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TATTOO INKS FROM A REGULATORY TOXICOLOGY POINT OF VIEW: CHALLENGES AND POSSIBLE COURSE OF ACTION

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Approaches to risk assessment of tattoo inks are at present not an easy task, because vital data are missing and concepts are only beginning to emerge. Compared to regulations in other areas like cosmetics or toys, regulation of tattoo inks needs to address specific features inherent to these substances and their use. To ensure that risk assessment and regulation are based on solid ground, some points need to be addressed, which will be discussed shortly in the presentation.

First, risk assessment is based on exposure to substances. Since individual persons' tattoos can vary considerably in size as well as in number, these variations have to be taken into account when evaluating the associated health risks.

A second point is the fact that for the testing of substances which are specifically applied under the skin, no validated OECD guidelines are available at present.

A third problem is the development of analytical methods (ISO standards) to measure potentially harmful substances in tattoo inks.

Another issue is the evaluation of pigments for a positive list, given the unmanageable multitude of pigments which could potentially be used in these inks. Here, a preselection process needs to be installed which narrows down the substances to be assessed from possibly a few hundred available pigments to about 15-20 which are sufficient to create all shades of color.

Last, the epidemiological basis to estimate tattoo-related complications is small. This means that surveillance or vigilance systems need to be developed (or existing systems to be amended for this specific group of products) which provide the data which are needed to assess whether putative risks are encountered in practice.

However, some risks as for example potential long term CMR effects of tattoo inks are difficult or impossible to assess directly; here, a structure analogues will have to be used. The generation of data on bio kinetics of tattoo inks is a vital point in this context.