



NATRUE Organization - Statement

Animal testing provisions in the NATRUE Label criteria

1.1 Regulatory background:

The EU regulatory framework for cosmetics (Regulation (EC) No 1223/2009) contains fully comprehensive provisions concerning animal testing. It repealed and fully replaced the EU Cosmetics Directive 76/768/EEC in July 2013.

All cosmetic products marketed in the EU must comply first and foremost with the essential requirements of the EU cosmetics regulation (i.e. composition, safety, efficacy and labelling) independent of the formulation. This regulation is a legal requirement, and therefore absolute, and does not discriminate or exclude a natural cosmetic product certified to a private standard (e.g. NATRUE).

1.2 History of enforcement of an animal testing ban in the EU

The 7th amendment to the EU Cosmetics Directive (76/768/EEC)¹, adopted in 2003, confirmed the initial regulatory framework for the phasing out of animal testing for cosmetic purposes. Successively, the testing of finished products has been forbidden since September 2004 and the testing of ingredients since March 2009. The phasing out of animal testing culminated with the Cosmetics Regulation², which came into force in March 2013, and includes provisions enforcing a full marketing ban of finished products and ingredients tested on animals. The Cosmetics Regulation prohibits **any** animal testing for cosmetic purposes in the EU irrespective of the availability of alternative tests.

However, whilst the EU Cosmetics Regulation prohibits animal testing on cosmetic ingredients, their formulation and the finished product in conjunction with the enforced marketing ban, this created uncertainty with the conflicting Regulation (EC) No 1907/2006 (Registration, Evaluation and Authorization of CHemicals)³ that may require data obtained by animal tests to ensure the safety of chemical substances both for human health and the environment.

It is worthy of note here that numerous ingredients formulated for use in natural cosmetics are **unmodified natural** substances and, as such, are excluded from the scope of REACH (Article 3(39)). It should be noted for clarity that in order to be excluded, such unmodified natural substances must be specifically extracted (using water only) and must not be labelled as a hazardous substance.

In September 2016, the Court of Justice of the European Union (Case C-592/14)⁴ clarified in its ruling that “Article 18(1)(b) of the EU Cosmetic Regulation **must be interpreted as meaning that it may prohibit the placing on the European Union market of cosmetic products containing some ingredients that have been tested on animals outside the European Union, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market.”**

The Court of Justice of the European Union’s ruling establishes that animal testing results should **not** be used (e.g. in the safety assessment or to defend substances from Annex IV, V and VI) in order to gain access to the EU internal market for cosmetics. As a result of the ruling, ECHA and the European Commission have



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announced that they are examining the need for revision of the October 2014 statement⁵ on the interface between REACH and the Cosmetics Regulation, as the ruling of the Court of Justice of the European Union did not express an opinion on the link with animal testing to comply with REACH.

1.3 Avoiding consumer confusion – the truth about animal testing

Although some private standards and manufacturers claim the absence of animal testing on their products, they do not disclose the fact that they use ingredients which **have or may have been tested on animals**, and/or the use of data resulting from **animal testing obtained by others**. According to the original European Commission Recommendation of 7 June 2006⁶, and recently incorporated within Regulation (EC) No 1223/2009 (Article 20 (3))², the claim 'no animal testing has been carried out' implies that not only have manufacturers and their suppliers not performed nor asked others to perform such tests on their behalf, but that ingredients are not used which have been tested on animals by others for the purpose of developing new cosmetic products. Knowing that virtually all ingredients used in cosmetic products were tested on animals at one point in time (even non-toxic substances such as water⁷), **setting a cut-off date for animal tests in criteria** (which other standards frequently do) **is meaningless and again misleading**, especially as according to the EU Commission, *'it does not matter where (inside or outside the EU) or when the tests have been performed'*⁵. Furthermore, in some countries, animal tests are required by law to ensure the safety of the cosmetic products (e.g. China⁸), and thus most of the claims add a clause such as *'unless required to do so by law'*. Such a claim, without understanding the regulatory context, is confusing and may mislead consumers who consequently opt for products which claim the complete absence of animal testing which in fact cannot realistically be made.

Animal testing is fundamentally against NATRUE's underlying values and ethics.

1.4 Alternatives to Animal Testing

At a global level there is a shift towards the use of alternatives to animal testing in the cosmetic sector, a trend which NATRUE definitely supports.

In Europe, the European Partnership for Alternative Approaches to Animal Testing ([EPAA](#)) was created to promote the development of new non-animal testing methods with the European Centre for the Validation of Alternative Methods ([ECVAM](#)) playing a key scientific role in the development, validation, and international recognition of alternative methods to animal testing.

Globally, the EU cooperates with the US, Japan and Canada in a dedicated forum: International Cooperation on Alternative Test Methods ([ICATM](#)), and the development, validation and legal acceptance of alternatives to animal testing has been reported recently by the [EU Commission](#).



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NATRUE considers the strict provisions of the European Cosmetics Regulation concerning animal testing as forward-looking and should be mirrored at a global level.

NATRUE's ultimate goal: no animal testing on cosmetic ingredients or finished products at a global level.

1.5 Natural ingredients contribute to the solution

As many naturally occurring substances without chemical modification are exempted from REACH, and do not therefore need to be tested on animals, NATRUE believes by promoting products with natural and organic ingredients, and the preferred use of natural substances, is an approach which contributes towards the reduction and avoidance of animal testing. [NATRUE members](#) choose to use many high quality natural ingredients, which have a long history of safe use.

Animal welfare is a core value of manufacturers of authentic Natural and Organic Cosmetics. By promoting and supporting the organic production of our ingredients, we protect wild life. NATRUE does not allow the use of artificial chemical substances and moreover the purchasing of organic products, generates important side benefits such as environmental care, increased biodiversity, animal welfare and rural development.

NATRUE and its member companies care deeply for the well-being of humans, animals and plant habitats in a holistic manner.

1.6 NATRUE products, third countries and China

The fact that animal testing is mandatory for all (imported) cosmetics, and that alternatives to animal testing are not accepted for imported products on the Chinese market, has obliged NATRUE to update the [NATRUE Label criteria](#).

It is for this reason that the NATRUE criteria (as of V2.9 onwards) extends the animal testing ban on finished cosmetic products, as regulated by Regulation (EC) No. 1223/2009, together with a ban on the marketing of NATRUE certified finished products to third countries outside the EU.

A direct consequence of this decision is that NATRUE certified products may not be supplied to the Chinese market if animal testing is required.

How does this affect new and existing Label Users?

All users must comply with the modified criteria. With regards to the current 211 NATRUE Label Users worldwide, only a handful of which are on the market in China, a transitional period for products already certified to the NATRUE Label is being kept to a strict minimum. This means that whilst no more animal testing may be carried out, current certification contract periods are respected. For more specific details concerning individual company policy please refer to the [NATRUE product database](#).



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New and existing Label Users must be able, during the certification process, to provide a statement guaranteeing that those of their cosmetic products that have been or will be introduced to the Chinese, or any other market outside the EU, without any animal testing. If this confirmation cannot be provided, certification for using the NATRUE Label will be refused.

References

¹ Directive 2003/15/EC of the European Parliament and of the council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31976L0768>

² Regulation (EC) No. 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetics products

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223>

³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

⁴ Case C-592/14: Judgment of the Court (First Chamber) of 21 September 2016 - Cosmetic products containing ingredients, or a combination of ingredients, which have been the subject of animal testing 'in order to meet the requirements of this Regulation' — Prohibition of marketing within the European Union

<http://curia.europa.eu/juris/celex.jsf?celex=62014CJ0592&lang1=en&type=TXT&ancre=>

⁵ ECHA - Clarity on interface between REACH and the Cosmetics Regulation

http://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation

⁶ Commission Recommendation of 7 June 2006: Establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Council Directive 76/768/EEC

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2006.158.01.0018.01.ENG&toc=OJ:L:2006:158:TOC

⁷ Material safety data sheet for water, available online:

<http://www.sciencelab.com/msds.php?msdsId=9927321>

⁸ Procedures and methods of safety evaluation for cosmetics, UDC 688.58.001.04 GB 7919-84 (in Chinese).



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About NATRUE:

NATRUE is an international not-for-profit organisation located in Brussels. It has promoted and protected authentic Natural and Organic Cosmetics since October 2007. The NATRUE Label sets a high standard which guarantees quality and integrity so people worldwide may identify and enjoy natural cosmetics truly worthy of that name. Products are listed on the publicly accessible website and database <http://www.natrue.org/> which can be used as a check list if you want to confirm whether a product is natural or organic.