



Australian Government
Department of Health and Ageing
NICNAS

Regulating chemicals for your protection

Cosmetics – New Regulations



Adrienne Adams

NICNAS Compliance
and Reporting

November 2007



Overview of presentation

- About NICNAS
- The new cosmetics legislation
- The Cosmetics Guidelines
(link on NICNAS website: [Current Issues/Cosmetics](#))
- The Cosmetics Standard
(link on NICNAS website: [Current Issues/Cosmetics](#))
- Registration
- Australian Inventory of Chemical Substances (AICS)
- NICNAS's approach to compliance



About NICNAS

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- Operates under Commonwealth legislation - *Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA)*
- Director, NICNAS, reports to Minister for Health and Ageing through the Parliamentary Secretary
- Operates under full cost recovery from industry
- Obligation to comply rests with the introducers – ie. manufacturers or importers



Objectives of the ICNA Act*

** Industrial Chemicals (Notification and Assessment) Act 1989*

- Aids in the **protection** of Australian **people** and the **environment**
- Provides **information** to stakeholders and makes **recommendations** to State/Territory regulatory authorities
- Gives effect to Australia's obligations under **international agreements** – eg. the Rotterdam and Stockholm Conventions
- Collects **statistics**
- Sets **national standards for cosmetics** imported into, or manufactured in, Australia and the enforcement of those standards



Cosmetics – prior to new legislation

- Previously regulated by *exclusion* – if **NOT** a therapeutic then a cosmetic
- Reliance on NCCTG Cosmetics Claims Guidelines



Cosmetics – the new legislation

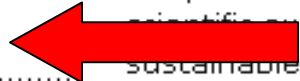
Amendments to the *Industrial Chemicals
(Notification and Assessment) Act 1989*

- Came into force **17 September 2007**
- Interim Permit arrangements ceased
- New Cosmetics Guidelines
- Cosmetics Standard 2007
- Move away from claims based guidelines





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Cosmetics Guidelines 1

The guidelines apply to all cosmetics:

1. Summary of requirements for cosmetics
2. Products that are regulated as cosmetics
 - Table A and Table B
3. Examples of products that continue to be therapeutic goods
4. List of prohibited or restricted cosmetic chemicals
5. Consequences of non-compliance



Cosmetics Guidelines 2

Requirements:

- **Meet definition in ICNA act:**

A substance or preparation intended for placement in contact with an *external part* of the human body including the mucous membranes of the oral cavity and teeth with a view to:

- Altering the odours of the body
- Changing its appearance
- Cleansing it
- Maintaining it in good condition
- Perfuming it
- Protecting it



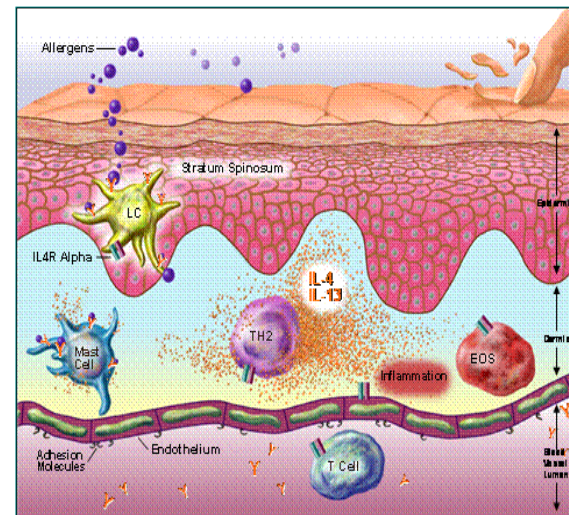
- **Does NOT include a therapeutic good within the meaning of the The Therapeutic Goods Act 1989**



Cosmetics Guidelines 3

Requirements (continued):

- NOT for preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons
- NOT in SUSDP Schedules 2, 3, 4 or 8
- **Marketed** as a cosmetic
- **Meets** any applicable standard in the *Cosmetics Standard*
- Does **NOT** contain chemicals prohibited for use and meets any restrictions.





Cosmetics Guidelines 4

Products that are regulated as cosmetics:

- **Table A**
 - **NO** product specific conditions
 - Must comply with general requirements
 - Not exhaustive
- **Table B**
 - Specific product types
 - Must comply with product-specific requirements as well as general requirements

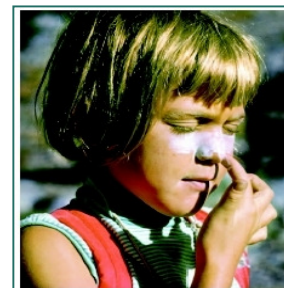


Cosmetics Guidelines 5

Examples of products that continue to be regulated as Therapeutic Goods:

- Meet **definition** of *Therapeutic Goods Act 1989*
- **Primary sunscreens** $SPF \geq 4$
- **Antibacterial skin products** which do not comply with the Cosmetics Standard
- Personal lubricants

This is NOT an exhaustive list...





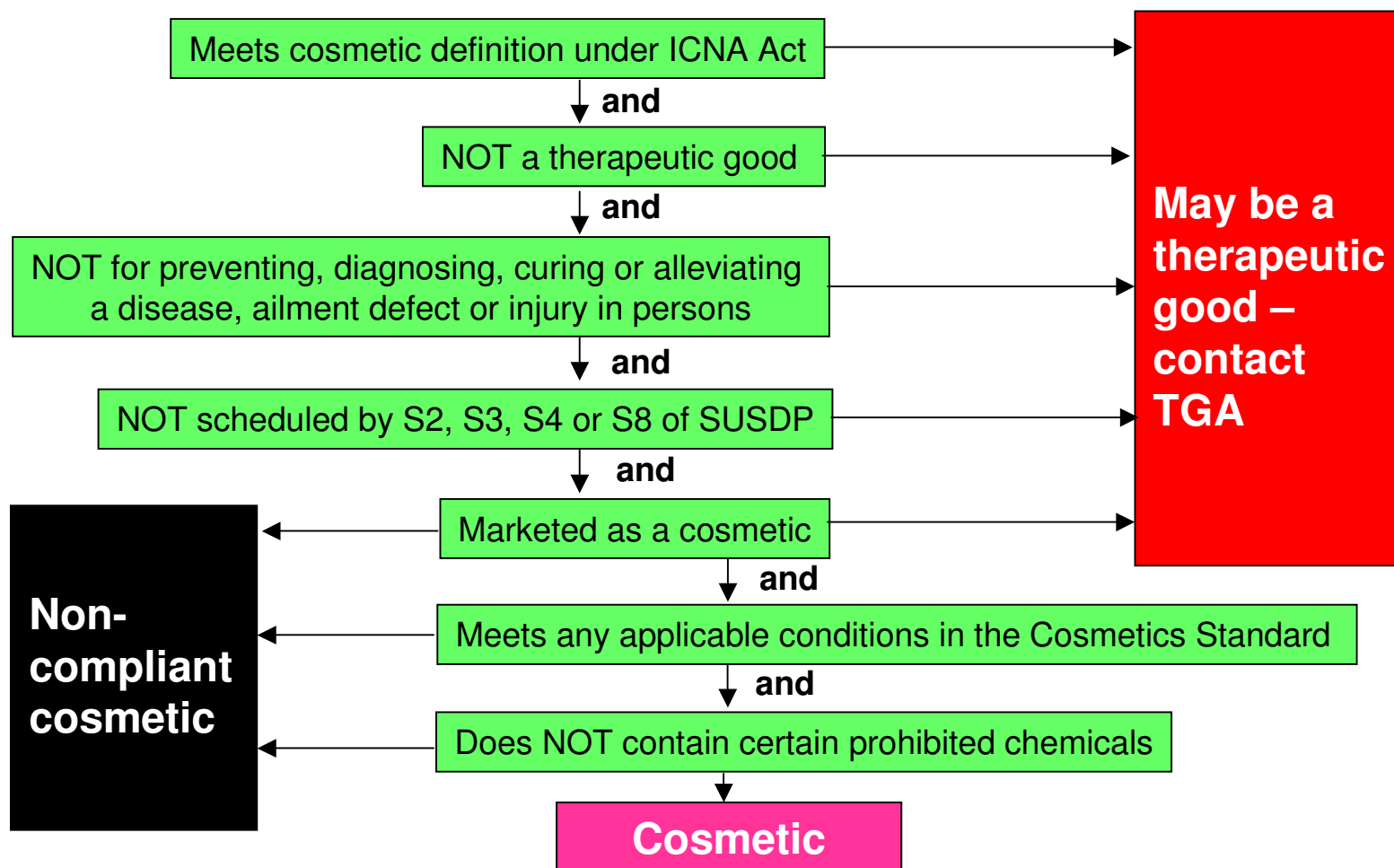
Cosmetics Guidelines 6

List of prohibited/restricted cosmetic ingredients:

- Not exhaustive and proposed to be based on existing controls/bans for cosmetic ingredients e.g.
 - SUSDP
 - Recommendations arising from NICNAS assessments
 - International negative lists (e.g. US FDA, EU Cosmetics Directive)
- Will be further developed and revised



Summary of Cosmetics Guidelines

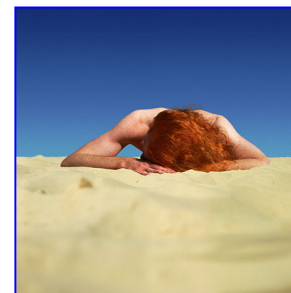
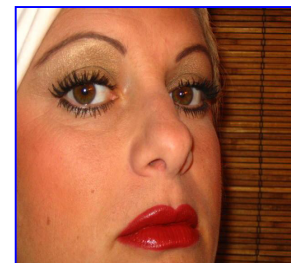




Cosmetics Standard 2007

Applies to six product categories only :

- Face and nail
 - ✓ Tinted bases and foundation
 - ✓ Lip products with sunscreen
- Skin care
 - ✓ Moisturises with sunscreen
 - ✓ Sunbathing products
- Skin care – Antibacterial skin products
- Skin care - Anti-acne products
- Oral hygiene – Care of teeth and mouth
- Hair care – Anti-dandruff products





Example of cosmetics standard

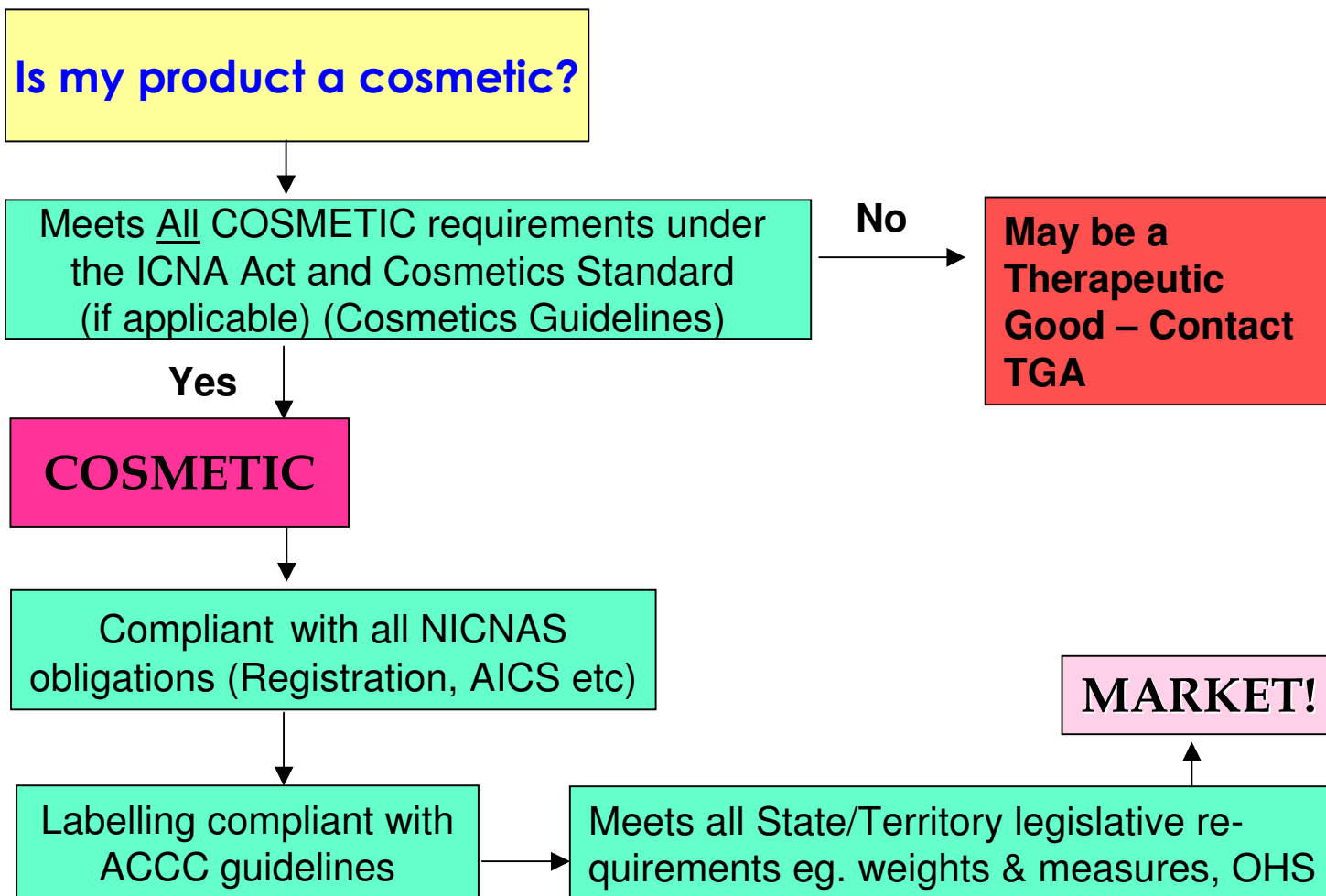
For lip products with sunscreen

Product category	Product type	Standards
1. Face & Nail	1.2 Products intended for application to the lips with sunscreen	(a) The product must be a secondary sunscreen product within the definition of <i>secondary sunscreen product</i> in AS/NZS 2604:1998; and (b) Any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 6.2 and 6.3 of AS/NZS 2604:1998





Cosmetics regulation – new





Labelling cosmetics

- **Products** – in accordance with the *Trade Practices Act 1974* – Consumer Product information mandatory standard guide (ACCC)
- **Ingredients and products** used in workplaces (eg. formulation and hair dressing salons) – *hazardous substances* must meet *labelling requirements* under State/Territory OHS (**OASCC*** Code of Practice for Labelling Workplace Substances)
- **Ingredients and products** containing *substances at scheduled concentrations* must meet requirements of *State/Territory poisons legislation (SUSDP)*

***OASCC** = Office of the Australian Safety and Compensation Council



NICNAS Registration 1

Who must be registered?

1. Importers of cosmetics
 2. Importers of cosmetic ingredients
 3. Manufacturers of cosmetic ingredients
- **NOT** cosmetic formulators/blenders who source chemicals locally

How to register:

- See registration link on left hand side of main web page



What is “manufacture”?

Manufacture

= creation of chemical/s

e.g. saponification

Formulating/blending

= no new chemicals

(no chemical reaction)

e.g. oil/water emulsions



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Registration 2

Tier	Total annual value of chemicals (including finished products) introduced	Registration amount 2007-08
1	\$1 - \$499,000	\$381
2	\$500,000 - \$4,999,999	\$1,522
3	\$5,000,000 or more	\$8,881



Registration 3

“Relevant industrial chemicals”

- **All industrial chemicals** *except:*
 - *a naturally-occurring chemical; or*
 - *a biological material; or*
 - *an incidentally-produced chemical; or*
 - *a reaction intermediate*
- **For any commercial purpose**



A note about “naturally occurring”

Many cosmetics refer to “natural” ingredients

- NICNAS legislation defines “naturally occurring” very strictly:
 - ***Unprocessed*** chemical in natural state
 - **OR *extracted only by*** manual, mechanical, gravitational means, dissolution in water, or heating to remove uncombined water, without any chemical change

This does not cover most “natural” cosmetics!



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- ✓ About NICNAS
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- **Australian Inventory of Chemical Substances (AICS)**
- **NICNAS's approach to compliance**



Australian Inventory of Chemical Substances (AICS) 1

Legal device distinguishing between new
and existing chemical

- ~38,000 chemicals listed
- Chemical identity only
- Search by CAS number or chemical name
- Can be annotated e.g. condition of use, secondary notification condition, information



AICS 2

- All cosmetic ingredients must be listed on AICS (existing industrial chemical) or
- Exempt from notification (depends on volume and use) or
- Notified to NICNAS



AICS 3

How to search AICS :

Chemical identity:

- CAS Number - the best
- CAS Name - second best
- Other chemical name (synonym) – may work
- Trade name – may work (not recommended)
- Molecular formula – unlikely (not recommended)



AICS 4

How to search AICS – Public/Confidential

- Public AICS: DIY via NICNAS website
- Public AICS: NICNAS can search, *for a fee*
- *Confidential AICS*: Only NICNAS can search
- Must check Public AICS first

Must have a genuine intent to introduce the chemical



How to search public AICS: 1

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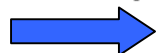
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AICS Search Tool

[Guidance Notes](#)

Search by CAS No



CAS No

Clear

Clear All

Go

OR...

Clear

Clear All

Go

Chemical Name

Contains all words



and

Contains all words



and

Contains all words



and

Contains all words



and

Contains all words



and

Contains all words



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AICS Listing



CAS No: 7732-18-5

Chemical Name: Water

Molecular Formula: H2O

Assessed by NICNAS: No

Associated Names: AQUA

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IMPORTANT INFORMATION ABOUT THIS CHEMICAL



High Volume Industrial Chemicals List (HVICL)

This chemical is introduced into Australia (manufactured or imported) in large quantities. NICNAS has compiled a list of such industrial chemicals (the Australian HVICL), based on the information supplied by industry during 2001/2002 and 2006. Only those chemicals with a combined import and manufacturing quantity of 1000 tonnes or more have been included in the Australian HVICL. This chemical is listed on the 2006 Australian HVICL.

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AICS Search Results

You searched for:
CAS No equals '77325-85-7'

No results returned.



12 December 2007 4:21:22 PM

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AICS 5

- Chemical on AICS, no conditions: “Existing” – regulatory obligations if a PEC
- Chemical not on AICS: “New” – regulatory obligations apply
- Chemical on AICS but annotated with condition of use: “New” if use is outside the condition – regulatory obligations apply
- Chemical on AICS (assessed) – regulatory obligations apply



New chemicals

- Under NICNAS legislation, a *new chemical* may not be introduced to Australia UNLESS:
 - The introducer holds an assessment certificate or permit for that specific chemical – ie. the chemical must be notified and assessed; OR
 - The chemical qualifies for an exemption



Cosmetic exemption categories

	Quantity restriction	Other criteria	Advice required?	Annual reporting?	Record keeping?
Cosmetic – low volume	<10 kg/yr	No unreasonable risk	No (Form 15)	Yes	*Yes
Cosmetic – low volume	10-100 kg/yr	No unreasonable risk	Yes – Form 15	Yes	*Yes
Cosmetic	≤1% of any product	Non hazardous	No	Yes	*Yes



Exemptions – cosmetic chemicals

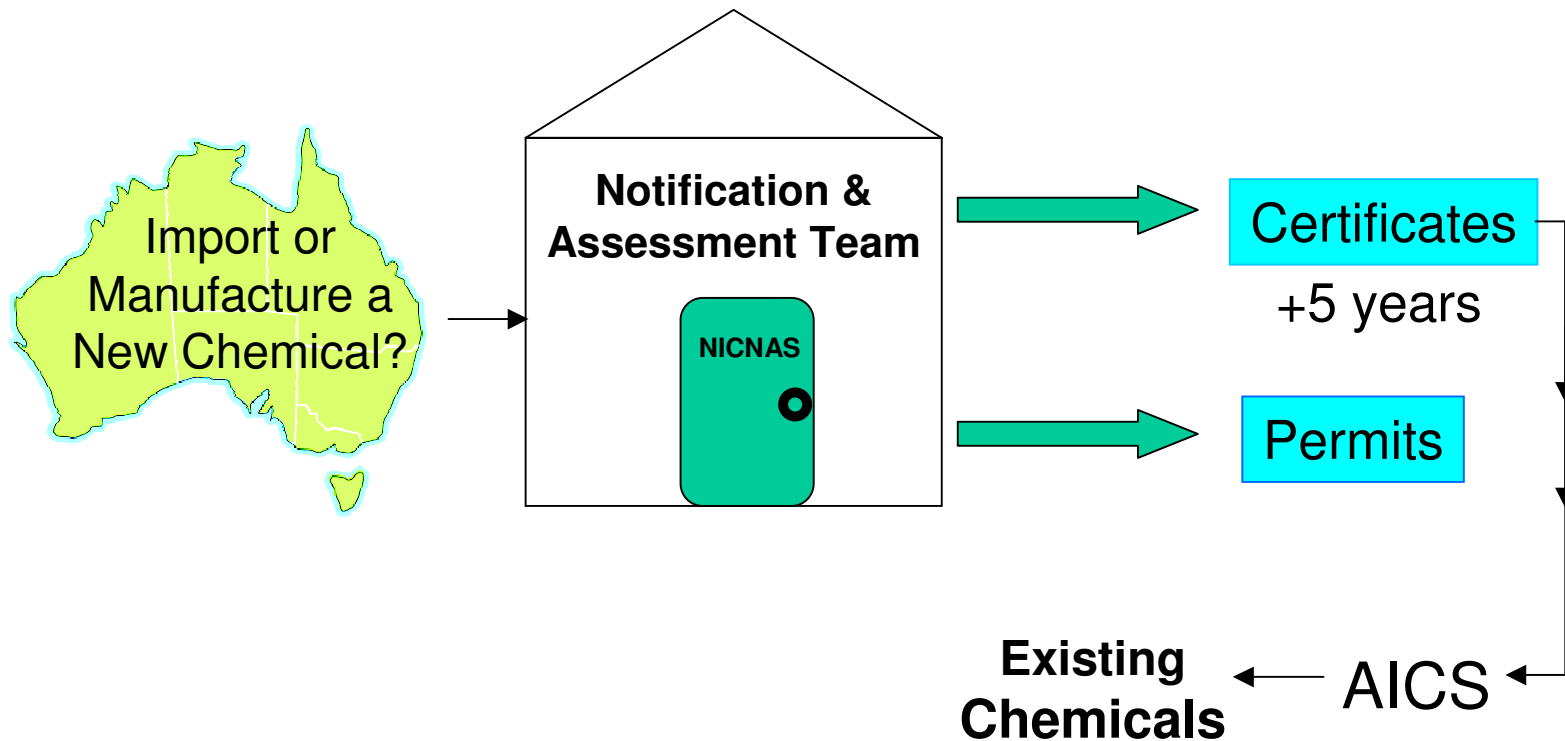
Cosmetic chemicals **not allowed** for exemptions:

- Preservative
- Colouring agent
- UV filter
- Prohibited or restricted for cosmetic use in US or EU





Notifying a new chemical





Annual reporting

- **Required for:**
 - All exemptions
 - New chemical permits
 - New chemical self-assessed assessment certificates
- Web based reporting model
- Annual deadline: **28 September**
- Report for the previous Registration year (1 September – 31 August)



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NICNAS's approach to compliance

1. NICNAS auditing
2. Self reporting breaches
3. Third party allegations
4. Proactive investigations



1. *NICNAS auditing*

- Auditing chemical introducers (registration) – powers to require information to be produced and questions answered
- Auditing annual reports, permits, certificates and exemptions – checking of records for volumes and permit conditions
- Auditing chemicals being used – testing and inspections to ensure all chemicals are on the AICS



Registration audits

- Customs data identifies importers who should be registered. Other data sources used to identify manufacturers
- **Weekly monitoring** enables real time action to be taken if necessary
- Compliance action:
advice/warning/seizure of goods/prosecution



New chemical audits

- **Audits of new chemical certificates and permits:**
 - Self-assessed certificates
 - Secondary notification conditions
 - Permit conditions
- **Exemption audits:**
 - Record keeping
 - Annual reporting
 - Introduction levels (<100kg or <1%)



2. Self reporting a breach

- **NICNAS encourages a self reporting process**
- **NICNAS will work with companies and individuals to assist them becoming compliant**
- **Forms available on the NICNAS Website**



3. Third Party allegations

- NICNAS accept third party allegations in writing
- Confidentiality is protected
- Outcomes of third party allegations are communicated to the complainant



4. Proactive investigations

- NICNAS Inspectors have **wide ranging powers** of entry and seizure of chemicals where an offence has been committed
- NICNAS has the capacity to **proactively investigate** offences



Summary of presentation

- About NICNAS
- The new legislation - amendments to the ICNA Act
- Interim arrangements – ceased
- Cosmetics Guidelines – apply to ALL cosmetics
- Cosmetics Standard – applies to six product categories
- Registration – importers of cosmetics and cosmetic ingredients & manufacturers of cosmetic chemicals
- AICS – all ingredients must be on AICS
- NICNAS's approach to compliance



Contacts

- **NICNAS**

- www.nicnas.gov.au
- Phone 1800 638 528
- Contact Officer: Dr Adrienne Adams
02 8577 8858
Adrienne.Adams@nicnas.gov.au

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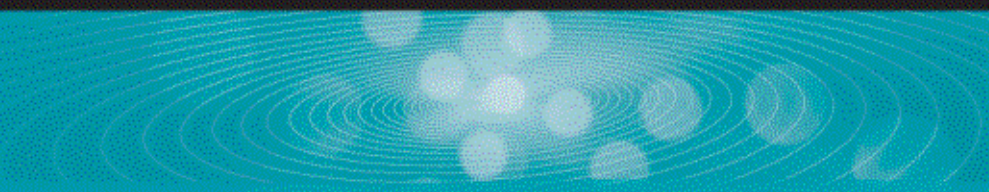
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