Cosmetic Safety Assessment – The Non-Animal Approach

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Abstract

In the UK there has been a ban on the animal testing of finished cosmetic products since 1996, and the latest EU Cosmetic Directive sets out to prohibit the testing of finished cosmetics on animals in all European countries. Furthermore from 2009 it will be illegal to market any cosmetic in Europe whose ingredients have been tested on animals. The exception to this will be for tests relating to repeated dose toxicity, reproductive toxicity and toxicokinetics. A prohibition on the marketing of products whose ingredients have been tested for these aspects will be introduced in 2013.

The result of such legislation will be an increased reliance on the non-animal safety assessment of cosmetics. In this article we will look at the role of the safety assessor along with the skills and qualifications required to legally perform this task. Also examined are the types of information available to an assessor, which can then be used to form an opinion of relative safety. Lastly we discuss the assessment process and some of the key issues involved in determining the likely risk a given product will pose to consumers.

Introduction

The traditional method of assessing the safety of Cosmetic products in the period just after the Second World War involved the use of animal models to generate data on irritancy and general toxicity. Tests were developed for the assessment of cosmetics which later became standard methods for general toxicological assessment; the Draize tests for skin and eye irritation still form a part of toxicological assessment procedures. These tests were, however, developed to discriminate between and identify potential problems with cosmetic products; products that if they are to be successful in the marketplace are generally of low or no irritant potential. The tests as developed were therefore necessarily stringent and, whilst this may not have been an ethical issue when used for the purpose that they were originally intended at that particular time, applying these same tests with little thought to a much wider range of products began to raise serious doubts about the validity of the results and the ethics of carrying out the test in the first place. In the early 1980s work was taking place across Europe under the aegis of the European Union (as it now is) to give a more appropriate foundation of animal testing protocols that could be applied to a broad range of industrial chemicals, which culminated in the Dangerous Substances Directive and the European scheme for the Classification of Dangerous Substances. These studies became mandatory for new Chemicals after 1981. This requirement coincided with a rapid growth in political pressure caused by the activities of various animal rights groups, who rather cleverly focussed on the testing of cosmetics – products that are not vital for survival and where use and exposure is a matter of choice and not necessity. The charge that the tests were carried out for profit went largely unanswered, which, given the high cost of carrying out such studies and the long time taken to obtain the results – a further cost to the industry, was surprising. At the same time the large cosmetic companies began to realize that they had, over the previous years, developed a large database containing not only the results of animal studies but also human trials and patch test results and were able to relate these data to marketplace performance. They were able, therefore, to relate what happened in real life, to the sort of effects that are seen in limited user trials, could see how user trials relate to patch test and other human experimental information and relate what happens in experiments on people to what was found in animals. They also, of course, knew exactly what was in each formulation they tested and made.

What was more important in terms of assessing the safety of their products, was that they had staff who had themselves done various aspects of the work, had access to all the data and