7th Amendment to the EU Cosmetics Directive

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Introduction

On the 11th March 2003, Directive 2003/15/EC was published in the Official Journal of the European Union amending, for the 7th time, the EU Cosmetics Directive 76/768/EEC.

This Directive has great significance for the Cosmetics Industry, particularly with regard to the labelling of Cosmetic products and the Perfume Industry in relation to product disclosure. The amendment comes into force on 11th March 2005.

There are 3 main issues addressed by the 7th Amendment:

1. Labelling of Perfume Ingredients
2. Animal Testing
3. Period after opening and the safety of the product.

1. Labelling of Perfume Ingredients

"Perfume" is the second most common cause of allergy (after Nickel) identified in patients with allergic dermatitis appearing at dermatology clinics. Of course "Perfume" is not the cause as people are not allergic to perfume but rather one or more of the chemicals within that perfume. Over the course of time, the perfume components most commonly shown to cause allergic responses have been identified and it is these chemicals that comprise the 26 perfume ingredients in the 7th Amendment.

The new Directive requires that if a Cosmetic Product contains any of 26 named fragrance chemicals at a concentration >0.001% in a leave-on product, or > 0.01% in a rinse-off product, then that chemical must be included individually in the list of ingredients. The chemicals concerned are well known perfume ingredients and some are also found in plant extracts and essential oils. The list of chemicals is shown in table 1.

The requirements of the Dangerous Preparations Directive (DPD), which came into force in 2002, has meant that European perfume suppliers now indicate on their Health and Safety Data Sheets the presence and concentration of any chemicals classified as "Dangerous" i.e. they have been assigned a "R Phrase" that identifies a health hazard. One of the R Phrases and the one of relevance to the 7th Amendment is R43 - May cause sensitisation by skin contact. The DPD regulatory concentration at which such disclosure becomes mandatory on a Safety Data Sheet is 0.1%.

In order for Cosmetic manufacturers to be able to comply with the requirements of the new directive, they will need to obtain from the suppliers of the fragrances used in their products, a statement disclosing the concentration present in the perfume that they purchase, of each of the chemicals listed in the table. Perfume suppliers to the cosmetics industry have been working since March 2003 on this, and now routinely supply an allergen declaration on request, that lists the concentration of each of the 26 allergens of concern. The Cosmetic manufacturer will then need to determine which of those chemicals must be included in the ingredients list on the package This will depend on:

1. the concentration of each individual chemical in the perfume
2. the concentration of perfume in the formulation, and
3. whether it is a leave-on or a rinse-off product.

It is a simple matter of arithmetic to determine the concentration of each fragrance ingredient in the final product. The question of whether the product is rinse-off or leave-on is mostly straightforward. There are however "grey" areas even here.

A face mask for instance is applied, left on for a short period and then rinsed off. Is a face mask a rinse-off or a leave-on product? Of course it is both as are some hair products where the product is applied, left for 30 minutes and then rinsed off.

When determining the labelling requirements for such products it is easy to get involved in legal discussions on the meaning of leave-on or rinse-off and to lose sight of the purpose of the legislation. The perfume labelling requirement of the 7th Amendment is designed not as a safety issue but as advice to consumers. The safety of the product and the perfume is assessed looking at the concentration of each ingredient and assessing the risk to the consumer. With allergic dermatitis the issues of concern are 1) will the product cause allergy and 2) will an individual with an allergy already, react to the product. The safety assessment addresses point 1 and no product that may induce allergy should be passed as fit for sale. Point 2 is less easy however and whilst this obviously forms a part of the safety assessment, it is known that there are products that are readily accepted by the majority of consumers but that cause an allergic reaction in a few people.

It is to warn individuals who are already sensitized that the labelling requirements of the 7th Amendment have been