Non-Animal Testing of Cosmetics and Cosmetic Ingredients – State of Play and Impact on Safety Assessment

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Abstract

It was just over 20 years after the publication of the original EU Cosmetics Directive, 76/768/EC, that the first legislative requirement for a Professional Safety Assessment of Cosmetic Products destined for sale in the EU was introduced (the 6th Amendment to the EU Cosmetics Directive (93/35/EC), published June 1993 and enforced since January 1997). 15 years on and the industry is in the midst of a fundamental overhaul to the way such safety assessments are performed; both in response to the 7th Amendment of the Directive (2003/15/EC, which prohibits the use of traditional animal testing for cosmetics and their ingredients) and the upcoming Cosmetic Regulation, 1223/2009, enforced July 2013 (that proscribes much more stringently the safety assessment process).

We begin this article with a brief look at the task faced by a safety assessor and the necessity for good quality, reliable and interpretable data. Following on from this, we consider some of the specific methods already validated and in use for various toxicological endpoints, before focussing on the situation surrounding those endpoints for which no methods are currently in place (toxicokinetics, skin sensitisation, repeated dose toxicity, carcinogenicity and reproductive toxicity). We shall see that it is unlikely that suitable alternative assays will be available by the March 2013 deadline for phasing out the existing animal test methods and discuss the potential impact this may have on data availability and safety assessment.

Introduction

Cosmetics, as a group of consumer chemicals, were first governed in the EU by their own specific legislation with the introduction of EU Directive 76/768/EC[1]; a directive that (at the time of writing) is still in force today and regularly amended. It is widely regarded as one of the most stringent pieces of legislation relating to cosmetics in force today, a situation which will only be reinforced by the introduction of the upcoming EU Cosmetics Regulation[2].

Since January 1997, and the enforcement of the 6th Amendment to the EU Directive[3], one of the cornerstones of the legislation has been the requirement for an "assessment of the safety for human health of the finished product" conducted by a 'qualified person'. The 6th amendment also included a ban on the testing of ingredients, or combinations of ingredients, on animals from January 1998, assuming that suitable non-animal replacement tests where available. It quickly became apparent that they would not be available on time and so this requirement was pushed back.

In 2003, 5 years after the intended deadline for prohibition of the 6th amendment, a 7th amendment[4] to the EU Cosmetics Directive was published. This also contained a requirement for the prohibition of the marketing of cosmetics (or cosmetics containing ingredients) whose safety had been proven based on existing animal tests. The deadline set was March 2009, excepting 5 areas (toxicokinetics, skin sensitisation, repeated dose toxicity, carcinogenicity and reproductive toxicity) for which it was considered a later date (March 2013) would be required based on the status of development of possible alternatives at that time.

It is important to note that 'alternative' (both in reference to the 2009 and 2013 deadlines) does not necessarily mean completely non-animal, though this is the hoped for longer-term goal. Whilst 'alternative' can mean non-animal this 'replacement' is only one of three axes of alternative. The others being 'refinement' and 'reduction', in which the suffering of test animals or the number of test animals required is, respectively, significantly reduced.

The first deadline has now passed and is enforced and the second is rapidly approaching. Indeed 2013 will be a major