



Australian Government

Department of Health

Australian Industrial Chemicals
Introduction Scheme

Ban on animal test data: meeting your obligations

April 2020



Key points and target audience

- From 1 July 2020, use of new animal test data will be restricted for:
 - chemicals with a sole use as a cosmetic ingredient
 - chemicals that will have an end use in cosmetics (even if they will also have other end uses)
- This video is:
 - for introducers of unlisted chemicals with an end use in cosmetics (the restrictions **do not** apply to listed introductions)
 - a practical guide on what the restrictions are and how they will apply



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Agenda

Use of animal test data

- When you can use animal test data
- Other information you can use
- How we'll know if you're using new animal test data



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When you can use animal test data



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New animal test data

- New animal test data
 - = animal test data obtained from tests conducted on or after 1 July 2020
- If your chemical will have an end use in cosmetics (even if it will also have other end uses), you **can't** use **new** animal test data:
 - to categorise your introduction
 - in an assessment certificate applicationunless an exception applies
- You can use existing animal test data - from tests conducted before 1 July 2020



When you can use new animal test data

	Exception 1	Exception 2	Exception 3	Exception 4
	Data from animal tests show a hazard	No alternative for environmental hazards	Read across information from non-cosmetic chemicals	Pre-approval given to use new animal test data
Chemical - end-use in cosmetics only	✓	✓	✓	✗
Chemical - multiple end uses (including cosmetics)	✓	✓	✓	✓



When you can use new animal test data

Exception 1: Data show a hazard - categorisation



If a test shows that your chemical has a hazard characteristic



if the test data result in a higher risk introduction category determination

Example:

You have new animal test data indicating your chemical has the potential to cause skin sensitisation

- without the data being considered, the introduction category is exempted
- the category is reported when you use the data



When you can use new animal test data

Exception 1: Data show a hazard – certificate application



If the test result shows that your chemical has a hazard characteristic



if the result conflicts with other information in your application

Example:

- You have new animal test data indicating that your chemical has the potential to cause skin sensitisation (not shown in other information)
- Requirements set out in the approved form must be met using other information



When you can use new animal test data

Exception 2: No alternative for environmental hazards

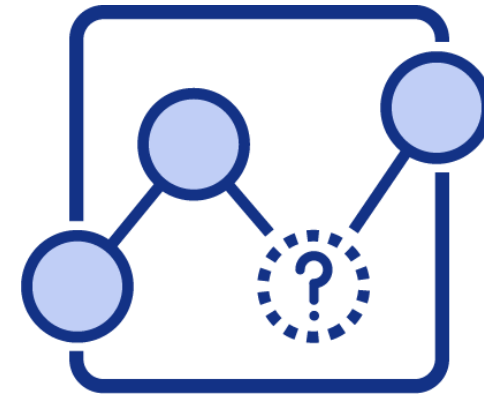


- If it is the only information that can demonstrate whether or not your chemical has a particular environment hazard characteristic
- There are no validated alternative tests that you can use

Example

Computer modelling is not accurate in predicting aquatic toxicity for many chemicals, such as surfactants and UVCBs





When you can use new animal test data

Exception 3: Read-across information from non-cosmetic chemicals



- If the animal test was conducted on another chemical that is **not** introduced by you for an end use in cosmetics
- This allows for use of read across information

Example

You have access to suitable read across information demonstrating that your chemical doesn't have the skin sensitisation hazard characteristic

- The test chemical:
 - is not introduced into Australia by you or
 - is introduced by you, but it does not have an end use in cosmetics



When you can use new animal test data

Exception 4: Pre-approval given to use new animal test data



- If your chemical will have multiple end uses (including in cosmetics) and we approve an application from you to use it:
 - to work out your introduction category
 - in your assessment certificate application

Note

- Does not apply if your chemical will only have an end use in cosmetics
- Further details on this application later in the video



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Other information you can use



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Alternatives to animal testing

- *In vitro* testing methods
 - use (reconstructed) tissues, whole cells or parts of cells
- *In silico* methods
 - computer simulations of effects based on chemical structure and physical properties
- Read-across (RAX) methods –
 - effects for one chemical are predicted using data for the same effect from another chemical, which is considered to be similar in terms of chemical structure, physico-chemical properties, or bioactivity



Reduced reliance on animal test data

Information requirements for categorisation and certificate applications

- Graduated information requirements for categorisation
 - data not needed at lower exposures
- Options for non-animal data provided wherever possible
 - where validated alternatives exist
- Information waivers where reasonable
 - so unnecessary testing not conducted
- Requirements are in Guidelines and approved forms
 - changes require Executive Director approval only - we can quickly respond to availability of new non-animal methods



Reduced reliance on animal test data

Non-animal options in the Categorisation Guidelines

Genetic toxicity	Skin corrosion	Eye damage	Skin sensitisation	Acute toxicity	Repeat dose toxicity	Skin irritation	Eye irritation	Fish toxicity
RAX in vitro in vitro/in silico*	RAX in vitro in silico*	RAX in vitro in silico*	RAX in vitro/in silico* in chemico/in vitro	RAX in vitro/in silico*	RAX	RAX in vitro in silico*	RAX in vitro in silico*	RAX in silico

*only acceptable for lower human health exposure bands



What if you don't have suitable alternative information?

Where none of the 4 exceptions apply

- Check to see if you can introduce your chemical under:
 - a higher risk introduction category - require less hazard information
 - e.g. reported instead of exempted
 - lower exposure scenarios - require less hazard information
 - e.g. lower volume or lower concentration
- Otherwise, you can't introduce your chemical for an end use in cosmetics



What if you don't have suitable alternative information?

Example

- You wish to introduce 300kg of your chemical (at >1% concentration) for use in cosmetics (human health exposure band 4)
- You can't demonstrate that your chemical **doesn't have** the acute toxicity (fatal or toxic) hazard characteristic – hazard band B
 - you can't use a new animal test (as an exception doesn't apply)
 - the non-animal testing options in the Guidelines don't apply

You take these steps

- You reduce the annual introduction quantity of the chemical to 100kg (human health exposure band 3) – information for this hazard characteristic is not required to be low indicative human health risk



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How we'll know if you're using new animal test data



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When you apply to use new animal test data (Exception 4)

- If your chemical will have multiple end uses (including an end use in cosmetics), you can apply to:
 - use new animal test data to work out your introduction category and/or
 - include new animal test data in your assessment certificate application
- Apply in AICIS Business Services
 - timeframe = 10 working days* / no fee
- Based on whether there is human or environmental exposure expected from the non-cosmetic end uses



You tell us if you're using new animal test data

- If your chemical has an end use in cosmetics, you need to tell us if you are using new animal test data to work out the highest indicative risk
 - Exempted introduction declarations
 - Pre-introduction reports (reported introductions)
- Through our post-introduction monitoring program, we will be confirming compliance with the restrictions on use of animal test data
 - if we ask for it, you need to provide us with the information you used to demonstrate the absence of hazard characteristics
 - penalties apply for non-compliance

Thank you!