



# Cosmetic Regulation and Alternatives to Animal Experimentation in India

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**Abstract.** United Kingdom was the first to ban animal testing of cosmetics, and it happened in 1998. The European Union (EU) went through legislations and endeavors implementing animal testing ban in a phased manner, and the final step was done in 2013. Consequent to this, there was enormous canvassing for ban of cosmetic testing on animals in India, to harmonize the marketing as well as import ban of EU. The Indian Drug and Cosmetic Regulatory Authority conceded the demand resulting in the final ban in 2014. This review traces the evolution of thought sequence resulting in the ban, and approval of adopting OECD Guidelines for *in vitro* testing of skin and eye irritation and corrosion.

**Keywords:** India · European Union · Cosmetic testing · Draize tests  
OECD

## Introduction

The EU defines a cosmetic product as “any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition”<sup>1</sup>.

Cosmetics and ingredients therein, however much applied only externally, are all chemicals, some of which are known or speculated to produce adverse reactions locally and occasionally systemically in view of dermal absorption or inhalation. Therefore, the regulatory authorities of cosmetics in many countries have mandated testing of the cosmetics/ingredients for risks/adverse effects. For much of the last century this testing has been done in animals, and different animals are used in different tests; for e.g. skin and eye irritation/corrosion are tested in rabbits (Draize tests); dermal penetration, 90 day repeated oral dose, carcinogenicity, reproductive toxicity, and acute oral toxicity in

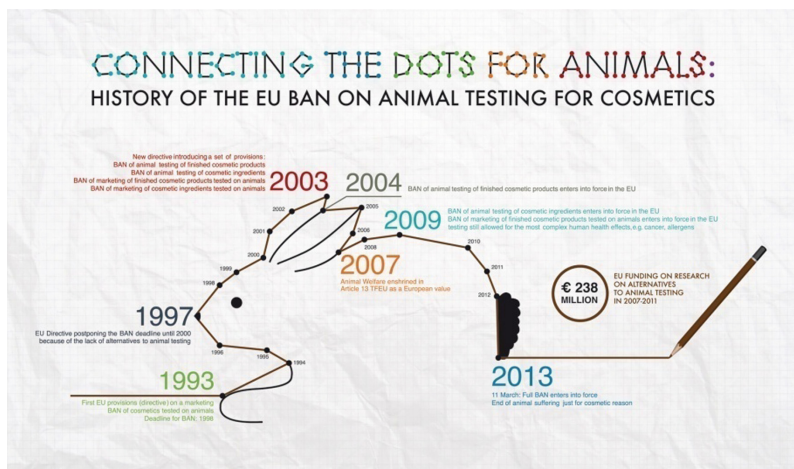
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<sup>1</sup> [www.cosmeticsinfo.org/Regulation-in-eu](http://www.cosmeticsinfo.org/Regulation-in-eu).

rat; skin sensitization and phototoxicity in guinea pig; genotoxicity in mouse; and phototoxicity and carcinogenicity in mouse also. In view of lack of relevance of data generated in animal models to humans in many instances, and the harm done to the animal subjects, this testing has been opposed. The awareness thus created resulted in European Union (EU) ban of cosmetic animal testing and sales in a phased manner, with the final stage falling through in 2013 [1–3]. Thereupon, towards harmonization of EU Cosmetic Regulation, several other countries- Israel, Norway, India, New Zealand, Taiwan, South Korea, Turkey, Switzerland, and Guatemala, and six states in Brazil, have banned or restricted animal testing of cosmetics [3, 4]. Similar legal measures have been proposed and are under political debate in several other countries, including the United States, Canada, Australia, and South Africa [5]. This article reviews the evolution of thought sequence in India.

## **History of Ban of Animal Testing of Cosmetics in EU**

The EU, consisting of 28 member states, became the world's first set of countries to ban cosmetic animal testing and trade. In 1993 the 6<sup>th</sup> Amendment to EU Directive 76/768/EEC was passed and contained a ban on the sale of newly animal-tested cosmetic products. To make sure that adequate time was given to find non-animal methods, the deadline for the ban to come into effect was 1<sup>st</sup> January 1998. In 1997 the ban was delayed until 30<sup>th</sup> June 2000, and then further delayed until 30<sup>th</sup> June 2002 due to a lack of adequate validated alternative methods. In 2003 the 7<sup>th</sup> Amendment to EU Directive 76/768/EEC was passed and contained a phased-in ban on animal testing for cosmetics with a deadline of 2013: Ban on animal testing of finished products, ban on animal testing of cosmetic ingredients, ban on marketing of finished products tested on animals post-enactment, and ban on marketing of cosmetics containing ingredients tested on animals post-ban. Thus, on 11<sup>th</sup> September 2004 the ban on animal testing of finished cosmetic products came into force. The sale of cosmetic ingredients tested on animals outside the EU using methods that have been replaced within the EU was also banned. On 11<sup>th</sup> March 2009 the ban on animal testing of cosmetic ingredients within the EU was implemented. The sale of cosmetic products containing newly animal-tested ingredients was banned; however, animal testing was still allowed for complex human health issues such as repeat dose toxicity, reproductive toxicity and toxicokinetics. On 11<sup>th</sup> March 2013 the full ban came into effect and it is now illegal to market or sell cosmetics in the EU where the finished product or ingredients have been tested on animals after enactment of the relevant phase of the ban. As of 11<sup>th</sup> July 2013 EU Directive 76/768/EEC has been replaced by EU Regulation 1223/2009 (Cosmetics Regulation), which contains all the same provisions (Fig. 1). Thus, the entire endeavor took more than 20 years to reach the final phase, as of now, and of course great lot of financial input from governmental agencies and cosmetic industry partners, and a great lot of scientific deliberations [1, 3], this long time and money to ensure that adequate



**Fig. 1.** Connecting the dots for animals: History of the EU ban on animal testing for cosmetics. [Adopted from [www.understandinganimalresearch.org.uk/policy/cosmetics/](http://www.understandinganimalresearch.org.uk/policy/cosmetics/)]

and appropriate non-animal testing methods have become available. Due to the development of non-animal techniques it became apparent that these animal studies were no longer required.<sup>2</sup>

## Cosmetic Regulation in India

The Central Drugs Standard Control Organization (CDSCO) is the Central Authority for discharging regulatory functions relating to drugs and cosmetics, assigned to the Central Government under the Drugs and Cosmetics Act, 1940 (D&C Act), and Drugs and Cosmetics Rules, 1945. It is headed by Drugs Controller General (India), headquartered in New Delhi. The vision of CDSCO is to protect and promote public health in India. It has as mission “to safeguard and enhance public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices”. Each of the 29 States and 7 Union Territories of India has its own Drug Control Authority (SDCA) headed by the Drug Controller/Commissioner/Director, who is responsible for discharging regulatory functions assigned under the provisions of the Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945.

The Bureau of Indian Standards (BIS) is a statutory organization under the Bureau of Indian Standards Act, 1986. The BIS formulates national standards and carries out conformity assessment by operating the Product and Management System Certification Scheme. One of the activities of BIS is to lay down standards for cosmetics in India. The Cosmetic Regulation is governed by Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, made under the Act.

<sup>2</sup> [www.understandinganimalresearch.org.uk/policy/cosmetics/](http://www.understandinganimalresearch.org.uk/policy/cosmetics/).

Cosmetic is defined under the D&C Act as any article intended for cleansing, beautifying, promoting attractiveness, altering the appearance and any article intended for use as a component of cosmetic. Under the said rule and law, no cosmetic can be manufactured for sale except in accordance with the conditions of manufacturing license issued by the respective SDCA. No cosmetic can be imported for sale except in accordance with the conditions of Import Registration Certificate issued by the DCGI. D&C Act and Rules require that cosmetics marketed in the country are safe and of standard quality; importation of sub-standard, misbranded, adulterated and spurious cosmetics is prohibited, and the Central Government has power under the D&C Act to prohibit manufacture or import of any cosmetic, use of which is likely to involve any risk to human beings.

Schedule-S to D&C Rules contains a list of 30 different cosmetics which include skin powders and creams, tooth powders and pastes, hair oils, powder hair dyes, shampoo, nail polish, lipstick, after-shave lotion, shaving creams, soaps, etc. The cosmetics in finished form included under Schedule-S of D&C Rules shall conform to the Indian Standards specifications laid down from time to time by the BIS. No cosmetic shall contain dyes, colours, and pigments other than those specified by the BIS (IS4707 Part 1 as amended) and Schedule-Q. The IS 4707 (Part 1) lists dyes, pigments and colors which are generally recognized as safe (GRAS) and which when used in concentrations conventionally adopted or within the limits as stipulated is permissible, and IS 4707 (Part 2) lists cosmetics raw materials and adjuncts, other than dyes, colors, and pigments in the following four groups: (A) list of substances classified as 'GRAS' which must not form part of the composition of cosmetic products -Annexure A of the standard; (B) list of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down (Annexure B of the standard); (C) list of preservatives allowed (Annexure C of the standard); and (D) list of UV filters allowed in sunscreen products (Annexure D of the standard). Cosmetic products formulated as per the restrictions imposed by IS 4707 (Parts 1 and 2) and the list of Cosmetics, Toiletry and Fragrance Association (CTFA), European Economic Community (EEC) and the guidelines of Cosmetics Europe Guidelines on Exchange of Information (IFRA) are likely to be safe, and such products may not warrant any safety testing, whereas products which contain novel ingredients which are not under the purview of the above documents shall require safety testing as per the guidelines provided in IS 4011. The IS 4011: 1997 laid down by BIS prescribes "Methods of test for safety evaluation of cosmetics". Requirement of labeling of products not tested for safety on animals with the statement "The product has not been tested on animals for safety" was deleted from the Standard in 2002. Skin irritation test and eye irritation test (Draize tests in rabbits) were removed from the Standard in 2007. In February 2014, the IS 4011 was amended specifying that when there is a need for safety evaluation of cosmetic products to demonstrate absence of oral toxicity and/or oral mucosal irritation, the manufacturer shall submit the safety data based on alternative non-animal test methods to the concerned State Licensing Authorities for their consideration and approval.

## **Ban on Use of Animals in Cosmetic Testing**

In response to public campaigning led by Humane Society International-India, PETA India, and PfA, the Drug Technical Advisory Board (DTAB), a statutory body under the D&C Act deliberated the issue of testing of cosmetics on animals in its 65<sup>th</sup> meeting held on 25.11.2013 and recommended prohibition of the same by amending the D&C Rules. Based on the recommendation, Government of India published a draft Rule vide G.S.R. 16(E) dated 13.01.2014 for prohibition of testing of cosmetics on animals. The draft rule was made available for public comments. After examination of the public comments, Government of India prohibited the testing of cosmetics on animals vide G.S.R. 346(E) dated 21.05.2014 by inserting the following rule in the D&C Rules, “148-C: Prohibition of testing of cosmetics on animals-No person shall use any animal for testing cosmetics”. Further, it was specified that when there is a need for safety evaluation of cosmetic products to demonstrate absence of oral toxicity and/or oral mucosal irritation, the manufacturer shall submit the safety data based on alternative non-animal test methods to the concerned State Licensing Authorities for their consideration and approval [6].

## **Prohibition of Import of Cosmetics Tested on Animals**

The Government of India published Draft Rules vide G.S.R. 311(E) dated 05.05.2014 for prohibition of import of cosmetics tested on animals. The draft rule was made available for public comments. After examination of the public comments, the Government of India amended the D&C Rules, which prohibited the import of cosmetics tested on animals vide G.S.R. 718(E) dated 13.10.2014. Further clarifications were issued on 15.02.2015 and 29.06.2015, according to which the importer should submit original undertaking from the manufacturer (legal/actual brand owner) of the registered products stating that cosmetic products have not been tested on animals on and after 12.11.2014; and new applicants should submit this undertaking along with registration dossier to CDSCO wherein copy of the undertaking may be produced at ports for clearing the consignments.

## **Conclusion**

It is of historical importance that India has earned reputation as the first south east Asian country to implement ban of animal testing of cosmetics, finished products as well as ingredients, domestic as well as import. Yet, it may be some more time before internationally recognized non-animal testing methods are fully implemented in India, and until full non-animal replacements are available for all endpoints. As of now, the OECD non-animal guidelines for skin and eye irritation and corrosion, skin sensitization, and other endpoints are to be followed, using weight of evidence and Integrated Approaches to Testing and Assessment (IATA), in order to assess the toxicity potential of novel cosmetic ingredients or finished product.

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