

## The EU Cosmetic Regulation 1223/2009 – A Review

Author: C. I. Betton B.Sc., FSB, C Biol, FIEMA, CEnv, FRSC, EUROTOX Registered Toxicologist, Delphic HSE Solutions Limited, Deepcut, Surrey, United Kingdom

### Introduction

The EU Cosmetic Regulation 1223/2009 was first seen as a Draft document in 2008 and was passed into Law in 2009, largely unchanged. The Regulation replaced the EU Cosmetics Directive 76/768/EEC and all of its amendments and harmonised the niggling differences in national legislation that had been introduced by the member states. There was a phased introduction of the Law which came fully into effect on 11th July 2013. This paper reviews the changes that the Regulation has brought about, not just in terms of what the new requirements actually are but also looks at the often quite fundamental changes that have occurred as a result in the way that the Industry has had to adapt – and is still adapting – to the new requirements. It also discusses what lessons we, as safety assessors and Responsible Persons, have learned and which may be of interest to those affected across the globe; for be in no doubt, although this is an EU Regulation, the effects that it has had are global and with increasing harmonisation of legislation, may be a taste of things-to-come for cosmetics manufacturers and importers everywhere.

### Immediate Effects

From the point of view of the safety assessor, the change in the legislation has reduced significantly the number of assessors that are available to do the work. After the publication of the Regulation in 2009, many small to medium sized companies stopped doing their own assessments. These typically used to be produced by the 'Company Chemist', a person who had a long working knowledge of the (often limited) product range and basically knew that a new product was similar to the old product and that had never been a problem.

On becoming aware of the scope of the Regulation, these people rightly recognised that their old approach was no longer acceptable and so the work would need to be sent to specialists. This happened to such an extent that more work was being sent to smaller numbers of people. It was also clear in the Regulation that any product on sale on July 11th 2013

would have to be compliant with the new requirements. Given that the lifespan of a cosmetic formulation can range from tens of years (think of some fine fragrances) to a matter of a week or so (some Halloween face paints for example), there was not an immediate rush to get all products assessed in line with the new requirements. We as a company were still being asked at the beginning of 2013 for assessments to the old Directive for some products, whereas some major UK Retailers, knowing that their own branded products would have a longer life-span, began requesting assessments to the Regulation requirements in 2010.

What also happened and which we were not entirely prepared for, was that some assessors would stop taking on any new work in March 2013 and indeed some had still not started any new work as of February 2014: almost a year dealing with the backlog. Of course all of this - more work and fewer assessors - conspired to increase the turnaround times for work that was submitted. Our turnaround for a Regulation assessment was two working weeks but, because of increasing workload, this was increased significantly to a peak of 12 weeks and only returned to our two week target in February 2014. This was a great inconvenience to our clients, who were amazingly understanding over the peak period but work carries on and patience is not infinite. Our staff were working at weekends late into the evening and in August 2013 we carried out 977 assessments to the new Regulation. This level of activity of course was not sustainable and the huge effort was compounded by some companies who left things to the last minute; we were approached by one company on the Monday of the week of 11th July 2013 who wanted 400 products assessed to the new Regulation by the Thursday.

Therefore the immediate effect of the Regulation was to increase the workload greatly but to diminish the number of individuals available to do the work. Also with the complexity of the work increasing as a result of the Regulation and the various guidance documents that have been produced by both