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**TATTOOING, “TOP-DOWN”, “BOTTOM-UP” AND “MIX” REGULATORY STRATEGIES IN A GLOBAL SCENE****Jørgen Serup<sup>1</sup>***<sup>1</sup>Department of Dermatology, the Tattoo Clinic, Bispebjerg University Hospital; (Copenhagen, Denmark).*

**Aim:** Regulation of tattooing and manufacturing and distribution of tattoo ink stock products is chaotic and of highly variable ambition with many countries having no regulation. Even in Europe there are, ten years after the Council of Europe resolution introduced a standard for this region, no countries sharing identical rule. The regulatory prerequisites and instruments shall be analysed, and their limitations and inadequacies behind this general failure of function shall be discussed as an introduction to a panel discussion

**Methods and Results:** Regulations can be “top-down”, i.e. the central authority decides rules followed by implementation, control and punishment, or it can be “bottom-up”, i.e. the central authority avoids strict rules and put emphasis on watching the business with detection, isolation and treatment of problems coming up under real life conditions, with learning and prevention as outcome. Failure of one element of “top-down” invalidates the whole strategy, which obviously is vulnerable. “Top-down” appears high cost and generally not very realistic, “bottom-up” low cost and generally realistic.

The efficiency of “top-down”, obviously, strongly depends on solid academic knowledge ranging from identification and quantification of the precise risk driver over the role of the driver(s) in tattooing, inks and the tattooist included, to the end point namely the existence of a significant health problem in real life, which elimination of the driver(s) can overcome or significantly influence. This depends on the success of implementation of all elements of the regulatory chain, and some level of acceptance by consumers, tattooists and ink manufacturers. Obviously, “top-down” is highly vulnerable at various levels. FDA of USA relies on “bottom-up”.

Regulation of the tattoo business is facing huge obstacles namely that is anchored in tradition, some 100 million people are already tattooed in Europe, composition of inks is widely unknown and crude, and traditional toxicology fails to have valid models for prediction of risk specifically of tattoo inks. Many players are not registered or unknown. There are many backyarders and inks move freely across borders from production plants anywhere in the world.

There is a third model namely the “regulatory mix”. In fields of special risk backed up by solid academic knowledge such as the obvious microbial risk of inks, a “top-down” strategy insisting on monodose and sterility would be rational and potentially efficient, while other fields of potential risk such as PAHs and PAAs in inks claimed carcinogenic

but nevertheless not associated with any measurable increase of cancer in the tattooed population despite many years of use would call for intensified epidemiologic research and special surveillance.

**Conclusion:** The tattoo business is extremely difficult to regulate and the state of art of regulation is, ten years after the Council of Europe resolution of 2003, a regulatory chaos. There is a need for rethinking regulatory strategies, initiate research and decide instruments, which are rational, realistic and possible to implement in a large territory. Strategies may easily have to build on a “regulatory mix”. It is in Europe with about 100 million people being tattooed a case for the European Union (EU).