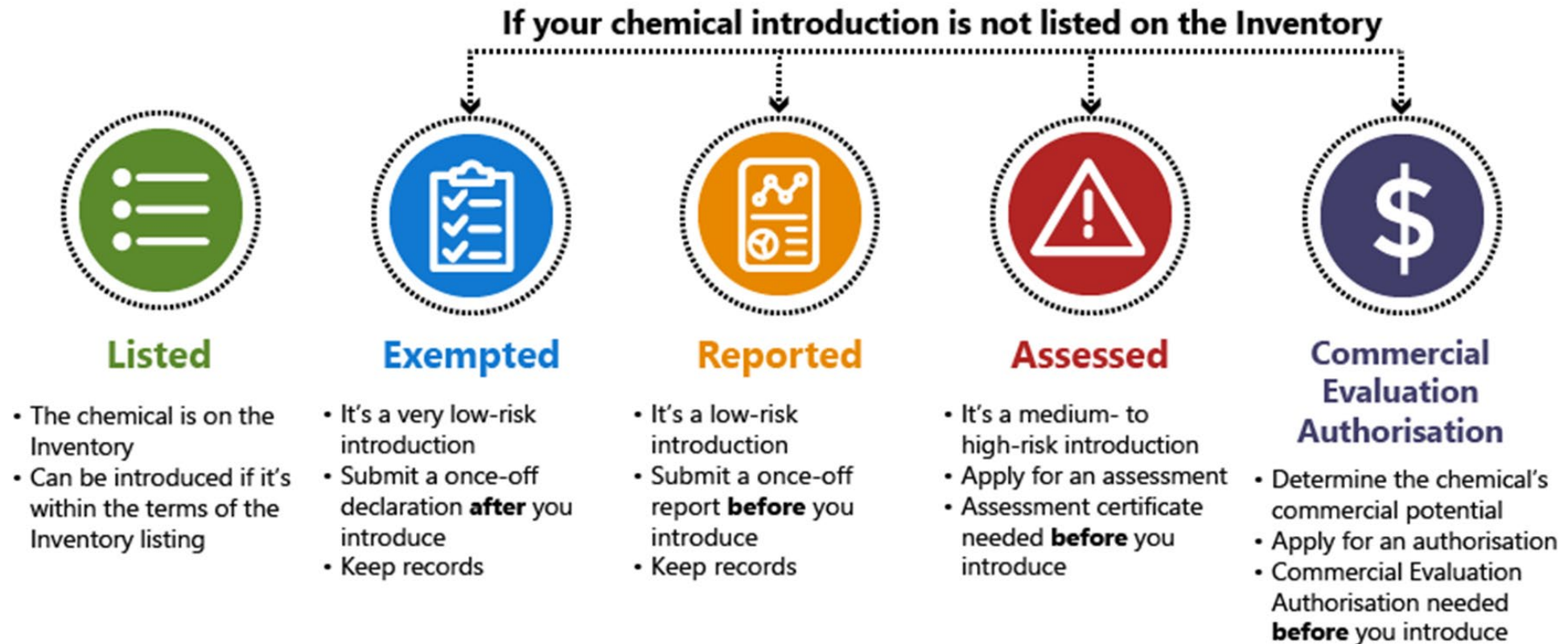
- Work out the 'category' of each introduction
- The category determines what other regulatory obligations apply to the chemical introduction
- Check all your ingredients against the Inventory
- Ignorance can be an offence





Introduction categories

Completely different to NICNAS





Record keeping

A bit different to NICNAS

- Information necessary to demonstrate:
 - What industrial chemicals you introduced and what category
 - How you determined categories
 - How you determined your registration charge
- Information about animal testing
- Information if required by a term of an Inventory listing
- Post-assessment information obligations
- Records must be kept for 5 years





Giving information to AICIS

Basically the same as NICNAS

- Executive Director can request information in various circumstances
 - any information required to be kept (record-keeping)
 - in relation to a risk assessment (pre- or post-introduction)
 - as part of monitoring and compliance activity
- Requests must be in writing
- Requests will have a deadline of at least 20 working days



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Basically the same

A bit different to NICNAS

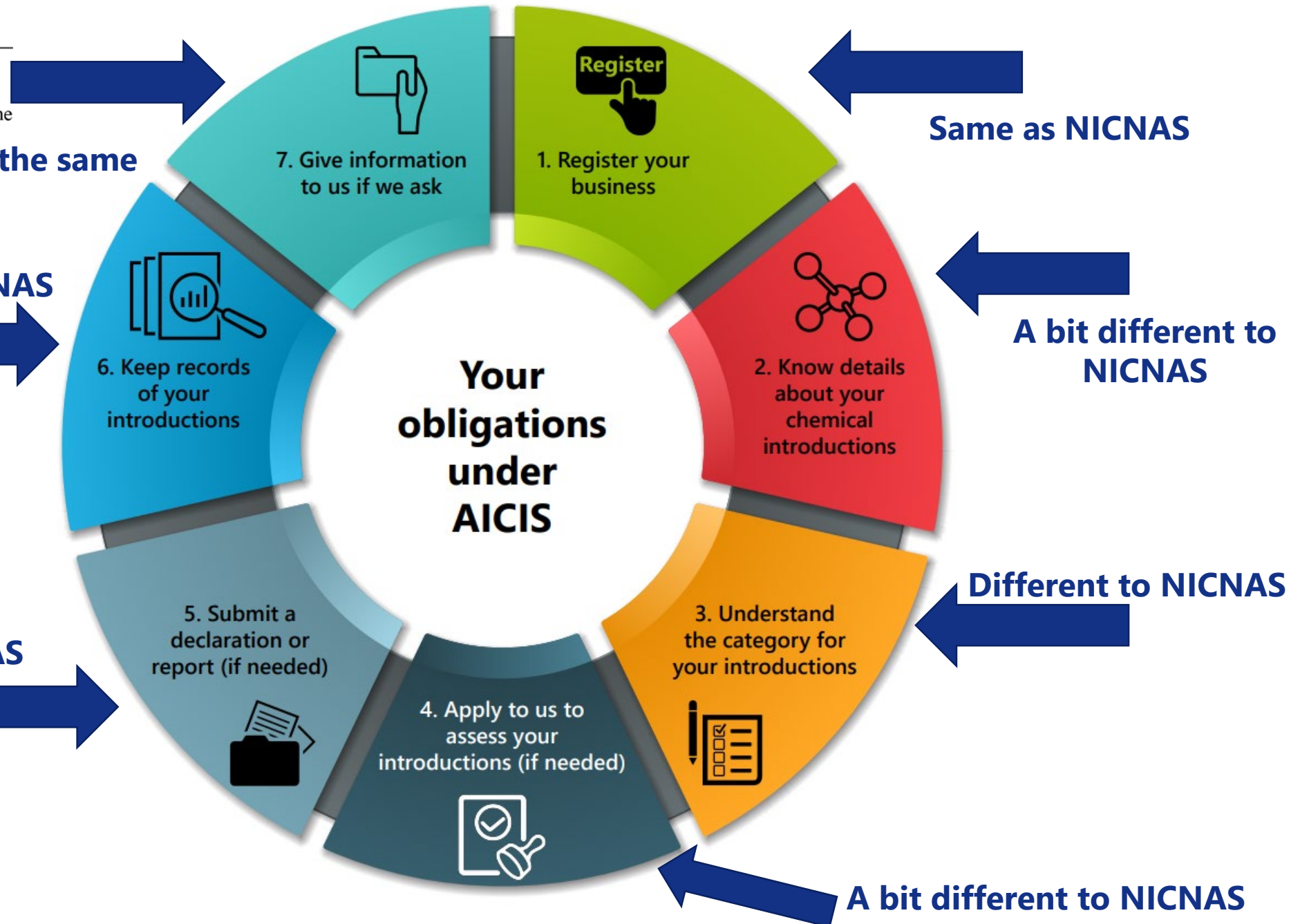
Different to NICNAS

Same as NICNAS

A bit different to
NICNAS

Different to NICNAS

A bit different to NICNAS





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Evaluation





A range of risk assessments

Triggers

- Prioritisation activities
- Monitoring and compliance
- Nomination
- Information obligations
- Inventory activities

Subjects

- Any industrial chemical
- Class or group of industrial chemicals
- Focus:
 - Identity
 - Hazard
 - Exposure (use)
 - Circumstances of introduction
 - Risk

Information and consultation

- Calls for information
 - Voluntary and mandatory
- Consultation
 - Certificate holders
 - Public
 - Risk managers





A range of risk assessments

Mandatory

- Evaluation Statement
 - Risk management recommendations
 - Risk Register
- Published on the AICIS website
- Linked to the Inventory listing(s)

Infrequent

- Vary certificate/ Inventory listing
- Add mis-identified chemical
- Add previously regulated chemical
- Review confidential business information (CBI)

Rare

- Cancel certificate
- Remove Inventory listing





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Thank you!

Our new website from 1 July:
industrialchemicals.gov.au

nicnas.gov.au