



## **Scenarios: Use of animals for testing of chemical ingredients or products**



# Scenarios: Use of animals for testing of chemical ingredients or products

The following information outlines scenarios where the use of animals is proposed to test chemical ingredients or products, and how the requirements in the *Australian code for the care and use of animals for scientific purposes* and the new *Section 7: Cosmetic testing* in the Code apply. This information does not apply to the application of the *Industrial Chemicals Act 2019* and does not include consideration of whether the data obtained from the animal studies could be used to support the introduction of a chemical under the *Industrial Chemicals Act 2019*.

#	Scenario	Comments	Key point in decision tree
1	A company seeks to use animals for testing of Chemical A that is intended for use only in a cosmetic (shampoo). <sup>1</sup>	Animals cannot be used for this purpose as <i>Section 7: Cosmetic testing</i> of the Code requires the use of animals to be justified by a purpose other than use in a cosmetic.	1
2	A company seeks to use animals to test the safety of Chemical B that is intended for use in a clothes detergent (non-cosmetic) and a shampoo (cosmetic). Of particular concern is whether Chemical B is toxic to fish when the detergent or shampoo is released into the waterways after use. There are no available valid non-animal alternatives for determining the risk to humans or the environment of exposure to Chemical B.	<i>Section 7: Cosmetic testing</i> of the Code requires the use of animals to be justified by a purpose other than use in a cosmetic.  Even though Chemical B is intended for use in a cosmetic, it is also intended for use in a non-cosmetic and the use of animals can be justified by the need to protect human health and the environment.	2
3	Similar to Scenario #2, a company seeks to use animals to test the safety of Chemical B that is intended for use in a clothes detergent (non-cosmetic) and a shampoo (cosmetic). Of particular concern is whether Chemical B is toxic to fish when the detergent or shampoo is released into the waterways after use. There are no available valid non-animal alternatives for determining the risk to humans or the environment of exposure to Chemical B.  Unlike Scenario #2, the company contracts research laboratories in two universities to conduct the studies, which will be part of a collaborative project.	As with Scenario #2, <i>Section 7: Cosmetic testing</i> of the Code requires the use of animals to be justified by a purpose other than use in a cosmetic. Even though Chemical B is intended for use in a cosmetic, it is also intended for use in a non-cosmetic and the use of animals can be justified by the need to protect human health and the environment.  Unlike Scenario #2, the study involves collaborative research involving more than one institution. Clauses 2.6.4–2.6.8 of the Code are therefore particularly relevant to this situation. The institution and AEC may also require specific details about the collaboration outlined in the AEC application form (Clause 2.7.4 [xxii] of the Code).	2

<sup>1</sup> 'Cosmetic' is defined in *Section 7: Cosmetic testing* in the Code

#	Scenario	Comments	Key point in decision tree
4	<p>A company has tested the safety of Chemical C using a non-animal alternative. Chemical C is found to be safe and is then used in the development of a finished cosmetic product (moisturiser).</p> <p>Before it can be sold to consumers, the safety of the moisturiser for human use must be tested (e.g. does not cause skin sensitivity).</p>	<p>Animals cannot be used for this purpose as <i>Section 7: Cosmetic testing</i> of the Code outlines that animals must not be used for testing of finished cosmetic products.</p> <p>If they wish to proceed, the company must use a non-animal alternative for testing the safety of the moisturiser.</p>	7
5	<p>Following approval from an animal ethics committee (AEC), animals were used to test the safety of Chemical D that was intended for use as an ingredient in a paint product (non-cosmetic). There were no valid non-animal alternatives to obtain this information. The data from the animal testing demonstrated that Chemical D is safe. The animal test data were used to support the introduction of Chemical D, which was then used as an ingredient in the paint product.</p> <p>The company now wishes to use Chemical D in a cosmetic (lipstick).</p>	<p><b>Original purpose:</b></p> <p>In the AEC application, the use of animals for testing of Chemical D in a paint product was justified by a purpose other than use in a cosmetic. Justification included protection of human health.</p> <p><b>Subsequent purpose:</b></p> <p>The questions now are about whether the results from the original animal tests (when intended for use in a paint product) are sufficient to show that Chemical D is safe for humans when intended for use in a lipstick, and whether the use of <b>additional animals</b> may be required.</p> <p>(a) If the results are sufficient, the use of <b>additional animals</b> is not required to test the safety of Chemical D for use in the lipstick as the data is already available.</p> <p>(b) If the results are NOT sufficient:</p> <ul style="list-style-type: none"> <li>• Additional data is required to prove that Chemical D is safe for humans when it is used in a lipstick.</li> <li>• The use of the additional animals to obtain this information cannot be justified by a purpose other than use in a cosmetic. The testing of Chemical D for a purpose other than in a cosmetic (that is, in the paint product) was relevant to the justification for the original animal testing and is separate to the justification for the use of these additional animals.</li> <li>• If they wish to proceed with using Chemical D in a lipstick, the company must use a non-animal alternative for testing the safety of Chemical D in the lipstick.</li> </ul>	<p>Use in paint product: 3, 4, 5, 6 and 8.</p> <p><b>Additional animals:</b></p> <p>Subsequent use in lipstick: (a) 7 (3,4, 5 and 6 already completed)</p> <p>(b) 1</p>

#	Scenario	Comments	Key point in decision tree
6	<p>A company obtained AEC approval to use animals to test the effectiveness of a tinted face cream that is intended to provide SPF 30+ sun protection (a therapeutic). There were no valid non-animal alternatives to obtain this information.</p> <p>Following completion of the study, the results demonstrate that the face cream is not effective in providing SPF 30+ sun protection.</p> <p>The company now wishes to use the face cream as a foundation (a finished cosmetic product).</p>	<p><b>Original purpose:</b></p> <p>As the tinted face cream provided SPF higher than 15, it is regulated as a therapeutic good under the <i>Therapeutic Goods Act 1989</i>. The use of animals for testing of the face cream must be in accordance with all requirements in the Code, including those related to the use of valid non-animal alternatives. <b>However, Section 7: Cosmetic testing of the Code did not apply.</b></p> <p><b>Subsequent purpose:</b></p> <p>The questions now are about whether the results from the original animal study (when the face cream was intended for use to provided SPF 30+ sun protection) are sufficient to show that the face cream is safe for humans when intended for use as a foundation, and whether the use of <b>additional animals</b> may be required.</p> <p>(a) If the results are sufficient, the use of <b>additional animals</b> is not required to test the safety of the face cream for use as a foundation as the information is already available.</p> <p>(b) If the results are NOT sufficient:</p> <ul style="list-style-type: none"> <li>• Additional information is required to prove that the face cream is safe for humans when it is used as a foundation.</li> <li>• The use of the additional animals to obtain this information cannot be justified by a purpose other than use in a cosmetic. The testing of the face cream for a purpose other than in a cosmetic (that is, as a face cream providing SPF greater than 15) was relevant to the justification for the original animal testing and is separate to the justification for the use of these additional animals.</li> <li>• If the company wishes to proceed with use of the face cream as a foundation, the company must use a non-animal alternative for testing the safety of the face cream as a foundation.</li> </ul>	<p>Use as a cream providing SPF greater than 15: 8</p> <p><b>Additional animals:</b> Subsequent use as a foundation: 7</p>

#	Scenario	Comments	Key point in decision tree
7	<p>Following AEC approval, animals were used to test the safety of Chemical E that was intended for use as an ingredient in a paint product (non-cosmetic). There were no valid non-animal alternatives to obtain this information. The data from the animal testing demonstrated that Chemical E is NOT safe. Use of Chemical E in the development of the paint product did not proceed.</p> <p>Another company now proposes to use Chemical E in a cosmetic (hair dye).</p>	<p>In the AEC application, the use of animals for testing of Chemical E in a paint product was justified by a purpose other than use in a cosmetic. Justification included protection of human health.</p> <p>The use of additional animals is not required to test the safety of Chemical E for use in the hair dye as the data are already available. However, the evidence provided by the animal test data must not be ignored. The use of Chemical E in the development of the hair dye does not proceed.</p>	<p>Use in paint product: 3, 4 and 5.</p> <p>Subsequent use in hair dye: 5</p>
8	<p>AEC approval is obtained for the use of animals to test the safety of Chemical F that is intended for use in a paint product (non-cosmetic).</p> <p>The use of animals proceeds and demonstrates that Chemical F is safe. However, Chemical F is used in the development of a lipstick, rather than the development of a paint product as outlined in the AEC approval.</p>	<p>The use of animals does not accord with that outlined in the application for AEC approval and is a breach of the Code and relevant legislation.</p> <p>This situation is covered by the requirements in the Code for:</p> <ul style="list-style-type: none"> <li>• monitoring and inspection by the AEC (Clauses 2.3.17-2.3.23)</li> <li>• reporting by investigators to the AEC (including annual and final reports) (Clauses 2.3.17-2.3.23)</li> <li>• management of non-compliance (Section 5 and Clause 2.3.5), including actions that must be taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include suspending or withdrawing approval for the project or activity.</li> </ul>	<p>As described in AEC application: 3, 4, 5 and 6</p> <p>However, should have commenced at 1 rather than 3.</p>

#	Scenario	Comments	Key point in decision tree
9	<p>AEC approval is obtained for the use of animals to test the safety of Chemical G that is intended for use in a detergent (non-cosmetic) as well as a shampoo (a cosmetic) – that is, multiple end uses as well as an end use in a cosmetic.</p> <p>The use of animals proceeds and demonstrates that Chemical G is safe. However, Chemical G is used ONLY in a shampoo. Chemical G was never intended to be used in a detergent.</p>	<p>The use of animals does not accord with that outlined in the application for AEC approval and is a breach of the Code and relevant legislation.</p> <p>If the AEC application had outlined the intended use of Chemical G only in a cosmetic, AEC approval would not have been granted as the use of animals could not be justified by a purpose other than use in a cosmetic.</p> <p>This situation is covered by the requirements in the Code for:</p> <ul style="list-style-type: none"> <li>• monitoring and inspection by the AEC (Clauses 2.3.17–2.3.23)</li> <li>• reporting by investigators to the AEC (including annual and final reports) (Clauses 2.3.17–2.3.23)</li> <li>• management of non-compliance (Section 5 and Clause 2.3.5), including actions that must be taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include suspending or withdrawing approval for the project or activity.</li> </ul>	<p>As described in AEC application: 2, 4, 5 and 6</p> <p>However, should have commenced at 1 rather than 2.</p>
10	<p>A company seeks to use animals to test Chemical H that is intended for use in an antibiotic for therapeutic use in humans.</p>	<p>Chemical H is not intended for use in a cosmetic as an antibiotic intended for therapeutic use in humans is not a cosmetic.</p> <p>The use of animals for testing of Chemical H must be in accordance with all requirements in the Code, including those related to the use of valid non-animal alternatives. <b>However, Section 7: Cosmetic testing of the Code does not apply.</b></p>	3
11	<p>Chemical I has been used to develop a cream intended for treatment of skin cancer in humans.</p> <p>Before it can be used on patients, the safety of the cream must be tested. The company seeks to use animals for this purpose.</p>	<p>The cream is not a cosmetic as it is intended for therapeutic use in humans.</p> <p>The use of animals for testing of the cream must be in accordance with all requirements in the Code, including those related to the use of valid non-animal alternatives. <b>However, Section 7: Cosmetic testing of the Code does not apply.</b></p>	8
12	<p>A cosmetic company wishes to use animals to test a face cream that also acts as a sunscreen with an SPF 30+.</p>	<p>The face cream is classified as a secondary sunscreen product. However, because the face cream has an SPF higher than 15, it is regulated as a therapeutic good under the <i>Therapeutic Goods Act 1989</i>. The face cream is not regulated as a cosmetic. (Information about the regulation of sunscreens is available on the <a href="#">Therapeutic Goods Administration website</a>.)</p> <p>The use of animals for testing of the face cream must be in accordance with all requirements in the Code, including those related to the use of valid non-animal alternatives. <b>However, Section 7: Cosmetic testing of the Code does not apply.</b></p>	8

