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# The European Landscape of National Regulations of Tattoo Inks and Businesses

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## Abstract

A rising number of tattooed people in all parts of society and increasing concerns regarding potential health effects triggered the development of specific regulatory measures at the beginning of the 21st century. The first principles considering chemical safety and hygienic aspects were laid down by two resolutions of the Council of Europe, in 2003 and 2008. The applied principle of ‘negative lists’ of substances that should not be used in tattoo inks has subsequently been transferred to national regulations. However, surveillance data show that in particular, the chemical quality of tattoo inks is still insufficient. The reasons are, amongst others, the lack of analytical methods, the implementation of different thresholds, and the lack of awareness of distributors and producers when it comes to potential health hazards.

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As tattooing was originally a practice limited to certain groups in Western society, the development of specific regulatory measures for tattoo-

ing started relatively late. Before this millennium, specific regulations were in place only in a few European countries. In Denmark, for example, a law from the year 1966 [1] prohibited tattooing of the head, hands, or neck. In the UK, the ‘Tattooing of Minors Act’ in 1969 [2] prohibited tattooing of persons under the age of 18 years. In the Netherlands, hepatitis B outbreaks in the 1980s were traced back to unacceptable hygienic conditions in tattoo parlours and led to the first guidelines for the prevention of infections [3]. Minimum ages and hygienic standards were also set in a number of other European countries [4] as a basic instrument for the protection of consumer health. Apart of these basic requirements, the safety of tattoo inks, representing diverse mixtures of substances that may reach the blood and lymph, has so far been the responsibility of the manufacturer or distributor. Because of their main purpose of beautification, tattoo inks are legally considered as products of daily use according to the General Product Safety Directive [5].

However, the rising popularity of tattoos in Europe has increased awareness of governmental bodies towards potential health hazards, such as microbes and potentially toxic substances, that might be present in tattoo inks. As a result, the European Commission has started to assess the safety of tattoos [4], and two resolutions of the Council of Europe on requirements and criteria for the safety of tattoos and permanent make-up were published: that is, ResAP(2003)2 [6] and the revised ResAP(2008)1 [7]. Already in ResAP(2003)2, substances that should not be present in tattoo inks are listed. Besides carcinogenic aromatic amines, these negative lists include a range of harmful pigments and solvents. The resolution further references the European Directives for Cosmetics [8] and Dangerous Substances [9]. Accordingly, substances forbidden or restricted in cosmetic products or classified as carcinogenic, mutagenic, or reprotoxic are not allowed for use in tattoo inks. In addition to these chemical requirements, Resolution ResAP(2003)2 postulates that tattoo inks should not contain preservatives, must be sterile until use, and should be supplied in packaging for single use only. The revised resolution ResAP(2008)1 has superseded ResAP(2003)2 and has introduced maximum allowed concentrations of 13 elements, including cadmium (0.2 ppm), nickel (as low as reasonably achievable), and lead (2 ppm). Polycyclic aromatic hydrocarbons (PAHs) are considered in general, with a limit for benzo[*a*]pyrene of 5 ppb and a general threshold of 0.5 ppm, without further specification of the kind of PAHs to be measured. Neither for elements nor for PAHs are analytical methods provided, making the application of uniform criteria difficult. According to ResAP(2008)1, tattoo inks have to fulfil the same purity criteria as colours in foodstuffs [10]. Furthermore, *para*-phenylenediamine was added to the 'negative list' of substances. Whereas preservatives were banned for use in tattoo inks according to the first resolution, they became allowed by ResAP(2008)1, but not just

for compensation for insufficient sterility. Both resolutions provide a basis for national regulations; however, they are not legally binding. Furthermore, not all member states have signed up; while ResAP(2003)2 has been worked out by 18 member states, only 16 contributed to ResAP(2008)1. The requirements laid down in these documents were adopted in national regulations in The Netherlands [11], France [12], Slovenia [13], Germany [14], Norway [15], Sweden [16], Spain [17], and Switzerland [18]. In the following, the specifics of the different national regulations, aside from the common requirements given above, are described. In The Netherlands, national legislation based on ResAP(2003)2 was established in 2003 [11]. Additionally, in 2007 an implementation guideline [19] was adopted, setting age limits and prohibiting the tattooing of certain body parts. Market surveillance of tattoo inks in 2013 comprised 701 selectively sampled red, yellow, orange, and green tattoo inks and revealed exceedance of the limits for aromatic amines and elements in 30 and 12%, respectively, of all samples. In France, national legislation on tattoo safety was introduced as part of a law on public health in 2004 [20]. Chemical requirements were adopted according to ResAP(2008)1 in 2013 [12]. Furthermore, the EU Ecolabel criteria applied to textile products were also assigned to tattoo inks [21], thus excluding the use of dyes with harmful properties. Tattoo inks also must not contain carcinogenic azo dyes or aromatic amines, in accordance with an opinion of the Scientific Committee on Cosmetic Products and Non-Food Products that refers to cosmetics [22]. The French vigilance programme [23] on tattoo products has been ongoing since 2008 and involves obligations for professional tattoo artists and medical personnel to give notification of undesirable and serious side effects. For consumers, such a notification of unwanted effects is only voluntary. Furthermore, chemical analysis of 52 tattoo inks in 2012 revealed non-conformity for 7 samples due to elevated levels of

*o*-anisidine, barium, or bacterial contamination. In Switzerland, national regulation of piercing, tattooing, permanent make-up, and related practices came into effect on January 1, 2014, as a part of a decree on items for human contact. Its principles were adapted from ResAP(2003)2 and ResAP(2008)1. Similar to both resolutions' reference to the European Directive for Cosmetics, the Swiss regulation references an equivalent national regulation [24]. However, in contrast to ResAP(2008)1, there are currently no maximum levels defined for antimony and nickel. In Switzerland, surveillance programmes are conducted on a regular basis. In 2013 [25], a total of 60 tattoo inks and permanent make-up samples were investigated, of which 39 (65%) were objectionable, and 33 were banned from further use. The reasons were inaccurate declaration, use of forbidden colourants or preservatives, detection of N-nitrosamines and PAHs, threshold exceedance for preservatives, and the presence of aromatic amines. Among them, two samples contained very high concentrations, or 32 and 84 mg/kg for the total of all (23) PAHs measured. With regard to the 8 carcinogenic PAHs considered in risk characterisation by the European Food Safety Authority, concentrations of 6.6 and 4 mg/kg, respectively, were measured. In Germany, a national regulation based on the principles of ResAP(2008)1 has been effective since May 1, 2009. The requirements are similar to those of ResAP(2008)1, with the exception of CI Solvent Yellow 14 (Sudan I), which is also being excluded from use by the German regulation. A federal surveillance programme on tattoo inks, targeting preservatives and heavy metals, was conducted in 2007 [26]. Out of 782 samples tested for preservatives, positive results were reported in 53 cases. Among the identified compounds were 1,2-benzisothiazolone, benzoic acid, and 2-methyl-4-isothiazolin-3-one. Furthermore, 878 samples were investigated according to the 13 elements mentioned in ResAP(2008)1, and the highest concentrations were found for copper,

iron, chromium, and zinc, with mean concentrations of 4,652, 79.2, 29.5, and 16.3 mg/kg, respectively. A monitoring programme in 2013 investigated 250 coloured and 129 black tattoo inks for its nickel contents. This allergen was found in 54.8 and 21.7%, respectively, of the samples, with maximum concentrations of 65.1 and 60 mg/kg, respectively. In Norway, a regulation assuming the principles of ResAP(2003)2 came into force on January 1, 2009 [15]. As a further regulatory measure, only 26 preservatives with supposedly low sensitisation potential are allowed. These substances have been selected through safety assessment and subsequent elimination of certain substances, such as triclosan, Kathon CG, and formaldehyde, from the 'positive list' of preservatives given in the EU Cosmetics Directive. The list has been suggested by Norway to the Committee of Experts on Cosmetic Products [27] but has not been implemented on the European level yet. A surveillance programme on tattoo inks has been ongoing since 2011. In 2013, 25 out of 35 products tested in total contained prohibited aromatic amines. In Sweden, national legislation on tattoo inks [28] that adopted the principles of ResAP(2008)1 came into force on August 1, 2012. An associated regulation [16] came into effect on February 1, 2013. The Swedish legislation is being enforced by the local municipalities and has predominantly revealed a lack of labelling as well as open questions regarding the legal use of certain pigments. The national regulation in Slovenia is equivalent to ResAP(2008)1 and came into force on January 2, 2010, as part of the regulation of sanitary and health requirements [13]. A survey on 34 tattoo inks in 2010 revealed element concentrations in 12 samples beyond the thresholds given in resolution ResAP(2008)1. Metals exceeding these limits were barium, copper, cadmium, and lead, with maximum concentrations of 900, 3,400, 0.38, and 18 mg/kg, respectively. Nickel was found in all 34 samples at concentrations of up to 3.1 mg/kg. In Spain, tattoo inks are covered by the national regulation of cosmetics

[29]. In 2008, the principles of ResAP(2008)1 were adopted, and tattoo inks have to be approved by the Spanish Agency for Medicines and Health Products on the basis of toxicological and quality data supplied by the distributor [17]. Approved products are included in a registry. In addition to these national requirements, there are regional regulations in the different Spanish provinces regarding hygiene requirements, registration of tattoo studios, and necessary qualification of tattoo artists. In Denmark, there is currently no regulation of tattooing. However, the Danish Ministry of the Environment published a recommendation on the safety of tattoo ink in 2014 [30]. The chemical parameters are similar to those in ResAP(2008)1 but are further modified in certain aspects. Aniline, a primary aromatic amine found in tattoo inks on the Danish market [31], was added to the list of forbidden substances. For the group of PAHs, the single compound benzo[*a*]pyrene is considered, with a threshold of 0.2 ppm, and an additive threshold of 2 ppm is assigned to benzo[*e*]pyrene, benz[*a*]anthracene, chrysene, dibenz[*a,h*]anthracene, and three isomeric benzofluoranthenes. For lead, a maximum content of 10 ppm is given; other elements are

not included. The recommendation contains further practical guidance on how to realise correct labelling, sterility testing, and expiry date setting. In the appendix of the document, guidelines for a safety assessment of tattoo inks, including exemplary calculations of a systemic exposure dosage and the margin of safety, are provided.

Summarising the efforts on national regulations of tattooing in European countries, there has been some progress in a limited number of countries since the first resolution was issued by the Council of Europe in 2003. However, also in these countries, implementation is currently suffering from insufficient analytical methods as well as from limited data on biokinetics and the toxicity of tattoo inks and their ingredients. However, most European countries remain without such a specific regulation at all. In light of the rising popularity of tattooing throughout Europe and the associated risks to human health, this situation actually is unacceptable. Thus, an initiative by both regulators and scientists at the international level appears to be quite urgent in order to overcome current scientific gaps and limited knowledge and to achieve a common protective regulation in all European countries.

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