

## O1. SUMMARY OF THE FINAL REPORTS ON TATTOO REGULATIONS PREPARED UNDER THE AUSPICES OF THE EUROPEAN UNION

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The European Union, aiming at regulations improving the safety of tattoos and permanent make-up, extended to the DG JUST and the Joint Research Centre in Ispra, Italy to provide evidence-based scientific support to the European policy-making process. Scientists and experts in different fields were involved. The work was structured in four work packages and concluded in a final report. The work took place between 2014 and 2016.

Work package 1, Compilation of information on legislative framework and analytical methods (1). The analysis showed that, at ISO and CEN level, there are neither international nor national standard methods for the analysis of aromatic amines, colorants, elements, polycyclic aromatic amines, phthalates and nitrosamines in tattoo and PMU products. On the contrary, in house validated methods and methods described in the literature are known.

Work package 2, State of play and trends in tattoo practices (2). About 12% of the European population is tattooed. Most tattoo inks used in Europe are imported from USA, while PMU inks are mostly produced in Europe. The number of “non-professional tattooists” might represent up to 10 times the number of “registered/professional” ones.

Work package 3, Adverse health effects and experience with the Council of Europe Resolution (2008)1 (3). Bacterial tattoo infection acquired through inks, tool or procedures is estimated up to 5%. The vast majority of tattoo/PMU adverse reactions are due to delayed and unpredictable hypersensitivity, involving allergy and/or autoimmunity. Direct causal relationship between tattooing and (skin) cancer has been so far neither proved nor excluded. Data gaps and research need were identified. Data needed for risk assessment are missing on absorption, distribution, metabolism and excretion (ADME) of ink ingredients, and on photo-degradation and derived no effect level (DNEL).

Work package 4, Safety of tattoos and permanent make-up. Final report (4). Regulation is hampered by lacking scientific insight in many fields of key importance, and research programs including prospective cohort studies should be developed to prepare valid risk assessment in the future. Harmonized analytical methods and Good Manufacturing Practices for tattoo inks should be developed. Meanwhile, precautionary actions can be undertaken with campaigns, harmonized hygiene guidelines, inspections of studios, and stop of backyard tattooing.

<sup>1</sup> Report EUR 27394 EN; ISBN 978-92-79-50394-8 (PDF).

<sup>2</sup> Report EUR 27528 EN; ISBN 978-92-79-52789-0 (PDF).

<sup>3</sup> Report EUR 27672 EN; ISBN 978-92-79-54234-3 (PDF).

<sup>4</sup> Report EUR 27947 EN; ISBN 978-92-79-58783-2 (PDF)