

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-018

OUTCOME 1: Population Health

Topic: International Bans on Testing Cosmetics on Animals

Type of Question: Written Question on Notice

Senator: Senator Rhiannon

Question:

EU legislation already prohibits the use of animals in safety testing of cosmetics produced throughout the EU. In March this year, an EU ban on the sale of cosmetics produced in other countries will come into force. Given Australia is an important market for cosmetics companies, what is the Australian Government doing to ensure Australia doesn't become a dumping ground for cosmetics produced by companies that persist in using out-dated and cruel animal tests?

Answer:

As part of the Australian Government's framework for managing chemical safety, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) assists in the protection of the Australian people and the environment by assessing the effects of industrial chemicals, including those used in cosmetics. NICNAS already has in place a number of provisions which can be utilised to minimise the use of animal testing for new cosmetic ingredients:

- NICNAS does not require the testing of each cosmetic product. Only new ingredients to be used in cosmetic products are notified to NICNAS and assessed to determine their safety, for both public health and the environment.
- NICNAS' approach to the assessment of new cosmetic ingredients is dependent on the predicted risk associated with their use. NICNAS only requires a full suite of health effects information on those chemicals considered to warrant more in-depth assessment (e.g. those introduced in high volumes and/or at high concentrations).
- Under the *Industrial Chemicals (Notification and Assessment) Act* (the IC(NA) Act) NICNAS has the ability to waive certain information requirements where the introducer can provide alternative data to enable an adequate risk assessment to be conducted. These alternative data could be from non-animal tests, from computer models which predict hazard, or data from animal testing which has previously been conducted on similar chemicals. To ensure safety standards are not compromised, it is important that data from computer models or non-animal tests can be demonstrated to give accurate and reliable information through a validation process.
- For health effects which have validated non-animal tests, such as skin and eye irritation, NICNAS currently accepts this information in lieu of animal testing results.

The Australian government, through NICNAS, is an active participant in the activities of the Organisation for Economic Co-operation and Development (OECD), which develops test guidelines for the conduct of toxicity tests. The OECD considers animal welfare in the development of these test methods and has looked at ways of replacing the use of animals, reducing the number of animals in tests and refining the test methods to reduce pain and distress wherever possible. Once a new alternative test method has been validated it is included in the OECD Test Guidelines.

While the European Union ban applies to new chemical ingredients used solely in cosmetics, many cosmetic ingredients are used for a range of other purposes and therefore animal testing to ensure their safety is likely to be conducted to meet the requirements of these other regulatory frameworks, even in Europe. The continued importation of cosmetics that contain new ingredients which have been tested on animals does not create a risk for consumers, because the current legislation regarding the assessment of cosmetic ingredients explicitly aims to protect the health of the Australian public, and the environment in which they live.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-019

OUTCOME 1: Population Health

Topic: International Bans on Testing Cosmetics on Animals

Type of Question: Written Question on Notice

Senator: Senator Rhiannon

Question:

Some years ago the EU introduced legislation to push forward the development of alternatives to animal testing and ensure the validation of those alternatives in the lead up to the ban. Would the government consider actively pursuing the same process?

Answer:

Through the *Industrial Chemicals (Notification and Assessment) Act* (the IC(NA) Act), the Australian Government has legislated to require an evaluation of the safety of industrial chemicals, including cosmetic ingredients, with the objective of protecting people at work, the general public and the environment from any harmful effects.

The vast majority of testing conducted on new cosmetic ingredients occurs outside of Australia. Therefore a testing ban to push forward the development of alternatives to animal testing in Australia would not have the same impact as in the European Union (EU). In addition, the new methodologies being developed in the EU, for which both the European Commission and the cosmetics industry have provided significant funding, can, and will, be adopted for Australian purposes once they have been shown to be valid replacements for other types of safety testing.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-020

OUTCOME 1: Population Health

Topic: International Bans on Testing Cosmetics on Animals

Type of Question: Written Question on Notice

Senator: Senator Rhiannon

Question:

Earlier this year Israel followed the EU by introducing legislation to ban the sale of cosmetics (ingredients or finished products) tested on animals. India has now indicated that it is considering introducing similar legislation in the very near future. Why is the Australian Government avoiding the introduction of similar legislation that would bring us in line with many other countries?

Answer:

The *Industrial Chemicals (Notification and Assessment) Act* (the IC(NA) Act) requires the provision of certain data necessary to determine the level of risk an industrial chemical (including cosmetic ingredients) may pose to human health or the environment. The IC(NA) Act affords the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) the ability to accept alternate testing data to that specified in legislation where it can be demonstrated to give accurate and reliable information through a validation process.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-021

OUTCOME 1: Population Health

Topic: International Bans on Testing Cosmetics on Animals

Type of Question: Written Question on Notice

Senator: Senator Rhiannon

Question:

In answer to my previous questions about Australia following the lead of the EU Parliament in banning the use of animals in cosmetic testing: could the Minister elaborate on the answer 'For many health effects, non-animal test methods have either not yet been developed, or are still in the process of being validated as reliable replacement methods.' My understanding is that there are very few areas in which alternatives to animal tests have not yet been developed and validated. What international research informed the Minister's answer?

Answer:

The National Industrial Chemicals Notification and Assessment Scheme maintains a watching brief on international activities related to alternative testing, especially in the application of the test methods, updates on their validation and regulatory status. The European Centre for the Validation of Alternative Methods, the US Interagency Coordinating Committee on the Validation of Alternative Methods and the Organisation for Economic Co-operation and Development are the main organisations involved in the validation on non-animal tests, and the reports from these organisations are relied upon to inform Australian Government agencies of the status of alternative tests.

In recent press statements regarding the ban which came into force on 11 March 2013, the European Commission has acknowledged that the replacement of animal testing methods is not yet possible for the evaluation of all health effects, particularly the complex health effects that concern the whole human organism.

A number of validated alternative methods exist that can be used as partial or full replacement of animal experiments, such as in the areas of skin and eye irritation and determining the ability of a chemical to penetrate the skin and enter the bloodstream. For some of the more complex human health end points, the validated alternative testing methods are not replacement methods, but rather supplemental methods for reducing the number of animals used in tests. These include tests for determining the potential for a chemical to

cause cancer, gene mutations, effects on the reproductive system or the developing foetus, or toxic effects after a single exposure. For determining whether a chemical can cause allergies in susceptible people there are currently no validated alternative testing methods, although there are several currently going through the validation process. There are no validated and accepted non-animal alternatives available for determining the potential for a chemical to cause adverse effects on the human body after repeated exposures (which is a particularly important endpoint for evaluating the safety of cosmetics since these chemicals are applied to the human body regularly).