

## **The 7<sup>th</sup> Amendment to the European Cosmetic Directive**

The European Union currently is regulated by the 6<sup>th</sup> Amendment to the Cosmetic Directive 76/768/EEC. After what seems like an endless debate it appears all sides have agreed on the new changes. These were passed February 27,2003.

Here are the major changes:

### **1. Animal Testing of Ingredients and/or Combination of Ingredients**

There are 4 changes:

1. The first concerns cosmetic formulations which have been tested on animals when a validated alternative method is available to replace this animal test. Any such cosmetic which has been tested after 2/27/03 is now prohibited.
2. Any ingredient (or combination of ingredients) which have been tested on animals to comply with this Directive, when a validated alternative method is available to replace this animal test, is now prohibited.
3. No animal testing of any finished cosmetic to comply with the EU Directive is allowed to be performed in the EU.
4. No animal testing of any ingredient to comply with this Directive is allowed to be performed in the EU after a validated alternative method is available.

What do these changes mean? No testing of cosmetics or ingredients used in cosmetics will be run within the EU and cannot be run outside the EU, when there are validated alternative methods.

Deadlines: The EU Commission after consultation with the SCCNFP and ECVAM and in coordination with OECD shall set up timetables for items 1,2 and 4. However the maximum allowed time after this Directive goes into force is 6 years. Item 3 and specifically the tests of repeat dose toxicity, reproductive toxicity and toxikinetics, (where there are no alternative methods even under consideration!) the maximum time is 10 years. (I wonder why they didn't mandate a cure for cancer with 10 years also!) Further these dates must be published and made available to the public.

To ensure that progress is being made to achieve these objectives, there should be a yearly report to the EU Commission updating them on this progress. The Commission shall study these reports and other technical difficulties in complying with this ban. If the Commission concludes prior to 2 years before the final date that this is not possible they must put forth a legislative proposal to the European Parliament.

The EU has inserted that there is one area allowing animal testing and that is the re-testing of a cosmetic ingredient. The conditions are that the ingredient is in wide use and cannot be replaced by another ingredient that can do the same thing, and that the specific human health problem is substantiated and the need to conduct animal testing is justified. If this is allowed, than the ingredient must be listed in the Annual report mentioned above. The only ingredient that I can think of that we cannot replace is water so this exemption is a farce!

### **2. Definition of a Cosmetic**

The EU is now including prototype products as being part of this definition. This closes a loop-hole where you can have a formulation with 75% water and test it animals, but than produce the product with 76% water and claim no animal testing. Further it excludes this as a way to get around the animal testing ban. Just think of the mischief you can do. You develop a formulation and test it on animals but never offer it commercially. Than anyone who brings a similar formulation onto the EU market, you scream your prototype was copied and was tested on animals so the competitor's product is banned! Sounds like fun to me.

### **3. Carcinogens, Mutagens or Toxic for Reproduction (CMR)**

This has the potential to be the worst part of the new regulations. If we don't test our products ( in the US) and they injure someone, well that's up to the lawyers. However the immediate ban of Category 1 and 2 CMR's and possible ban of Category 3 CMR's will severely limit your ability to formulate. The first nightmare will be to find what is in danger and than see if we can replace these ingredients. The worst part is that this is prohibiting chemicals, not by a risk assessment but by the fact that they are on some list.

#### **5. Minimum Durability**

This is just what you need to clutter up your labels and allow marketing to dictate bad regulations. What have they agreed to? That products which have over 30 months stability (if not, they require "best used by" dating) you must put a new symbol of an open jar and beneath this symbol the months and/or years that the product is safe to use after it is opened.

#### **6. Labeling of Cosmetics Regarding Animal Testing**

You will not be allowed to claim "no animal testing" if your product or any raw material was ever tested on animals for any reason.

#### **7. Accessibility of Product Information Packages**

Now your PIP (or dossiers) must be available to the public, preferably electronically! The exemption is the quantitative formulations with the exception of any ingredients that is on the Dangerous Substance Directive. Further under the section of Proof Of Claims, you will have to list all animal testing done anywhere, at anytime, for any purpose, for any ingredient used or prototype of any ingredient. Have fun trying to get this data!

#### **8. Fragrance Listings**

The "dirty" 26 fragrance components must now be part of the ingredient declaration in the EU (but not the US). This list can be found at: *Perfumer & Flavorist* Vol. 27 (3) May/June 2002 pages 40-46 or contact me for the list and the levels that trigger listings.

What steps should you take now?

1. Contact your fragrance supplier and be sure you know the levels of the 26 allergens in your fragrances that you purchase. The same goes for any essential oils. Than calculate if you need to list them and than make up new ingredient declarations.
2. Contact your ingredient suppliers and get from them electronically for your dossiers, a listing of all animal tests run, the dates and the purpose of the test. Insert this into your dossiers.
3. Remove the quantitative formulae from your dossiers and have them as separate dossiers marked confidential.
4. Try to figure out what dates you can put on your labels by the open jar symbol. The CTFA and COLIPA are working on trying to establish suggested months by product category. When they do come out with this, I'll let you know.

Call me if you have any questions.

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