

**Guidelines for implementation of GSR 346 (E), F. No. X-11014/7/2013-DFQC,
Issued by Ministry of Health and Family Welfare, Dated May 21, 2014**

Background:

Whereas the Ministry of Health and Family Welfare (hereinafter referred to as “Ministry”) issued a Gazette Notification GSR 346 (E), dated 21 May 2014 amending the Drugs and Cosmetics Rules 1945, to ban testing of cosmetics in animals,

And whereas, the said amendment introduced rule 148C as “*Provision of testing of cosmetics on animals – No person shall use any animal for testing on cosmetics*”

And whereas Ministry has also issued a draft Notification GSR 311 (E), **No.X-11014/11/2013-DFQC**. Dated May 5, 2014, introducing Rule 135-B in Drugs and Cosmetics Rules 1945 as “135-B. Import of cosmetics tested on animals prohibited – No cosmetic tested on animals shall be imported”.

And whereas the aforesaid ban of using animals for testing on cosmetics was promulgated after certain stakeholders approached ministry to have such provisions in India citing example of European Union (EU), where such testing has been banned from 2013 onwards,

And whereas many Industry and trade associations have informed the Ministry that, while Industry is committed to phase out animal testing for cosmetics, unavailability of scientifically validated alternate methods for certain endpoints will jeopardize the cosmetics business,

And whereas the representatives of animal welfare organizations, while agreeing that there are still few critical tests for which non-animal approaches are not developed, are of the opinion that forcing the ban will help accelerate such scientific methods,

And whereas the Industry associations have expressed that Industry has invested heavily and along with reputed laboratories is working relentlessly to develop alternate methods and has succeeded in many of such test methods,

And whereas the stakeholders are also of the view that to further accelerate development of alternative methods for remaining tests, efforts should be made by the Government of India, the Industry and other stakeholders to initiate research in Indian Public laboratories such as Indian Institute of Toxicology Research and other relevant CSIR laboratories,

And whereas the Industry has informed the Ministry following facts about ban of animal testing on cosmetics by the European Union (EU):

- a. That EU first notified the proposed ban in 1993, which was to come to effect on 1998. However, since validated alternative tests were not developed by 1998, the ban was deferred further,

- b. That EU banned the cosmetic products from being tested on animals in 2004, ingredients in 2009 and sale of cosmetic products tested on animals only after 2013 thereby taking over 20 years from the date of contemplating a ban since it was actually enforced,
- c. That in 2013 the European Commission has clarified its own interpretation of the scope of the ban explaining that it is not a blanket ban,
- d. That EU considers that the animal testing that has clearly been conducted in compliance with non-cosmetic related legislative frameworks shall not be considered to have been carried out in violation of the EU directive banning the animal testing for cosmetics. Use of such ingredients in cosmetic products eventually will also not trigger the non-compliance of the said EU directive on ban of animal testing on cosmetic products.

And whereas the Industry also informed the Ministry that consumer safety is key priority for Industry and therefore robust safety assessments of ingredients and products are paramount to ensure the highest level of safety assurance, before they are sold to the consumers. If product safety cannot be demonstrated, the product simply cannot be marketed. Therefore, reduced access to cosmetics ingredients led by the ban will deprive the consumers of innovative products.

And whereas the stakeholders including the Industry have informed the Ministry that the amendment to Rule 148 C vide Gazette Notification GSR 346 (E), dated 21 May 2014 does not clarify certain points, which may be clarified by the Ministry to avoid any ambiguity,

And whereas a large number of ingredients used in cosmetic products are in use in many other consumer and industrial products, such as in pharmaceuticals, detergents, foods and animal testing may be necessary to ensure compliance with the legal framework applicable to the said products,

Now, therefore, in exercise of the powers conferred under section/rule (CDSCO to fill) read with section/rule_(CDSCO to fill)_ of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the all the stakeholders hereby issues the following amendment in Rule 148C of the Drugs and Cosmetics Rules, 1945.

- 1. Rule 148C as introduced by amendment to Drugs & Cosmetics Rules, vide GSR 346 (E), dated 21 May 2014 (hereinafter referred to as “Rule 148C”) stands implemented in India with effect from May 21, 2014.**
- 2. Provisions of Rule 148C are not applicable for any cosmetic product or ingredients therein, tested on animals prior to 21 May 2014, irrespective of whether the product was tested in India or outside India.**
- 3. If any ingredients are tested on animals in India for any non-cosmetics purposes, and if such ingredients eventually are found useful for use in cosmetics, the use of such ingredients in cosmetics shall not be impacted by the provisions of Rule 148C. However, the applicant will have to give an undertaking in writing to DCGI that testing of such ingredient on animals was not conducted for its use in cosmetics.**
- 4. Provisions of Rule 148C will not be applicable for any imported ingredient or cosmetic products, which might contain any ingredient, which is tested in animals outside India to fulfill any regulatory requirement in any of the country outside India. - (The matter will be debated further during review of GSR 311 (E), No.X-**

11014/11/2013-DFQC. Dated May 5, 2014, introducing Rule 135-B in Drugs and Cosmetics Rules 1945.)

5. Cosmetics being exported outside India will need to comply with regulations on animal testing which is applicable in the country of import and will not be impacted by rule 148C.
6. Considering that there are still few endpoints namely – “Systemic Toxicity”, “Skin Sensitization”, “Reproductive Toxicity” and “Carcinogenicity”, for which non-animal alternate methods are not yet available, and recognizing the fact that efforts are afoot to develop such methods by international laboratories in collaboration with industry and other stakeholders and the fact that Indian industry does not have the capability to establish safety without these tests, Central Drugs Standards Control Organization (CDSCO) shall establish an interim mechanism to ascertain the safety of cosmetics and their ingredients in respect of these important human health effects. CDSCO shall also prepare a roadmap for transition from the animal tests to non-animal alternative methods.
7. The Drugs Controller General (India) shall establish a “Cosmetics Technical Advisory Committee (CTAC)” with representation from all relevant stakeholders including Industry and toxicological experts. This committee shall deliberate all aspects related to safety of cosmetics/cosmetic ingredients including a stepwise approach to establish safety of cosmetic ingredients in view of Rule 148C. CTAC shall also monitor the status of non-animal alternate methods especially for the endpoints mentioned in clause 6 as hereinabove and also discuss the ways in which non-animal alternate testing could be initiated and accelerated in India jointly by the Government, Industry and other stakeholders. *(CDSCO will need to prepare the TORs for the CTAC)*

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