

O11. EUROPEAN COMMISSION SUMMARY OF ANALYTICAL METHODS, REPORT EUR 27394 EN. DEATH OR GLORY FOR RESAP(2008)1

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The majority of laws for Tattoo and Permanent Make-Up (PMU) inks in EU countries are based on ResAP(2008)1, a document published by the Council of Europe over 9 years ago. At a meeting of EU Member States and representatives from the Council of Europe in November 2014 one goal was to collect details of analytical methods being used by authorities in the EU for Tattoo and PMU inks and another was to publish the results as a book. The collected and listed methods are those being used to test whether the inks comply to either ResAP(2008)1 or to local legislation. It is important to take into consideration that less than 40% of EU Member States were present at this meeting. Subsequently, this means that for more than 60% of EU Member States no details of the applied analytical methods at domestic level were collected with the required accuracy. For less than 40% of EU Member States 46 different methods were collected. The subsequently published book of the meeting is hence not only a summary of the large amount of methods being used by a minority but also a documentation of the catastrophic and unclear situation within the EU. These circumstances are troublesome and confusing for local authorities but especially for the international and local manufacturers of tattoo and PMU inks and further for the importers of these products. It is hard to believe that the EU can justly be called a „common market“ in this field if there is no common denominator.

A closer look at the listed methods reveals that for the analysis of heavy metals alone 25 different analytical methods are in use by less than 40% of EU Member States. The work-up of these 25 methods varies from simple extraction with artificial gastric fluid to digestion with strong acids under high pressure or in a microwave system. This broad range in work-up methods ultimately leads to a broad variation in the achieved results in different EU countries. Consequently, manufacturers and importers are having different legal problems with one and the same ink in different EU countries: this is leading to an increase in legal proceedings between local authorities and manufacturers or importers.

Another aspect in this context are RAPEX notifications. RAPEX is the EU rapid alert system for dangerous products based on EU Directive 2001/95/EC. It is used to warn all EU Member States of hazardous substances in products on the EU market.

For the majority of products being notified in the RAPEX System, e.g. toys, textiles, EU harmonised analytical methods are being used. In practice this means all EU Member States achieve the same results if they test the same product. This is obviously not the case for tattoo and PMU inks as no harmonised methods exist. Warnings from one EU country can, therefore, surely only be valid for the country conducting the analysis and not for the whole of the EU. Likewise, a withdrawal of products based on the analysis performed in one country cannot be valid for all EU countries as different countries would have found different results due to using other analytical methods.

ResAP(2008)1 is widely accepted by tattoo and PMU ink manufacturers as a minimum requirement. It is further the basis for several national laws. The abundance of testing methods, each leading to different results, makes it impossible for any manufacturer to fulfil the requirements in all EU Member States. Under these circumstances it is questionable whether ResAP(2008)1 will have any relevance in the future.