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Resolution for ACR AGM 2016

Title of Resolution

Tatoos and Regulating dangerous tattoo inks

Name of individual sybmitting the resolution

Grace Attard ACR General Secretary

Background Information

Tattoo inks are covered by the General Product Safety Directive (GPSD, 2001/95/EC). The GPSD is not an adequate instrument to set chemical requirements for any kind of product. Several Member States have implemented legislation on tattoo inks (France, Germany, Netherlands, Sweden). Austria and Denmark have notified draft legislation.

The Council of Europe (CoE) adopted a resolution "on requirements and criteria for the safety of tattoos and permanent make-up" (Resolution ResAP(2008)1)29. This resolution formed the basis of some of the national regulations mentioned above. It does not allow using:

- aromatic amines as such or from azocolourants
- listed colourants
- substances which are not allowed to be used in accordance with European cosmetics legislation (at the time Directive 76/768/EEC, now Regulation (EC) No 1223/2009) or colourants with restricted application carcinogenic, mutagenic and reprotoxic substances (CMR) of all categories
- In addition, there are some other requirements e.g. concerning impurity (e.g. metals, PAHs) and sterility or recommendations concerning product information and preservatives.

Justifications, reasons and current situations to be addressed

This resolution constituted a step forward at the time but it is also clear that it is not really satisfactory as the level of safety is considerably lower compared with rules on cosmetics. For instance, the Cosmetics Regulation requires an approval of colorants and preservatives (positive list) and includes specific requirements for nanomaterials.

The resolution recommends that the governments: "Regulate the use of substances in tattoos and PMU by taking steps towards establishing – on the basis of safety assessments carried out by the competent bodies and harmonised at European level – an exhaustive list of substances proved safe for this use under certain conditions ("positive list")".

Hence, the implementation of the CoE resolution can be only an interim step in the development of a more robust regulation representing a similarly high level of protection as the Cosmetics Regulation (e.g. by expanding its scope).

Tattoo inks can contain several hazardous chemicals, including substances that are carcinogenic, mutagenic or toxic for reproduction (CMR), or are skin sensitizers. The inks can include polycyclic aromatic hydrocarbons (PAH), primary aromatic amines (PAA), isothiazolinones and heavy metals.

Up to 20% of the European population has at least one tattoo. The proportion with tattoos in the age range 20 to 40 years is even higher, and the trend is upwards. This means at least 50 million people in Europe are exposed to risk.

Although progress was made in 2014 and the Commission Services planned to hold a vote of Member States on the emergency measure in December 2014, with the arrival of the Juncker Commission, and no proposal is likely ahead of further data collection, including the results of a JRC research project that are not expected for another 12 months.

The failure to act now continues to put the health of millions potentially at risk. We call again on the Commission and Member States to proceed with the emergency measure. If no prompt action at the European level is possible, then Member States must be free to protect the health of their citizens through national measures.

Proposals/Recommendations

Tattoo inks represent a product group for which EU legislation (Regulation) must be implemented as soon as possible as a matter of highest priority.

The regulation shall follow the principles of the Cosmetics Regulation (Regulation (EC) No 1223/2009) and include the positive approval of ingredients – colorants and preservatives in particular - based on an assessment of an independent scientific committee.

Preference should be given to a stand-alone regulation for tattoos. Alternatively, requirements for tattoos could be incorporated into the Cosmetics Regulation.

As an interim step, the rules based on the Council of Europe Resolution cited above (for instance, in the form of temporary emergency measures under Article 13 of the General Product Safety Directive (GPSD)) can be accepted.

Complementary requirements regarding tattooing services could be established in form of a European Standard which should include requirements to permit only the use of tattoo inks in compliance with the regulatory provisions to be adopted.

