



CRUELTY FREE  
COSMETICS?



NOT TESTED  
ON ANIMALS

are they  
here?



NOT TESTED  
ON ANIMALS?





**Choose Cruelty Free (CCF)** is a positive action campaign. It has been in operation since 1992.

CCF is an independent, non-profit organisation run entirely by volunteers.

CCF is a registered company limited by guarantee and without share capital. It is administered by a committee of members elected as directors.

CCF is the only independent body acting as a watchdog for company claims about animal testing in Australia.

CCF has a broad base of supporters including many Australian celebrities.

The main aims of CCF are:

- To educate consumers about animal testing of cosmetics and household products.
- Provide an ethical shopping guide.
- Encourage manufacturers to use alternatives to animal testing

To this end CCF:

- Surveys companies which claim to be cruelty-free.
- Accredits companies which satisfy our standards.
- Produces and distributes, free of charge, The Preferred Products List (PPL), an ethical shopping guide listing companies which have met our cruelty-free criteria.
- Makes available, by way of a licensing arrangement, the CCF logo which manufacturers can incorporate into their labelling and advertising if they wish to do so.
- Provides information to the public about animal testing and promotes alternatives.

## CONTENTS

What are cosmetics?	5
What are animal safety tests?	7
Material Safety Data Sheets	10
Who does animal testing?	13
History of animal testing	14
Search for alternatives	17
Alternative safety tests	19
Who pays for it?	21
Validation of tests	24
Legal or otherwise	26
Australian situation	29
Labelling	33
Implications and future directions	37



## What are cosmetics?

We all use them. Cosmetics are not just make-up but also shampoo, soap, toothpaste and deodorants.

In 2005 the value of the Australian cosmetics and toiletries market was estimated by industry organisations at \$5,200 million. Expenditure on hair care was largest, accounting for 24% of retail sales. (Regulation of Cosmetic Chemicals: Final Report and Recommendations 1 November 2005, Australian Government, Dept of Health and Ageing.)

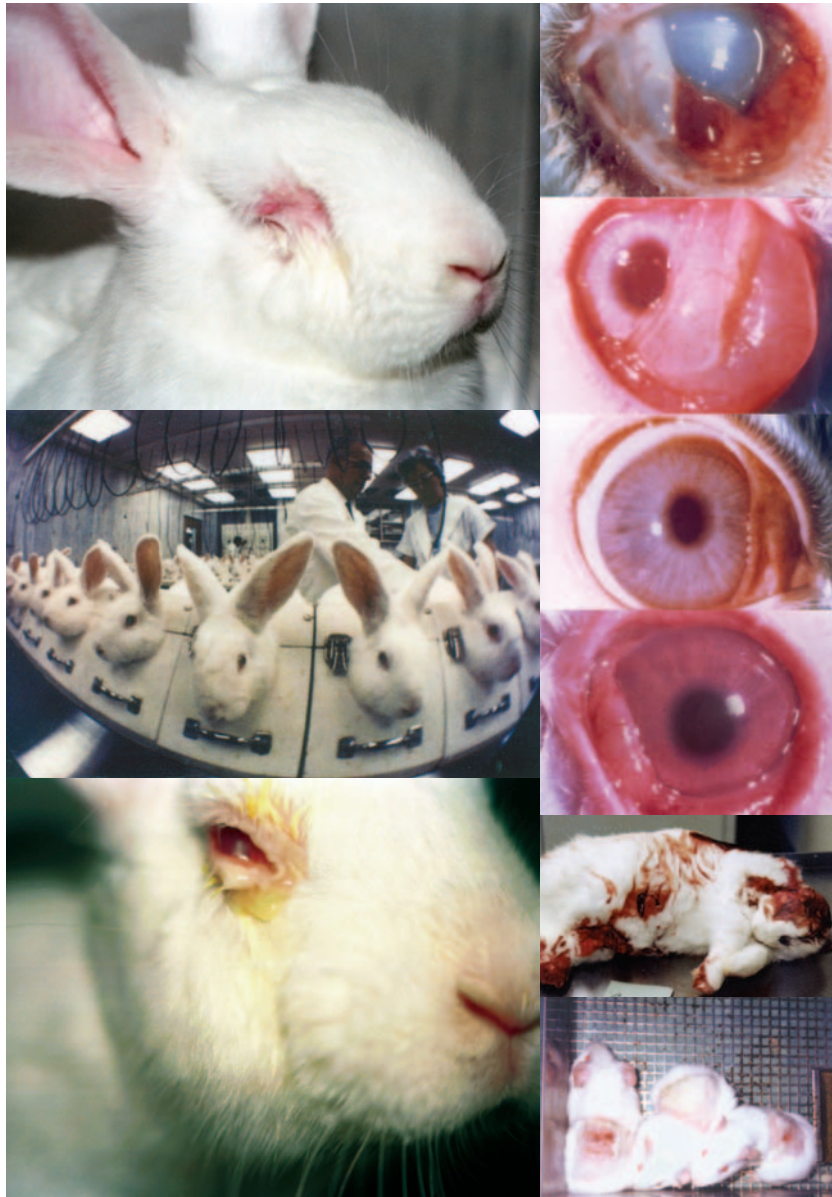
Cosmetics help us care for our bodies and make ourselves more attractive. They are probably our most basic consumer category apart from food, and expenditure on cosmetics is increasing every year.

There is however a hidden price to cosmetics – one that we don't pay. This price is the suffering of animals used in safety testing.

In safety tests animals are poisoned, burned and blinded by exposure to much higher concentrations of product ingredients than we would ever experience in daily life.

Although the use of animals for the testing of cosmetics has been highly criticised for many years it still continues. Many of the cosmetics on Australian shelves today have been tested on animals.

This booklet looks into the questions, 'Why are they still using animal tests?' and 'What can we do?'



## What are animal safety tests?

In safety testing a group of animals is subjected to a substance over a period of time. The animals receive no pain relief as it is believed that analgesics might alter the results.

Animals involved in these tests are always killed – by the effects of the test substance, in ‘dosing accidents’, or by terminal ‘sacrifice’ at the end of the procedure.

There are many different types of animal safety tests and they may be ‘acute’ or ‘chronic’, some lasting for months or even years.

Acute toxicity tests involve oral, dermal, and inhalation exposure to a test substance for a number of days or weeks.

### Acute toxicity tests

#### Oral toxicity tests

Until fairly recently the internationally recognised test for oral toxicity was Lethal Dose 50% (LD50). In this test large groups of animals were force fed increasing doses of a substance until 50% of them died.

Sometimes the animals were killed not by the chemical nature of the substance but by the sheer volume administered.

Fortunately, today the dosing is usually discontinued after a certain volume is reached.

Also, in 2002 the Organisation for Economic Cooperation and Development (OECD) recommended that the LD50 be replaced by tests which used smaller numbers of animals (the Fixed Dose

Procedure, the Acute Toxic Class method, and the Up-and-Down Procedure).

Although an improvement on the LD50 as fewer animals are used, these tests still cause great suffering to the animals involved.

In the Fixed Dose Procedure the animals are euthanised once they show evident signs of poisoning, but in both the Acute Toxic Class and Up-and -Down methods the experiment does not end until the animals die from the effects of the substance (termed 'death as an end point'). Oral toxicity tests are usually conducted on two species – a rodent and a non-rodent.



### Acute inhalation toxicity tests

Animals are forced to inhale a test substance for no less than four hours and are monitored for 14 days. As with the LD50,

the aim is to determine the concentration of a substance which will kill 50% of the animals. This is termed Lethal Concentration 50% (LC50.)

### Aquatic toxicity

This is determined using fish and other aquatic species such as crustaceans. The fish 96 hour LC50 is the standard acute toxicity test. This measures the concentration of a substance that is lethal to 50% of a group of fish within 96 hours.

### Dermal toxicity

Rabbits, guinea pigs or rats are shaved and the test substance is

applied to no less than 10% of the area of their skin. They are then observed for 14 days for evidence of skin corrosion.

### Eye Irritation

The Draize Eye Irritation Test is the standard method for evaluating ocular irritation. In this test a material is squirted into one eye of an albino rabbit (the other eye serving as the negative control). The rabbits are sometimes restrained in stocks or have Elizabethan collars placed around their necks to prevent them from trying to rub the substance from their eye. They are observed for 21 days.

### Chronic toxicity tests

These include oral, dermal and inhalation repeated dose studies.

The substance is administered at lower doses than in acute toxicity tests but for a longer period of time.

These tests are often performed on rats, however, non-rodents, typically dogs or non-human primates, are also used. Some experiments last for 28 or 90 days, others for years.

### Carcinogenicity

The objective of this test is to observe animals for a major portion of their life span. The study is usually conducted using two species. The animals are dosed by oral, dermal and inhalation exposures. Dosing typically lasts around two years.

### Neurotoxicity

These tests look for alterations to the function of the nervous system. Often hens or rodents are dosed for periods of a year or more.

This list is not exhaustive, with other tests investigating areas such as genotoxicity, pharmacokinetics and reproductive function.

Data generated in these tests is recorded in Material Data Safety Sheets.



- In safety testing no painkillers are used
- Substances are tested on various species of animal
- All animals in safety tests die during, or at the end of, the experiments

## What are Material Safety Data Sheets?

A Material Safety Data Sheet (MSDS) is a document which gives information about a single chemical or a number of chemicals combined (for example in a shampoo or cleaning product).

A typical MSDS contains information about the scientific and common names of a substance, its physical characteristics, health hazards, precautions for safe transport, handling and use, first aid measures and toxicological information. Toxicological information is a compilation of data, usually from animal tests.

In the case of carbon tetrachloride (previously used in the production of refrigeration fluid and propellants for aerosol cans, as a pesti-

cide, a cleaning fluid, a degreasing agent, in fire extinguishers, and in spot removers) Fisher Scientific Canada produced a MSDS containing the following data for Draize, LD50, and LC50 tests.

Draize test	rabbit	eye	500 mg/24H
Draize test	rabbit	skin	500 mg/24H
Oral	mouse	LD50	7749 mg/kg;
Oral	rabbit	LD50	5760 mg/kg
Oral	rat	LD50	2350 mg/kg
Inhalation	mouse	LC50	34500 mg/m <sup>3</sup> /2H
Inhalation	rat	LC50	46000 mg/m <sup>3</sup> /6H

(MSDS created 1999, revised 2006, CAS Number 56-23-5)

These figures may seem confusing to the lay person. In practical terms they tell us that when 500mg of carbon tetrachloride was dripped into the eyes of a group of rabbits mild damage to the eye was observed after 24 hours.

Likewise when 500 mg was applied to the shaved skin of rabbits mild damage was observed.

When a group of mice were force-fed carbon tetrachloride at a ratio of 7,749 mg per kg of their bodyweight half of them died as did half of a group of rabbits at a ratio of 5,760 mg per kg bodyweight and rats at 2,350 mg per kg bodyweight.

Similarly, when a group of mice were exposed to carbon tetrachloride vapour at a concentration of 34,500 mg per cubic meter for two hours half of them died, as did half of a group of rats exposed to 46,000 mg per cubic meter for six hours.

These tests are crude and could even be described as sadistic. No

wonder the deaths of animals involved in such trials are recorded in laboratory notes as 'sacrifices'. All animals used in toxicity testing are 'sacrificed' – not only those which are poisoned during the experiment but also the survivors – and some animals die along the way.

Survival data for male rats used in a three day Oral LD50 test for carbon tetrachloride listed under CAS Number 56-23-5 reveal that four died due to 'dosing accidents' and another was 'accidentally' killed.

The fate of any animal which survives to the end of the trial is 'terminal sacrifice'. A MSDS has been created for probably every substance we use. There is a MSDS for sugar (Oral, rat: LD50 29,700 mg/kg), for baking soda (Oral, rat: LD50 4,220 mg/kg) and for table salt (Oral, rat: LD50 3,000 mg/kg).

Even distilled (pure) water has a MSDS (CAS Number 7732-18-5). This gives the Oral LD50 for rats as greater than 90 ml/kg, by which we assume that the researchers stopped increasing the dosage when they reached a dosage rate of 90 ml/kg of animal.



WHO DOES

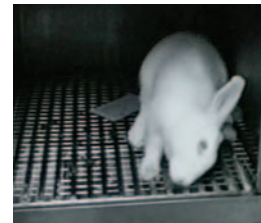
- **Results of animal tests are recorded in Material Safety Data Sheets (MSDS)**
- **MSDS record damage to the eyes and skin of animals caused by a substance, together the amount required to poison them**
- **These tests have been conducted for every substance we use, even distilled water**

## WHO DOES animal testing?

Companies either conduct tests in their own laboratories or contract out testing to laboratories which specialise in this area such as MPI Scientific or Huntingdon Life Sciences (HLS).

HLS is perhaps the largest contract animal testing company with facilities in the UK, US and Japan. It services private clients worldwide and conducts safety testing using a variety of species including rats, rabbits, pigs, dogs and primates.

In 1997, film secretly recorded inside laboratories of HLS in the UK and US by People for the Ethical Treatment of Animals (PETA) showed serious breaches of animal protection laws including a beagle puppy being held up by the scruff of the neck and repeatedly punched in the face, and animals being taunted while they were being subjected to obviously painful procedures.



Subsequently, the campaign Stop Huntingdon Animal Cruelty (SHAC) was launched in the UK and US. Recent reports from ex-workers at HLS suggest that acts of cruelty are still occurring. For further information visit [www.shac.org](http://www.shac.org)

Contract testing laboratories are commercial enterprises. Companies may choose to commission tests which do not use live animals or they may choose animal tests. MB Research Labs in the US, for example, offers

a range of approved tests *in vitro* (not in living animals) but also a gruesome selection of *in vivo* (in living animals) procedures. These include acute oral, dermal, ocular and inhalation toxicity tests as well as vaginal, anal and penile irritation and long term toxicity studies using rats and dogs.

At a contract testing laboratory you get what you pay for.



- **Many companies use contract testing laboratories which specialise in safety testing**
- **Cruelty to animals at contract testing laboratories has been exposed by animal rights groups**
- **Companies can choose to commission either animal tests or alternative testing methods**

## history of animal testing

Toxicology using animals is not an old 'science'. The LD50 was only developed in the late 1920s by British pharmacologist J. W. Trevan.

The Draize Eye Irritancy Test was the brainchild of John Draize in the forties and was initially used to assess the irritancy of agents of chemical warfare.

Draize also developed the Skin Irritancy Test. These tests provid-

ed a rather crude indication of the toxicity of substances to mammals. Unfortunately for the animals involved, animal tests appealed to government regulators and, in the years that followed, were adopted as the standard by which authorities determined which chemicals were considered safe for human use.

Companies also seized on the concept of animal testing and began to test everything they released onto the market, even when there was no legal requirement to do so. For companies animal testing provided a convenient protection against consumer claims for damages if they had an adverse reaction to a product. Today, animal toxicity tests are conducted on an enormous scale worldwide to assess the 'safety' of almost everything we use including consumer products such as cosmetics.

In the mid 1970s people began to speak out against the blatant cruelty involved in animal testing. Initially their protests had little impact.

However, in 1979, a New York activist, Henry Spira, began a campaign specifically targeting the use of the Draize Eye Irritancy Test. He set in motion the most successful animal rights campaign of our time. He organised almost 400 animal protection groups into the 'Coalition to Stop Draize Rabbit Blinding Tests'. By placing full page advertisements in daily newspapers describing what the Draize Eye Irritancy Test actually entailed he stirred up a public outcry.

As a result, in 1981, the first centre for the development of alternatives to animal testing was established at John Hopkins University.

In the eighties a number of scientists also began to voice concerns about the usefulness of toxicological data generated from animal

tests. The validity of such tests rested on the assumption that adverse effects observed in one species could be translated to other species.

It was pointed out that different species often responded differently to chemicals – the most famous example being penicillin which, although fatal to guinea pigs, proved to be an invaluable antibiotic for humans. The reliability of results was also questioned as the data collected from animal tests often varied from laboratory to laboratory and even from animal to animal. Some scientists also suggested that the extremely high doses administered to animals in laboratories had little relevance to the much lower exposure levels that humans would be expected to experience in real life.

Due partly to scientific concerns, but mainly as a response to public pressure, funding began to be put towards research into finding alternatives to animal safety tests. Such tests are given the broad name of 'alternative' safety tests.



- **Animal safety tests became popular with government regulators in the 1950s**
- **Companies saw animal testing as an easy way to protect themselves from consumer claims for damages**
- **In the 1970s people began to question the cruelty and accuracy of animal tests**

## SEARCH FOR alternatives

In 1959 William Russell and Rex Burch published the book *Principles of Humane Experimental Technique* which proposed the principle of the Three Rs – Refine, Reduce and Replace the use of animals in scientific research. It became something of a bible for those dedicated to helping animals in laboratories.



### United Kingdom

In 1969 Dorothy Hegarty and biologist Charles Foister registered the Fund for the Replacement of Animals in Medical Experiments (FRAME) as a charity in the UK. Their aim was to raise funds to put the Three Rs into practice. Initially FRAME had a bank balance of £100 and was based in a room in the Hegarty house in Wimbledon, London. By 1991 FRAME had raised enough money to open the FRAME Alternatives Laboratory (FAL) at the University of Nottingham Medical School. In 2007 the FAL laboratory was expanded and completely remodelled in a £240,000 overhaul, the costs being shared equally between FRAME and the University.

Research programs funded by FRAME include: development of cytotoxicity assays as replacements for acute toxicity tests (for example the kenacid blue test); the neutral red release assay as a replacement for the Draize Eye Irritancy Test (marketed as Predisaft); and the development of a 3D human skin model for irritancy testing. FRAME also produces the ATLA Abstracts (Alternatives To Laboratory Animals), a periodic collection of abstracts of relevant papers from scientific journals.

## United States

In 1980 Henry Spira's Coalition to Stop Draize Rabbit Blinding Tests succeeded in generating considerable funds towards research into alternatives. Subsequently, in 1981, The Center for Alternatives to Animal Testing (CAAT) was established at John Hopkins University, US. Today CAAT works from a diverse base of corporate, private, and public funding. CAAT also manages Altweb, an international online clearinghouse of alternatives news and resources. Some animal rights groups are critical of CAAT. People for the Ethical Treatment of Animals (PETA) has accused the Center of concentrating solely on 'refinement' techniques and neglecting to develop true alternatives to current animal tests. Others, such as the Humane Society of the United States, claim that CAAT has played an instrumental role in developing the scientific foundation of *in vitro* testing using tissue culture. It is interesting to note that Charles River Laboratories, the world's largest supplier of laboratory animals, donates a nominal amount of funding to FRAME and CAAT. A public relations exercise perhaps?

Much of the scientific work on alternatives is conducted in Europe and, to a lesser extent, in the US. In 1993 the EU created the European Centre for the Validation of Alternative Methods (ECVAM). The main purpose of ECVAM was to provide a mechanism for the validation and regulatory acceptance of the alternatives which were being developed. A year later, in the US, a similar regulatory body was established, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). In Japan, the Japanese Centre for the Validation of Alternative Methods (JaCVAM) was more recently established. At an international level the Organisation for Economic Cooperation and Development (OECD)

maintains a set of 'internationally harmonised test guidelines' which serve as a register of both animal and alternative tests approved under OECD guidelines. In recent years a number of alternatives have achieved validation, not only in the area of safety testing, but in other areas of animal-based research.



- Late last century, due to growing public concern, research centres were set up in the UK and US to develop alternatives to animal tests
- The group FRAME in the UK and the Coalition to Stop Draize Rabbit Blinding Tests in the US were instrumental in pushing for the replacement of animal tests

## Alternative safety tests

There are already many alternatives to testing substances on live animals and more are being developed all the time. These alternatives give data that is less variable, less costly and less cruelly derived.

### Some alternatives in use are in the areas of:

- Computerised models which predict the biological/toxicological properties of a substance based on its chemical structure

and knowledge of similar structures. One example is TOPKAT, a system which generates and validates accurate, rapid assessments of chemical toxicity solely from a chemical's molecular structure. TOPKAT can be used for tests including physical/chemical, environmental fate, ecotoxicity, toxicity, mutagenicity, and subchronic reproductive/developmental. Computerised models can also predict toxicity based on the wealth of data which currently exists about chemical substances. An example is DEREK, a computer program that operates from a constantly updated data base of scientific data gathered from around the world. DEREK can be used to determine which chemicals are particularly likely to be toxic. It provides information about the possible mechanism of activity when a chemical is found to be toxic to illustrate where small modifications could be made to the molecular structure in order to reduce toxicity.

- *In vitro* cell and tissue cultures, using freshly harvested cells, tissues or organs; self-sustaining 'cell lines' such as the Mouse 3T3 Cell Line (commonly used for evaluating the potential for sunlight-induced 'phototoxicity') and reconstructed tissue models such as EpiDerm which consists of normal, human-derived epidermal cells cultured to form a multilayered, highly differentiated model of the human epidermis.
- Embryos and foetal stages utilising embryonic stem cells before sentience develops.
- Bacteria such as Salmonella to detect genetic toxicity.
- Human epidemiology and volunteer studies such as human

patch tests to detect skin irritation and sensitisation. These are used by many companies opposed to animal testing and are more likely to generate results relevant to humans than are animal models.

For further information about alternative tests and the validation process visit AltTox [www.alttox.org](http://www.alttox.org)



- Many alternative tests have already been developed
- Alternatives include computerised models, *in vitro* cell and tissue cultures, embryonic stem cells, bacteria and human epidemiology

## Who pays for it?

Ironically, much of the funding for research into finding alternatives has been provided by the very companies responsible for much of the animal testing. One should not jump to conclusions and assume this is just because they feel sorry for small furry animals. Companies react directly to consumer pressure. This was used to great effect by Henry Spira in the 80s with the 'Coalition to Stop Draize Rabbit Blinding Tests'.

The history of Henry Spira's campaign to obtain funding for research into alternatives is both inspiring and entertaining. It is documented in Peter Singer's book *Ethics into Action*.

Spira thought it would not be unreasonable to ask companies using animal tests to contribute funds towards finding alternatives. He decided to begin with the cosmetics industry and first approached Revlon, the company he felt had the highest public profile.

At that time Revlon was spending \$162 million annually on advertising alone. Spira proposed that Revlon donate one hundredth of one percent of their annual profits towards research into alternatives to the Draize Eye Irritancy Test. For Revlon this would have amounted to \$170,000 a year. Revlon was not interested in the proposition.

In April 1980, Spira placed a full page advertisement in the *New York Times* with the heading 'How many rabbits does Revlon blind for beauty's sake?' He followed this up with ongoing demonstrations outside Revlon's Head Office and a second newspaper advertisement in October of that year.

Spira gained the attention and the support of the public. In December 1980, Revlon had a change of heart and donated \$750,000 towards research into alternatives. Spira then turned his attention to Avon. Not surprisingly, Avon and subsequently EsteeLauder, Max Factor, Chanel, Mary Kay, Bristol-Myers and Proctor and Gamble found it in their hearts to donate funds.

Since Spira's campaign many alternative tests have been developed, some by the cosmetics companies themselves. For example, in April 2007, Episkin, an alternative to the Draize Skin Irritancy Test, achieved validation. According to the European Center for the Validation of Alternative Methods (ECVAM), Episkin 'predicts the skin irritancy potential of chemicals with great accuracy and precision and will therefore fully replace (skin) tests.'

The Episkin model uses a human epidermis reconstructed on collagen. It was developed in the laboratories of L'Oreal. The acceptance of Episkin as a replacement for the Draize Skin Irritancy Test should stop an enormous amount of animal suffering.



Unfortunately, the wheels turn very slowly in the acceptance of alternatives. In the case of Episkin, L'Oreal claims to have been working on the project since the eighties and the actual validation process for Episkin took from 1999 to 2007!



**WATO POINTS**

- Henry Spira's campaign to stop the Draize Eye Test targeted Revlon. He asked the company to donate a small percentage of their profits for research into alternatives to animal testing
- Revlon was unresponsive so Spira launched a media campaign
- In response to public outcry Revlon, and later other cosmetic companies, donated funding towards the development of alternatives

## Validation of tests

The aim of validation is to prove that a new type of test is as accurate as a previously used testing method.

The validation process was developed in the late 1980s. Criteria for validation have now been developed in Europe, the US, Japan and internationally through the OECD. Validation involves using a new test method on a wide array of chemicals in multiple laboratories. The results are then compared to either pre-existing or newly generated data from the corresponding animal test. The process is both expensive and time consuming.

The Humane Society of the United States outlines the steps towards validation as follows:

- Research and development, which is generally undertaken and/or funded by regulated industry or government.
- Pre-validation, an approximately two year process which aims to establish the mechanistic basis of a test; standardise and optimise the test protocol; evaluate within-lab variability using a training set of coded chemicals; and define a 'prediction model' or 'data interpretation procedure', which articulates the process by which test results are used to predict toxicological endpoints *in vivo*.
- Validation, an approximately one year process which aims to evaluate a test's transferability to a second laboratory, together with a test's between-labs variability and reproducibility (involving up to four outside laboratories).
- If a test performs well during the preceding steps a peer

review is undertaken to independently evaluate the results of the validation study. This process requires approximately one year, depending on whether an existing peer review body (e.g., the ECVAM Scientific Advisory Committee, or ESAC) is used, or whether a new ad hoc expert panel is convened.

- Processes for regulatory acceptance can take two years or more at the national/regional level and longer in the case of international consensus-driven bodies such as OECD.

Interestingly, animal tests have never been subjected to the rigors of validation. If they had been it is unlikely that any of them would be in use today.

Take, for example, the Draize Eye Irritancy Test. This test is simply a subjective assessment of the degree of damage to rabbits' eyes. In the Draize Eye Irritancy Test a group of albino rabbits have a test substance dripped or squirted into one of their eyes. A technician then observes at 1, 24, 48 and 72 hours damage to the eyes. The technician 'scores' them by comparing their eyes to a sheet of photographs of damaged rabbit eyes. The maximum score possible is 110 which equates to complete destruction of the eye. Observation of the animals continues until the full magnitude and reversibility of ocular injury can be evaluated – usually 21 days. Then the rabbits are 'sacrificed'.

If individuals were to torture animals using the procedures followed in these tests they could be prosecuted for cruelty. However, under the guise of science, these procedures are carried out routinely in laboratories every day.

Apart from the obvious cruelty, the accuracy of a method such as the Draize Eye Irritancy Test is highly questionable science. Data collected in these tests would vary from technician to technician and

from rabbit to rabbit. It does leave one wondering how those 'scientists' who hold up animal tests as a standard beyond question can possibly sleep straight in their beds at night.



- **The validation process was developed in the late 1980s specifically to deal with acceptance of alternatives to animal tests**
- **The process is lengthy and expensive**
- **Animal tests have never been subjected to validation**

## legal or otherwise

Generally, there are no laws requiring the use of animals in safety testing. Tests involving the use of live animals are simply listed as the standard method to evaluate the safety of products. To its credit Victoria led the world in reforming cosmetic testing regulations. In 1986, bans on the use of the Draize Eye Irritancy Test and Lethal Dose testing with respect to cosmetics (and some other products) were introduced in that State. In 2006 the relevant regulations were amended. These laws now preclude:

- Any scientific procedure involving the eye of any animal to determine the irritancy of any chemical or biological agent unless it is carried out under terminal anaesthesia.
- Any scientific procedure involving death as a deliberate end

point and where there is no intervention to kill the animal humanely before death occurs in the course of the procedure (there are some exceptions to this prohibition but these exceptions do not apply to cosmetics).

Although commendable in principle, these laws have had little effect. The major suppliers of Australian cosmetics are subsidiaries of foreign companies with most imports coming from the US (38%), France (19%), the UK (11%) and Germany (4%). (Regulation of Cosmetic Chemicals: Final Report and Recommendations 1 November 2005, Australian Government, Dept of Health and Ageing.)

In the US, the Food and Drug Administration (FDA) has no explicit animal testing requirements for cosmetics (except in the case of certain colouring agents that are tested for carcinogenicity). However, the agency has historically used animal toxicity data as its standard to settle safety issues. On its website the FDA states:

*The Food and Drug Administration (FDA) is responsible for assuring that cosmetics are safe and properly labelled. This mission is accomplished through enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C Act), related statutes, and regulations promulgated under these laws.*

*The FD&C Act does not specifically require the use of animals in testing cosmetics for safety, nor does the Act subject cosmetics to FDA premarket approval. However, the agency has consistently advised cosmetic manufacturers to employ whatever testing is appropriate and effective for substantiating the safety of their products. It remains the responsibility of the manufacturer to substantiate the safety of both ingredients and finished cosmetic products prior to marketing.*

The situation is brighter in Europe. In 1999 the UK introduced a ban on animal testing of cosmetics. As with the Victorian ban this did not prevent companies from performing animal tests off-shore, then marketing products in the UK. However, in 2003, the European Parliament and the 15 member states of the EU passed 'The 7th Amendment to the Cosmetics Directive' effectively banning the use of animals in cosmetic testing throughout Europe and the import of any cosmetics that have been tested on animals.

The testing and sale of finished products tested on animals was banned in 2004, and the testing of ingredients will be phased out by 2009 or, in the case of some tests, 2013. This will apply to the sale of all cosmetic products. The ban was legally challenged by the French Government and the European Federation for Cosmetics Ingredients, representing 70 companies in Switzerland, Belgium, France, Germany and Italy but fortunately their protests were not upheld.

Such legislation is a major step forward and was achieved as a result of many years of campaigning by animal rights groups.



WASH POINTS

- **Most cosmetics sold in Australia are imported with the US being our largest supplier**
- **In 2003 the EU introduced legislation banning the sale of cosmetics tested on animals. The ban will be in full effect by 2013**

## Australian situation

Until recently in Australia cosmetics were very loosely defined as substances intended for placement in contact with an external part of the body which did not fall under the definition of 'therapeutic goods'.

On 17 September 2007 the Industrial Chemicals (Notification and Assessment) Act 1989 was amended to create the Cosmetics Standard 2007. The amendments to the Industrial Chemicals (Notification and Assessment) Act 1989 aimed to clarify the distinction between cosmetics and therapeutics and to formalise the regulatory process.

Six cosmetic categories were listed and defined: face and nail; skin care (moisturisers); skin care (anti-bacterial); skin care (anti-acne); oral hygiene; and hair care.

By virtue of these changes some products previously considered 'therapeutic goods', such as anti-dandruff shampoos and anti-acne washes, moved from the realm of therapeutic to cosmetic products.

Even so, the definitions were largely concerned with claims made on product labels and in promotional material. For example, an anti-dandruff shampoo could be presented as controlling or preventing dandruff through cleansing, moisturising, exfoliating or drying the scalp, but it could not be promoted as a cure for dandruff. If it did so it would be making the claim that it was therapeutic and should legally be registered as a medicine.

## Bathing in industrial chemicals

In Australia cosmetics come under the definition 'industrial chemi-

cals'. For regulatory purposes they are lumped with substances such as those used in mineral and petroleum processing, refrigeration and laboratory chemicals.

Strange bedfellows one would think! The regulating body is the National Industrial Chemicals Notification Scheme (NICNAS) which comes under the umbrella of the Commonwealth Department of Health and Ageing.

## NICNAS

NICNAS maintains a register of companies and individuals who import or manufacture industrial ingredients or finished products for commercial purposes.

Registration is mandatory and incurs an annual fee, the amount depending on the value of substances imported or manufactured each year.

Some companies are exempt from registration with NICNAS. These are generally cosmetics formulators using natural ingredients sourced from Australian suppliers.

The term 'natural' is, however, very narrowly defined. Many chemicals which are naturally occurring are not 'natural' by Australian regulatory standards. Under the Industrial Chemicals (Notification and Assessment) Act 1989 it is considered that only mechanical processes such as dissolution in water or cold-pressing are allowed if substances are to retain their naturally-occurring status. Ingredients obtained from natural sources by extraction processes such as steam distillation or solvent extraction are not considered 'natural'.

## AICS

NICNAS is also responsible for the maintenance of the Australian

Inventory of Chemical Substances (AICS). At present this lists approximately 40,000 industrial chemicals registered for use in Australia. The majority of these are chemicals which have been in use for many years and are therefore regarded as safe. Companies registered with NICNAS are required to consult the AICS data base and check that all ingredients in their products are listed and do not have any restrictions placed on them.

If a cosmetic ingredient is not listed on AICS it is classified as a 'new industrial chemical'. The company manufacturing or importing a new industrial chemical is required to notify NICNAS. In some cases NICNAS simply monitors the chemical for five years after it is introduced (by requiring annual reports from the company).

However, in the case of other chemicals, even those which fall into the category 'non-hazardous' but may be manufactured/imported at high volumes, NICNAS requires detailed information, including a MSDS with toxicological data. And, of course, 'toxicological data' traditionally means animal tests.

Even when toxicological data is not required companies may choose to conduct animal tests and submit the results to NICNAS. The chemical may be obviously non-hazardous yet there is nothing to stop a company from subjecting animals to totally unnecessary 'safety' tests as in the case of Dow Corning 2501 Cosmetic Wax. The NICNAS Summary Report (NA/311) for this product states:

*According to the Act, toxicological data are not required for polymers with number-average molecular*



weight (NAMW) greater than 1000 although the data summarised below were submitted by the notifier for Dow Corning' 2501 Cosmetic Wax.

The notified chemical exhibited low acute oral toxicity in rats (LD50 greater than 5000 mg/kg) and low acute dermal toxicity in rabbits (LD50 greater than 2000 mg/kg). It was found not to be a skin or eye irritant in rabbits. (1)

Similarly, although not legally required, L'Oreal submitted to NICNAS results from animal tests when applying for Australian registration of Mexoryl SX, an ingredient used in some of their sunscreens and moisturisers.

The tests included Oral LD50, Draize Eye and Skin Tests and Repeated Dose Toxicity using rats, mice and guinea pigs. (NICNAS, File No: NA/399)

(1) Dow Corning is the company against which many women filed law suits in the late 1990s following health problems associated with leaking breast implants. In 1998 Dow Corning and Dow Chemicals paid billions of dollars to settle these claims. Dow had tested the breast implants on animals prior to release on the market.



**WOM POWERS**

- **In Australia the regulating body for cosmetics is the National Industrial Chemicals Notification Scheme (NICNAS) which comes under the umbrella of the Commonwealth Department of Health and Ageing**
- **Companies importing or manufacturing cosmetics/ingredients must register with NICNAS (with few exceptions)**
- **NICNAS requires toxicological data for new ingredients**

**labelling**

## Legislation

The Australian Competition and Consumer Commission (ACCC) regulates packaging and labelling requirements for cosmetic products at a national level in Australia. It operates under Federal legislation called the Trade Practices Act 1974. Similar legislation operates at State levels around Australia to cover manufacturers and retailers who are not subject to Federal legislation.

The Trade Practices Act 1974 (and equivalent State legislation) contains prohibitions against conduct or representations that mislead or deceive or are likely to mislead or deceive. (Such representations include labels that make statements, claims or implications about goods.)

The Trade Practices Act 1974 also introduced consumer product information standards to give those using goods information on the quantity, quality, nature or value of different categories of goods. In June 1998, a review of the mandatory cosmetic ingredient labelling standard under the Trade Practices Act 1974 was completed by a committee comprising representatives of the Department of Industry, Science and Tourism, the Australian Competition and Consumer Commission and the Department of Health and Family Services. The following is an extract from the committee's Regulation impact statement:

***Labelling with a positive or negative statement about animal testing***

*The committee considered that this requirement is outside the scope of a product information standard under the Trade Practices Act, since it relates more to ideological considerations than to the quantity, quality, nature or value of the goods. Manufacturers are not barred from making accurate claims about their products not being tested on animals, and would do so if they believed it would enhance the market standing of their products.*

State and Territory Government agencies also play roles in regulating cosmetic labelling in their respective jurisdictions. The relevant agencies are Consumer Affairs Victoria, Office of Fair Trading (NSW), Department of Tourism, Fair Trading and Wine Industry Development (Qld), Office of Consumer and Business Affairs (SA), Department of Consumer and Employment Protection (WA), Consumer Affairs and Fair Trading (Tas), Office of Consumer and Business Affairs (NT) and Office of Fair Trading (ACT). There are no specific requirements in any of the Australian States or Territories for labelling in regard to animal testing.

## **Voluntary labelling**

Within the food industry in Australia some businesses have responded to growing consumer concern about the conditions under which their food is produced.

A number of accreditation schemes now exist, for example, Free Range Egg Producers Associations, Organic and Bio-dynamic accreditation schemes and RSPCA endorsement.

The Australia Egg Corporation, an industry body representing egg

producers across Australia, has developed Egg Corp Assured, a quality assurance program which requires its members to label egg cartons according to the method of production – cage, free-range or barn laid.

Unfortunately, the cosmetics industry does not see the need to set up a quality assurance program such as this – despite the fact that many consumers have indicated they would prefer to know if the products they are using have been tested on animals.

## **Cruelty-free claim on packaging**

Individual cosmetics companies, however, have recognised consumer concerns and often include a cruelty-free claim on their packaging. Such a claim is very ambiguous. It might apply to the finished product, the ingredients or both.

Many of the larger cosmetics companies stopped testing their finished products back in the 90s but continue to test their new ingredients on animals. Yet, if their finished product is not tested on animals, a ‘not tested’ claim would not, technically, be breaching any regulations.



In Australia, CCF is the Non-Government Organisation which offers a quality assurance program for cruelty-free cosmetics. CCF maintains a list of companies which fulfill well defined criteria with regard to animal testing. All companies on the CCF Preferred Products List must complete a detailed questionnaire and sign a legally binding assurance that they have not conducted, or commis-

sioned animal testing of their products at any point along the production or supply chain. Accreditation by CCF is free of charge and voluntary. Companies involved in animal testing generally decline the invitation for assessment.

It is therefore only possible for CCF to inform consumers about companies which do not conduct tests, not those which do.



- **Packaging and labelling requirements for cosmetic products come under the Trade Practices Act 1974. State and Territory Governments also have regulations**
- **There are no requirements at a national level or in any of the Australian states or territories for labelling regarding animal testing**
- **The cosmetics industry in Australia does not have a quality assurance programme. CCF acts as a consumer watchdog for cruelty-free cosmetics**

## **FUTURE** directions

If we were to replace all animal safety testing of ingredients used in cosmetic products the implications would be far reaching. By developing and validating non animal safety tests the scientific community would be giving approval to the use of such methods, not only in relation to the safety testing of cosmetics, but to all new ingredients. Once validated, there is no reason a non animal test should not completely replace the parallel animal safety test in all areas of research.

The use of non animal testing methods could, for example, be used in the development of pharmaceuticals and industrial chemicals. The use of animals in testing the chemicals we use in our lives is one of the most inhumane areas of animal based research.

The animals involved in the studies are given no pain relief and they are always sacrificed during, or at the completion of the experiments. If we were to replace the use of animals in safety testing all species of animals – from rats to monkeys – would be spared unnecessary torture and death. The alternatives are being developed but whether they are used or not depends on the attitude of the general public. There is no point developing alternatives if we do not also ensure that their use is enforced.

## **Status quo is very resistant to change**

We have come a long way from the eighties when Henry Spira caught the attention of the cosmetics industry with the Coalition to Stop Draize Rabbit Blinding Tests. Prior to that companies would never

have considered finding ways of testing their products on anything other than live animals. It was the status quo. And the status quo is very resistant to change – especially when someone is making money from it. The industry supplying animals to laboratories is large and profitable.

The mechanisms have now been set in place to move forward from the animal testing of cosmetics to more humane, and more reliable, methods of establishing that products are safe for human use. Europe has set a commendable example by introducing laws prohibiting the production and sale of cosmetics tested on animals.

Australian regulatory authorities, however, have shown no interest in introducing similar laws. And a substantial amount of our cosmetics come from countries where animal testing of cosmetics is still permitted.

## Without blood on our hands

If we ever want to be able to freely use products such as make-up, soap, shampoo, deodorant and toothpaste without having blood on our hands we need to change the regulations in Australia. We need to stand up and demand a total ban on the importation and sale of cosmetics tested on animals. It won't happen by itself.

Under section 81(1) of the Industrial Chemicals (Notification and Assessment) Act 1989 (Cth) ('the Act'), the Minister for Health and Ageing has the power to 'determine standards for cosmetics imported into, or manufactured in, Australia, having regard to Australia's international obligations.' It is an offence under s 81A for a person to import into, or manufacture in, Australia a cosmetic that does not

meet an applicable standard set by the Minister. We at CCF are asking that you contact the Minister for Health and Ageing and ask for the introduction of a standard under s 81 of the Act stating that no cosmetic shall be imported into Australia if the final product or its ingredients have been tested on animals.

**'Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has.'** - Margaret Mead.



- **There is no reason validated alternative tests cannot completely replace parallel animal safety tests. At present companies manufacturing outside Australia and the EU can choose to use either method**
- **The EU has introduced legislation to ban the manufacture and import of cosmetics tested on animals**
- **We are asking the Australian Government to introduce legislation similar to the EU**

COVER PHOTOS of Fletcher Humphys by © Christian Alexander  
RABBITS IN THE LABORATORY courtesy PETA.org  
WRITER HIP HOP KID 03 © Tuncindas | Dreamstime.com  
MAN SHAVING © Stuart Miles | Dreamstime.com  
YOUNG WELLNESS GIRL WITH DEODORANT © Dnf-style | Dreamstime.com

BRUSHING TEETH © Kati1313 | Dreamstime.com  
MAKEUP © Duane Ellison | Dreamstime.com  
MAKEUP PRODUCTS © Mondo2k42 | Dreamstime.com  
MACSARA © Bg\_knight | Dreamstime.com  
CREAM IN HAND © Imarin | Dreamstime.com



The contents of  
this publication is  
the property of  
© Choose Cruelty  
Free Limited



### **Choose Cruelty Free Limited**

PO Box 12005 A'Beckett St Melbourne Australia 3000

Tele: 00 61 3 9328 1377 Fax: 00 61 3 9328 2117

Email: [admin@choosecrueltyfree.org.au](mailto:admin@choosecrueltyfree.org.au)

Website: [www.choosecrueltyfree.org.au](http://www.choosecrueltyfree.org.au)

Printing costs kindly donated by Voiceless

