



AICIS Implementation

Assessed Chemical Introductions





Agenda

- Assessed introductions and certificate assessment types
- Assessment process
- Certificate holder rights
- Applying for assessment certificate



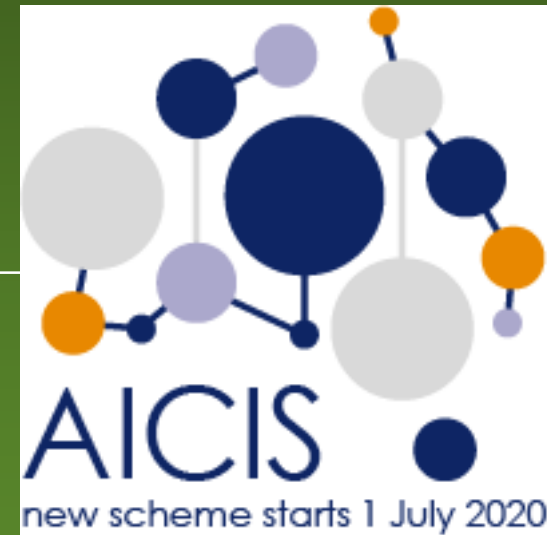
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Notification and Assessment Scheme

Assessed introductions and certificate assessment types





What is an assessed introduction?

- Introduction of an industrial chemical that
 - poses a medium to high risk to human health OR the environment
 - is authorised by an assessment certificate
 - meets the terms of the assessment certificate
- Requires pre-introduction assessment by AICIS
- Pathway for listing on the Inventory





Assessed introduction

		Indicative human health risk		
		Very low	Low	Medium to high
Indicative environment risk	Very low	Exempted	Reported	Assessed
	Low	Reported	Reported	Assessed
	Medium to high	Assessed	Assessed	Assessed



Certificate assessment types



Indicative human health risk	Indicative environment risk	Apply for assessment	Certificate assessment type
Medium to high	Medium to high	Yes	Health and environment focus
Medium to high	Very low or low	Yes	Health focus
Very low or low	Medium to high	Yes	Environment focus
Very low or low	Very low or low	Your choice	Very low to low risk



Information requirements

IUCLID Sections	IUCLID Sub-section / document	AICIS Application Types			
		Health and Environment focus	Health focus	Environment focus	Very low to low risk
1. General information	1.1 Identification 1.2 Composition 1.4 Analytical information	Required	Required	Required	Required
2. Classification, labelling 13.SDS		Required	Required	Required	Required
3. Manufacture, use & exposure		Required	Required	Required	Required
4. Physical & chemical properties	4.1 – 4.8, 4.21	Required	Required	Required	Required
	4.11 – 4.15	Required	Required	If available*	If available*
	4.9, 4.10, 4.16, 4.20, 4.22, 4.23, 4.27	If available*	If available*	If available*	If available*
5. Environmental fate and pathways	5.1.2 Hydrolysis	Required	Required	Required	Required
	5.2 Biodegradation 5.3 Bioaccumulation	Required	If available*	Required	If available*
	5.4.1 Adsorption/desorption	Required	Required	Required	Required
6. Ecotoxicological information	6.1 Aquatic toxicity	Required	If available*	Required	If available*
	All other endpoints	If available*	If available*	If available*	If available*
7. Toxicological information	7.2 – 7.6	Required	Required	If available*	If available*
	All other endpoints	If available*	If available*	If available*	If available*
11.Guidance on safe use		Required	Required	Required	Required

*If information is available for this endpoint then it must be provided to AICIS.



Reduced fee options

- Consolidated assessment
 - application contains more than one chemical and chemicals on the application have a similar structure and the same use
- Comparable hazard assessment
 - hazards for human health and/or the environment have been assessed by certain Australian or overseas agencies



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Assessment process





Who can apply for a certificate?

ICNA Act

- A manufacturer or importer of a new industrial chemical – a 'notifier'
 - i.e. registered businesses with a genuine intent to introduce

IC Act

- Any person – an 'applicant'
 - Australian business – registered or unregistered
 - Overseas business with ARBN – may register
 - Overseas business without ARBN – cannot register

same

Joint applications allowed

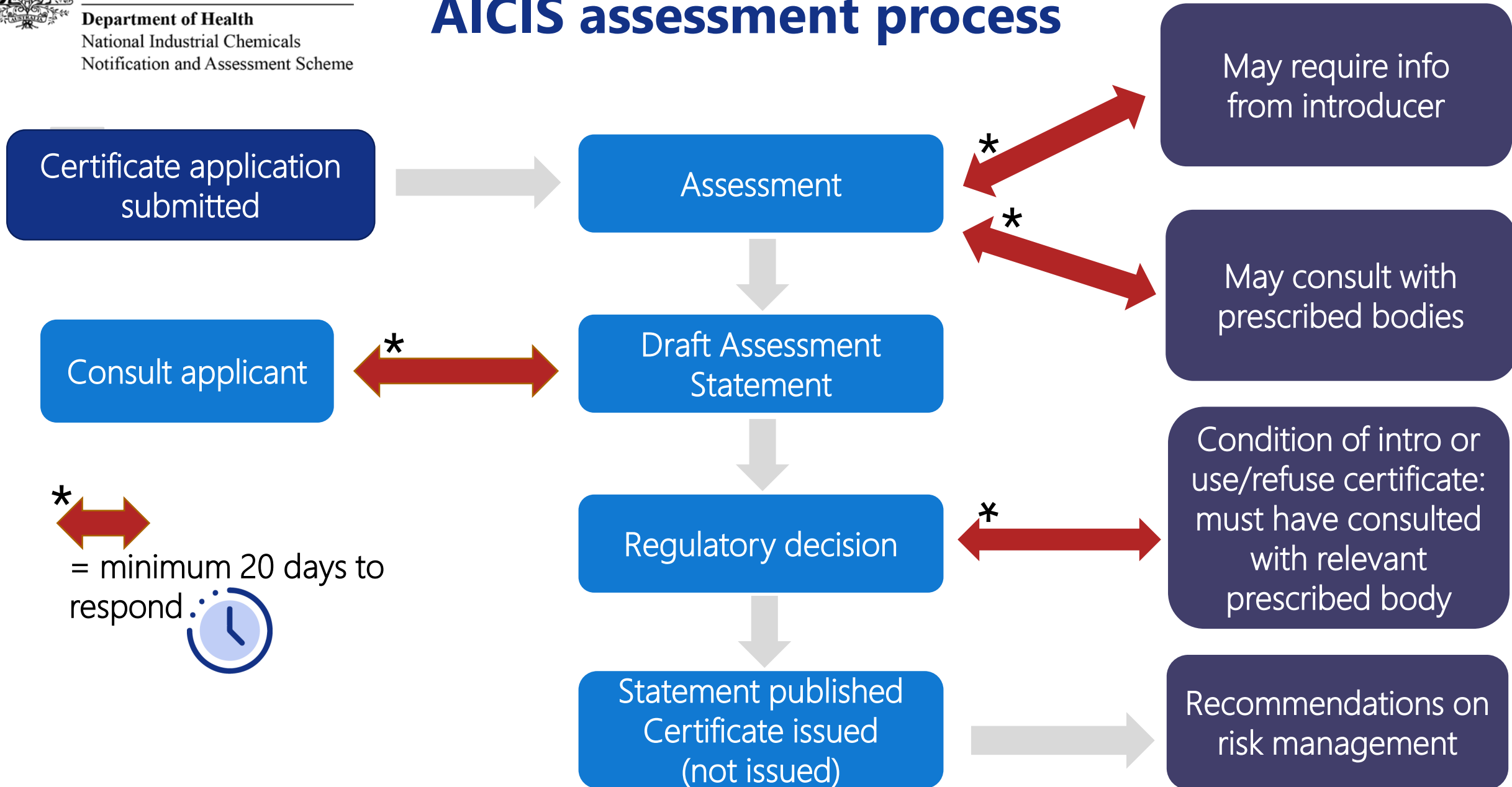


Joint applications allowed





AICIS assessment process





Assessment timeframe

ICNA Act

- 90 calendar days
- Clock can only be stopped and restarted
- Clock starts when we decide application is valid
- When draft assessment report is given this ends the timeframe

IC Act

- 70 working days
- Timeframe can be adjusted by mutual agreement
- Clock can be paused, then resumed
- Clock starts when applicant submits form
- Draft assessment statement issued - decision on certificate made within period



Assessment certificate terms

- Proper name or AICIS Approved Chemical Name (AACN)
- Defined scope of assessment
- Conditions of introduction or use (if necessary to manage risk)
 - volume
 - site
 - duration
- Specific requirement to provide information



Assessment Statement

- Proper name or AICIS Approved Chemical Name (AACN)
- End use or generalised end use (GEU)
- Defined scope of assessment
- Summary of the assessment and any risks to human health or the environment from the introduction or use of the industrial chemical
- The means for managing any risks - recommendations
- Any other information that is relevant





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Certificate holder rights



nicnas.gov.au



What can holder of an assessment certificate do?

- Holder of the assessment certificate
 - a person AICIS issues an assessment certificate to
- Can introduce the chemical if registered with AICIS
- Holder of the assessment certificate may apply to:
 - vary a certificate's terms
 - add a person to be covered by a certificate
 - change certificate holders
 - cancel a certificate



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Applying for certificate assessment





Applying for assessment certificate via online portal

- Apply for certificate assessment and CBI (if required)
- Create and pay invoice
- Submit chemical information
 - directly via portal or
 - attachment of validated IUCLID dossier





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Thank you!

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

nicnas.gov.au