Ministry for Primary Industries
Manatū Ahu Matua

Animal testing of finished cosmetic products and ingredients used in cosmetics

Regulatory Impact Statement

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New Zealand Government

Growing and Protecting New Zealand

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Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

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Agency Disclosure Statement

This Regulatory Impact Statement (RIS) has been prepared by the Ministry for Primary Industries (MPI) to assess the Government's options for responding to public concern at the use of animals to test non-essential products, such as cosmetics[1]. This concern manifested itself during the Primary Production Select Committee process of the Animal Welfare Amendment Bill (the Bill).

MPI acknowledges the limitations of the Regulatory Impact Assessment (RIA) associated with this RIS and considers it partially meets Quality Assessment criteria because of the reasons outlined below.

- The ability to include a cost-benefit analysis in this RIA of the different options is constrained by a lack of data. This is due to the fact that cosmetics and their ingredients are not known to be tested on animals in New Zealand and as such there is limited impact on the cosmetic industry or benefit to animal welfare outcomes. These activities are also unlikely to occur in the future under the existing ethical framework within the Animal Welfare Act 1999 (the Act).

- The analysis of the benefits is constrained as no specific consultation has been undertaken to determine the public's and sector's views on the proposed options. The analysis of the public's perception within this RIS is based on the public debate and submission process of the Bill. We assume, for the purposes of this RIS, that debate provides a good indication of the public's views on the policy intent around the use of animals to test non-essential products such as cosmetics and that further consultation would be unlikely to give a different result.

The benefits of taking steps beyond the status quo lie primarily around providing domestic and international individuals and organisations, that are concerned with the use of animals in research, testing and teaching (RTT) for non-essential products, with certainty that this type of RTT cannot happen in the future.

In November 2014, the global charity World Animal Protection ranked New Zealand first equal, out of 50 countries, for our animal welfare legislation and policy system, alongside the UK, Austria and Switzerland. Adopting a legislative ban on the use of animals to test cosmetics would provide a visible demonstration of NZ's commitment to continuous improvement and excellence in the delivery of a world leading animal welfare system.

Regardless of which option the Government decides to support, additional work will be required to communicate the new requirements to affected parties. This work will be undertaken by MPI, the National Animal Ethics Advisory Committee (NAEAC) and animal ethics committees (AECs). The current public concern around the use of

[1] The Animal Welfare Act 1999 does not currently define the term cosmetics but in general terms it includes products whose primary purpose is to cleanse, improve attractiveness, change the appearance, moisturise or deodorise. Options 2, 3, and 4 propose including a definition of cosmetics within the Act.

animals to test cosmetics and cosmetic ingredients indicates that additional work is also required to inform interested parties about current RTT practices, that is, that this type of RTT is not known to occur in New Zealand.

Julie Collins
Director Biosecurity and Animal Welfare 5 March 2015

Status quo

In New Zealand there is no recorded history of animals being used to test finished cosmetic products or ingredients intended to be used exclusively in cosmetics. This type of testing is unlikely to occur in the future under the existing ethical framework within the Act. This ethical framework incorporates systems and processes that provide oversight of the organisations undertaking the research and individual evaluation of RTT projects, including that:

- no person may carry out RTT unless they:
    - hold a code of ethical conduct[2] approved by the Director-General of MPI under Part 6 of the Act; or
    - are authorised or required by contract, entered into with a person of the kind described above, to undertake RTT
- individual projects must also be approved by an animal ethics committee[3] (AEC) and be carried out in accordance with any conditions imposed by that committee;
- AECs must be satisfied that the benefits of using animals in RTT are not outweighed by the likely harm to the animals involved (harm/benefit test)—if the project cannot demonstrate that its benefits (to human beings, animals or ecosystems) justify the harm caused to the animals involved, then the project cannot take place.

The type of RTT that is undertaken in New Zealand changes from year to year in response to RTT needs. However, in general the majority of RTT using animals undertaken in New Zealand relates to veterinary, biological and medical research, animal husbandry or testing for public health or regulatory requirements.[4] The testing of products such as household cleaners and cosmetics is carried out overseas.

The Animal Welfare Amendment Bill

The Bill was introduced into the House on 8 May 2013. The Bill was reported back from the Primary Production Select Committee on 26 June 2014 and received its second reading on 26 November 2014. It is now awaiting Committee of the Whole House stage and its third reading. The Bill is MPI's top legislative priority for 2015.

While the Bill was at Select Committee there was considerable public debate on the use of animals in testing various products. Over 4000 written submissions were made during the Select Committee process, more than half of which called for stricter rules around RTT. Some called for all RTT using animals to be banned, while others wanted bans for specific practices or purposes, for example, testing of cosmetics, psychoactive substances, or household products, despite these types of RTT not being known to have occurred in New Zealand.

[2] Codes of ethical conduct set out the policies and procedures that need to be adopted and followed by the RTT organisation and its animal ethics committees

[3] AECs include representatives of the RTT organisation but also have three external members: a nominee of an approved animal welfare organisation; a nominee of the NZ Veterinary Association; and a lay person to represent the public interest (and nominated by a local government body)

[4] Annual reports on animal use in RTT are available on MPI's website

Public concern around testing for psychoactive substances led to an urgent amendment to the Psychoactive Substances Act 2013. The Psychoactive Substances Act was amended to prohibit information gained from trials involving animals from being taken into account when determining whether a psychoactive substance poses a low risk of harm. The results of animal studies can, however, be used to show that a psychoactive substance poses more than a low risk of harm.

SOP 44

On 18 March 2014, a non-Government Supplementary Order Paper (SOP), SOP 423, to the Bill was released seeking to ban the testing of finished cosmetic products and ingredients used in cosmetics on animals in New Zealand. This was subsequently replaced by SOP 473 on 26 June 2014 and has now been replaced again by SOP 44, which was released on 11 February 2015. SOP 44 does not materially change the issues raised in SOP 423.

International situation

Some jurisdictions, most notably the European Union (EU) and India, have bans in place around the use of animals to test finished cosmetic products, and ingredients used in cosmetics, within their jurisdictions. The EU's ban was phased in and came into full effect in 2009 while India's ban was implemented in 2014. In 2013 and 2014, respectively, the EU[5] and India also implemented bans on the sale and/or importation of cosmetics that have been tested on animals outside their jurisdiction.

[5] The EU's sales and marketing ban was phased in from 2009.

Problem definition

There is broad public concern about animals in New Zealand being used to test the safety and efficacy of non-essential products such as cosmetics. This concern reflects a growing trend, nationally and internationally, around the use of animals and the desire to see better animal welfare outcomes. During the Select Committee consideration of the Bill more than half of the submissions received called for stricter rules around RTT.

The status quo does not appear to address this concern to the satisfaction of many individuals and organisations. This may be because:

- the status quo does not provide an absolute guarantee that finished cosmetic products or ingredients, intended to be used exclusively in cosmetics, would never be tested on animals in New Zealand and/or
- there is limited awareness that in New Zealand that:
    - there has been no history of animals being used to test finished cosmetic products or ingredients intended to be used exclusively for cosmetics; and
    - the harm/benefit test within the ethical framework of the Act is highly unlikely to allow this type of testing to happen in the future.

Objectives

MPI's overarching objective is to address the public's concern in a way that:

- is consistent with the principle purpose of RTT within the Act; and
- takes into account practicality and economic impact.

The principal purpose, in relation to RTT within the Act, is to ensure that the use of animals is confined to cases in which there are good reasons to believe that the outcome of the RTT will enhance, among other things, the understanding of human beings, animals and ecosystems; and the maintenance or protection of human or animal health and welfare. There also needs to be good reason to believe that the benefits derived from the use of animals in RTT are not outweighed by the likely harm to the animals.

The following criteria were used to assess the options against the objectives:

- Is there certainty that animals in New Zealand will not be used to test finished cosmetic products or ingredients intended to be used exclusively in cosmetics?
- Is the use of animals in RTT confined to cases where the benefits outweigh the likely harms to the animals?
- Is the impact on New Zealand business being minimised?

Options and impact analysis

Table 1 outlines how the different options achieved each of the criteria described above. These options are described in more detail below the table.

Table 1: Analysis of options against the criteria

Summary of Options	**Criteria**		
	Certainty that testing in NZ won't occur	***RTT constrained to situations where benefits outweigh harm***	***Impact on New Zealand business is minimised***
Option 1 – Status Quo	✘ No absolute guarantee that NZ animals won't be used to test cosmetics or their ingredients.	✓✓ Individual research & testing projects assessed on own merit—cosmetic testing unlikely to occur under existing ethical framework in the Act.	✓✓ This type of testing does not occur in NZ and is unlikely under existing ethical framework within the Act.
Option 2 – Govt SOP: NZ ban on animal testing for cosmetic products	✓ Provides guarantee that NZ animals won't be used to test cosmetic products. Does not provide same guarantee around ingredients to be used exclusively in cosmetics	✓✓ Bans animal testing for finished cosmetic products. Ingredient related projects assessed on own merit—unlikely to occur under existing ethical framework within the Act.	✓✓ This type of testing does not occur in NZ and is unlikely under existing framework within the Act.
Option 3 – Govt SOP: NZ ban on animal testing for cosmetic products and ingredients to be used exclusively in cosmetics	✓✓ Provides guarantee that NZ animals won't be used to test cosmetics and ingredients to be used exclusively in cosmetics.	✓✓ Bans the use of animals in research and testing for finished cosmetic products and cosmetic ingredients intended to be used exclusively in cosmetics.	✓✓ This type of testing does not occur in NZ and is unlikely under existing framework within the Act.
Option 4 – SOP 44: NZ ban on animal testing for cosmetic products and ingredients	✓✓ Provides a guarantee that NZ animals won't be used to test cosmetic products and ingredients.	✓ Bans the use of animals in research and testing for finished cosmetic products. However, projects with wider benefits to human and animal health and welfare may be prohibited.	✘ May impact non-cosmetic industries by: - preventing ingredients intended for cosmetics being tested for other purposes. - preventing mandatory testing of products under different regulatory regimes. - capturing products with positive health benefits.

Key: ✘ = criteria unlikely to be met; ✓ = criteria is partially met; ✓✓ =criteria is likely to be met.

OPTION 1 – STATUS QUO

Maintaining the status quo is unlikely to have any impact on New Zealand's cosmetic industry or the use of animals in RTT as:

- MPI is unaware of any situations in New Zealand where animals have been used to test cosmetic products or ingredients intended for the exclusive use in cosmetics;
- AECs are unlikely to approve RTT for cosmetic products or their ingredients in the future as the benefits derived from RTT for these types of products are unlikely to outweigh the likely harm to the animals; and
- the majority (93%) of cosmetic products in New Zealand are imported.

However, maintaining the status quo is likely to negatively impact on the perceptions or values of those that have concerns around testing non-essential products, such as cosmetics, in New Zealand. As noted earlier, during the Select Committee stage of the Bill there was considerable public debate on the use of animals in RTT, which led to amendments to the Psychoactive Substances Act.

In November 2014, the global charity World Animal Protection ranked New Zealand first equal, out of 50 countries, for our animal welfare legislation and policy system, alongside the UK, Austria and Switzerland. If other jurisdictions adopt a legislative ban on the use of animals to test cosmetics but New Zealand does not, this could compromise New Zealand's world leading reputation.

While animals in New Zealand are not used, and are unlikely to be used, to test finished cosmetic products and ingredients intended to be used exclusively in cosmetics, the status quo does not provide an absolute guarantee that it will not occur in the future.

If the Government chooses to maintain the status quo, additional work will be required to mitigate public concern around on this issue. This could be achieved through increasing awareness of the current status of cosmetic testing in New Zealand, that is, that animals in New Zealand are not used to test finished cosmetic products or ingredients intended to be used exclusively in cosmetics and that this is unlikely to change in the future under the existing harm/benefit test within the ethical framework of the Act.

OPTION 2 – GOVERNMENT SOP: NEW ZEALAND BAN ON ANIMAL TESTING FOR FINISHED COSMETIC PRODUCTS

Option 2 would impose a ban on the use of animals to test finished cosmetic products within New Zealand. It would not impose a ban on animal testing for ingredients that are used in the development of cosmetics.

MPI considers that a ban on testing for finished cosmetic products would be consistent with the principal purpose of RTT within the Act. It is unlikely that the outcomes of RTT for finished cosmetic products, would enhance the understanding of human beings, or

enhance the maintenance or protection of human health and welfare and therefore meet the harm/benefit test within the ethical framework of the Act.

Banning animal testing of finished cosmetic products would not negatively impact New Zealand businesses or improve animal welfare outcomes in New Zealand. MPI is unaware of any situations where animals have been used to test finished cosmetic products in New Zealand; AECs are unlikely to approve such testing in the future; and the majority of cosmetic products in New Zealand are imported.

There may be a positive impact on those who have concerns around testing non-essential products, such as cosmetics, in New Zealand. Option 2 provides a guarantee that finished cosmetic products will not be able to be tested on animals in New Zealand. However, this might be tempered by the fact that Option 2 only bans animal testing in relation to finished cosmetic products. It does not impose a ban on animal testing for ingredients that are used in the development of cosmetics.

There is a potential risk that banning animal testing for finished cosmetic products could unintentionally capture products that deliver positive health benefits. MPI considers that this risk can be mitigated with a Government SOP through clear drafting of the definition of "cosmetic" and prohibiting the use animals in RTT that relate to developing, making or testing a cosmetic.

OPTION 3 – GOVERNMENT SOP: NEW ZEALAND BAN ON ANIMAL TESTING FOR FINISHED COSMETIC PRODUCTS AND INGREDIENTS TO BE USED EXCLUSIVELY IN COSMETICS

Option 3 would impose a ban in New Zealand on the use of animals to test finished cosmetic products and ingredients intended to be used exclusively in cosmetics.

As with Option 2, a ban would:

- be consistent with the principle purpose of RTT within the Act, as it relates to human beings; and
- not negatively impact on New Zealand businesses or improve animal welfare outcomes in New Zealand as this type of testing does not occur in New Zealand and is unlikely to occur under the existing ethical framework within the Act.

Option 3 is likely to address concerns by some around testing non-essential products, such as cosmetics, in New Zealand. Option 3 provides a guarantee that finished cosmetic products and ingredients that are intended to be exclusively used in cosmetics will not be able to be tested on animals in New Zealand.

In addition to the potential unintended risks noted for Option 2, there is also the potential that imposing a ban on ingredients, used in cosmetics, could impact industries outside the cosmetic industry by hindering their ability to develop non-cosmetic products. Ingredients, such as, preservatives or formulation aids used in cosmetics are also commonly used in non-cosmetic products, including human and animal medicines.

As with Option 2, MPI considers that a Government SOP could mitigate this through clear drafting of the definition of "cosmetic" and prohibiting the use of animals in RTT that relate to developing, making or testing a cosmetic or ingredient that is intended exclusively for use in a cosmetic.

OPTION 4 –SOP 44: NEW ZEALAND BAN ON ANIMAL TESTING FOR FINISHED COSMETIC PRODUCTS AND INGREDIENTS

A non-Government SOP, SOP 44, was released on 11 February 2015 (and supersedes SOP 423 and 473). SOP 44 seeks to ban the testing of finished cosmetic products and ingredients used in cosmetics on animals in New Zealand.

For the same reasons discussed under Option 3, this option is:

- likely to address concern by some around testing non-essential products, such as cosmetics, on animals in New Zealand; and
- unlikely to improve animal welfare outcomes in New Zealand.

However, as currently drafted, SOP 44 is not fully consistent with the principal purpose of RTT within the Act. As a result of how the word "cosmetics" is defined, SOP 44 could prohibit RTT projects that have benefits to human and animal health and welfare. This option could also potentially impact industries outside the cosmetic industry and hinder their ability to develop non-cosmetic products or determine the safety and efficacy of such products. As it stands, SOP 44 could have a significant impact on a number of areas. It could:

- prevent ingredients intended for use in cosmetics from being tested for other purposes e.g. preservatives or formulation aids that are commonly used in both cosmetics and non-cosmetic products, including human and animal medicines;
- prevent required animal testing of products under different regulatory regimes, for example, related products under the Medicines Act 1981, hazardous substances under the Hazardous Substances and New Organisms Act 1996; and
- capture, within the ban, products such as primary sunscreens and fluoride toothpastes that deliver positive health benefits, unless regulations were made to exclude such products.

Regulations could be developed under SOP 44 to exclude a significant portion of the individual products captured by the last two points above—although not all. However, these same regulation making powers could not be used to allow ingredients, which are to be used in cosmetics, to be tested for another purpose. In addition, using the regulation making powers to exclude key categories of products (such as related products) is not good regulatory practice. The policy intent should be clear within the Act.

Consultation

MPI has not undertaken any specific non-government consultation on this issue, with the exception of the National Animal Ethics Advisory Committee. The rationale being:

- there has already been significant public debate on the issue both domestically and internationally and we consider that further public consultation is unlikely to give a different result; and
- the banned activities under Option 2 and 3 do not occur and are unlikely to occur in New Zealand.

During the passage of the Bill through the House, the Minister and the Select Committee both received a considerable number of ministerials and submissions, respectively, in support of banning cosmetic testing on animals in New Zealand.

As noted earlier, over 4000 written submissions were made during the Select Committee process, more than half of which called for stricter rules around RTT. Some called for all RTT using animals to be banned, while others wanted specific practices or purposes banned, for example, testing of cosmetics, psychoactive substances, or household products.

Internationally, concern around the use of animals for testing cosmetics has led to some jurisdictions, most notably the European Union and India, prohibiting the testing of cosmetic on animals within their jurisdictions.

NAEAC was consulted to determine the impact an express ban would have on AECs. They confirmed that any express ban imposed under Options 2 or 3 would not place a significant additional burden on AECs. AECs must already ascertain the full nature of any project seeking ethics approval in order to determine that the likely benefits of the project are not outweighed by any likely harm to the animals.

Conclusions and recommendations

There is broad public concern about animals in New Zealand being used to test the safety and efficacy of non-essential products, such as cosmetics. This RIS presents the following four options for responding to this public concern:

Option 1 - Increasing awareness of the status quo, that is, that cosmetic RTT has not historically occurred in New Zealand and is unlikely to occur under the existing ethical framework within the Act.

Option 2 – Providing an absolute guarantee that finished cosmetic products are not tested on animals in New Zealand, through a Government SOP.

Option 3 - Providing an absolute guarantee that finished cosmetic products, and ingredients to be used exclusively in cosmetics, are not tested on animals in New Zealand, through a Government SOP.

Option 4 – Adopting SOP 44, which seeks to ban animals in New Zealand being used to test cosmetics and ingredients used, though not exclusively, in cosmetics.

Options 1, 2 or 3 do not impinge on RTT activities that would be appropriate under the harm/benefit test within ethical framework of the Act, that is, they would not prohibit projects where the benefits outweigh the harm to the animals. These options would not impact New Zealand businesses, affect animal welfare outcomes, or AECs' work load as:

- the proposed banned activities under Options 2 and 3 do not currently occur in New Zealand and are unlikely to occur under the status quo (Option 1);
- AECs already weigh the benefit and harm of all projects. Any ban on testing finished cosmetic products, or ingredients intended to be used exclusively in cosmetics, would simply be part of that consideration.

In addition, any public concern around Options 1, 2, and 3 could potentially be mitigated through increasing awareness of the current status of cosmetic testing in New Zealand. Animals in New Zealand are not used to test finished cosmetic products, or ingredients intended to be used exclusively in cosmetics, and this is unlikely to change in the future under the existing ethical framework.

MPI considers that SOP 44 (Option 4) is not consistent with the principal purpose of RTT within the Act. As noted earlier, SOP 44 could prohibit some RTT projects that have benefits to human and animal health and welfare and hinder the ability of non-cosmetic industries to develop their products or determine the safety and efficacy of those products.

Implementation plan

AECs, established under the Act, will be responsible for ensuring the delivery of any ban on the use of animals to test cosmetics and cosmetic specific ingredients. If a ban is instigated, AECs will need to assure themselves that a project does not relate to finished cosmetic products or ingredients intended for the exclusive use in cosmetics before (or as part of) their deliberation of a RTT project seeking ethics approval.

Additional work will be required to communicate the new requirements to affected parties. This work will be undertaken by MPI, the National Animal Ethics Advisory Committee (NAEAC) and animal ethics committees (AECs). MPI will work with NAEAC to update AECs on the new constraints and directly update its accredited reviewers.[6] This work will include providing clarity around the definition of cosmetic, as necessary.

Additional work is also required to inform interested parties about current RTT practices, that is, that this type of RTT is not known to occur in New Zealand and is unlikely to occur in the future. This will be especially important if the Government supports Options 1 and 2.

[6] Reviewers are accredited by the Director-General of MPI under section 109 of the Act. A list of MPI accredited reviewers is available on the following link: https://www.biosecurity.govt.nz/animal-welfare/naeac/accredited-reviewers.htm

Monitoring, evaluation and review

Organisations permitted to carry out RTT on animals and their AEC must undergo an independent review (by MPI accredited reviewers) at least once every five years. The purpose of the review is to assess the organisation's and the AEC's compliance with the requirements of the Animal Welfare Act, the Animal Welfare (Records and Statistics) Regulations 1999 and their code of ethical conduct (which is approved under the Act).

Compliance with the new bans will be assessed within this established review process.