Minutes | 21th May, 2025

# 5th Meeting of the BfR Commission on Tattoo Inks

The BfR Commission on Tattoo Inks advises the German Federal Institute for Risk Assessment (BfR) as an honorary and independent expert body on issues of tattoo ink safety and risk assessment by giving counsel to the BfR on the development and adjustment of analytical and toxicological methods suitable for inks and pigments. Furthermore, the Commission ensures a continuous dialogue of the BfR with the state surveillance agencies.

With its scientific expertise, the Commission advises the BfR and can assist the Institute as a network of experts in the event of a crisis. The Commission consists of 23 members appointed for a four-year term through an open tender and application procedure. They distinguish themselves through scientific expertise in their respective field. The members of the Commission are obliged to preserve confidentiality towards third parties and to fulfil their duties impartially. Any conflicts of interest regarding individual agenda items discussed in the meeting are subject to transparent queries and disclosure. The meeting minutes below reflect the scientific opinion of the BfR Commission. The Commission's recommendations are entirely advisory in nature. The Commission itself does not issue any decisions or expert opinions and is not authorised to issue instructions to the BfR (and vice versa) nor involved in its risk assessments.

## Item 1 BfR - Welcome and approval of agenda

The managing director, Dr. Peter Laux, opens the commission's 5th meeting and welcomes the participants. As requested by some commission members, the managing director informs that the number of subcommission meetings will be reduced. Alternatively, workgroups can be established to address specific topics. He announced the new appointment period for the commission, which will run from 2026 to 2029. The call for experts for the new appointment period was published in the beginning of 2025. Experts are encouraged to apply. Attendees do not raise objections or propose additions to the agenda.

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## Item 2 Declaration on conflicts of interest

The participants declare to have no conflict of interest.

## Item 3 Analytics

The chair person, Prof. Dr. Marilena Carbone, gives a summary about the previous subcommission meetings.

The BfR presents an update on the recent progress with regard to the analysis of tattoo pigments, in particular the advances regarding the development of a high performance liquid chromatography (HPLC) method. The BfR demonstrated that 14 pigments can now be successfully separated and detected. Furthermore, the BfR is working on the pigment quantification and method validation. Sample preparation, solvent selection, stability, and separation were discussed between several commission members and BfR participants.

## Item 4 Toxicology

### Milena Foerster (IARC) – First insights from the Cancer Risk Attributable to the Body Art of Tattooing (CRABAT) cohort

Dr. Milena Foerster from the International Agency for Research on Cancer (IARC), who is an expert in tattoo epidemiology, gave an update on ongoing tattoo cohort studies. First, an overview of known human carcinogens identified in tattoo inks was presented. However, it remains unclear whether these substances cause cancer through the tattooing exposure route as most of these carcinogens were classified based on oral or respiratory exposure data. Tattoos and permanent make up are now listed as emerging priority in the *Monographs* program of the IARC. Particularly skin and lymphatic cancers are of concern because of the long-term exposure of pigments to the body is relevant, especially because pigments are found to accumulate 7 times more in the dermis, and their subsequent high accumulation in the lymph nodes where pigment concentrations are estimated to be 7 times higher than in skin. Upon exposure cancer might be triggered by the photodegradation of pigments and/or an immune response to them, for instance, due to chronic inflammation through increased phagocytic activity. Furthermore, pigment overload may block the normal function of lymph nodes. The distortion of the immune homeostasis might act on cancer formation and/or progression. The chronic inflammation in the lymph nodes due to pigment aggregation could lead to an increased lymphoma risk. Lymphomas are a very heterogenous type of malignancy with >50 subtypes, and are mainly associated with infections, immunodeficiencies and environmental factors like exposures to pesticides and solvents. Main skin cancers types are cutaneous melanoma and cutaneous squamous cell carcinoma

and their subtypes, and are related to risk factors like UV exposure, immune-deficiency and fair skin.

There is an increased popularity of tattoos not only in US and EU but also in low- and middle-income countries and the market is expected to double by 2030. Younger persons tend to have larger tattoos, especially younger men. In Europe, the tattoo prevalence is highest in young women.

Yet, only a few epidemiologic studies investigating the correlation of lymphoma and tattoo were published:

| Study | Outcome |
|---|---|
| Nielsen et al., 2024[1] | Largest study, 21% increased risk (age group 20-60 years) |
| McCarty et al., 2024[2] | No correlation for lymphoma overall, however high risk for the sub-type of B-Cell non-Hodgkin lymphoma (NHL)in the subgroup of participants 20-60 years |
| Warner et al., 2020[3] | No risk for NHL |
| Clemmensen et al, 2025[4] | Tattoos identified as risk factors for lymphoma however, limited sample size did not allow final interpretation |

Epidemiological studies that were published on skin cancer:

| Study | Outcome |
|---|---|
| Liljedahl et al., 2025[5] | No increased risk for cutaneous squamous cell carcinoma |
| Barton et al., 2020[6] | Increased risk for basal cell carcinoma |
| Clemmensen et al., 2025[4] | Increased risk for different skin cancer types however, due to limited sample size no interpretation possible |

These conflicting results do not allow for any causal interpretation so far. The observed bias (e.g. selection/response bias, recall bias) might be due to the retrospective study design. In contrast, only prospective cohort studies will be able to link current tattoo exposure to future cancer risks.

Dr. Foerster presented two such studies, that are currently ongoing: The Tattoo Ink and the CRABAT cohort, both nested in the national cohort infrastructures NAKO (German health study of a national cohort) and Constances in Germany and France, respectively. Together, they investigate ca. 300.000 individuals overall among which ca. 30.000 having a tattoo. Tattoo exposure of the participants was assessed in two phases. In a first phase, all NAKO (at

[1] DOI: 10.1016/j.eclinm.2024.102649
[2] DOI: 10.1002/cam4.70260
[3] DOI: 10.1158/1055-9965.EPI-20-0515
[4] DOI: 10.1186/s12889-025-21413-3
[5] DOI: 10.1007/s10654-025-01230-z
[6] DOI: 10.1097/EDE.0000000000001179

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baseline 2012-18) and Constances (in 2020) participants were asked about their tattoo status. In the second phase, detailed exposure data were assessed in the previously identified tattooed individuals by the validated tattoo exposure questionnaire EpiTAT (epidemiologic tattoo study). This phase is not completed yet. Future cancer cases are followed up during ~15-20 years via the national cancer registers. Statistics of the current assessment are presented. Final results allowing decent statistical analysis of registries in Germany and national insurance records in France. The French data are already available, the German data are currently at data entry stage. First reliable risk estimates for effect sizes as high as ~25% risk differences for melanoma and lymphoma are expected in between 2030-2035.

First analyses of the CRABAT associations between tattoo exposure and sociodemographic factors were presented. Using multivariate logistic models being tattooed was associated with many life-style factors, especially smoking. Such analyses are important to identify confounders that need to be considered when calculating cancer risks. For example, besides the hypothesis that lymphatic pigment disposal could lead to lymphoma, the act of tattooing itself might also increase lymphoma risk by an increased risk of infection.

Cross sectional preliminary analysis of the CRABAT cohort and selected health outcomes was also presented. Summary statistics of overall skin cancer risk and tattoo exposure showed reduced cumulative incidences in tattooed individuals which are partly due to the differences in age of the compared groups. In multivariate logistic regression models controlled for a multitude of skin cancer risk factors, being tattooed was associated with skin cancer but risks seemed to decrease with increasing tattoo surface. While this result needs to be interpreted with very much caution, tattoo pigments might indeed protect from sun-induced skin damage by shielding from ultraviolet light absorption. T-cell priming might be another mechanism for explanation which is currently investigated by the BfR. Unfortunately, because cancers are rare diseases, it will take still many years until a sufficient number of skin cancer cases is reached for reliable analyses.

Dr. Förster emphasizes that it might be helpful to consider data from non-European countries. Concerning infections, hepatitis infections can lead to liver inflammation associated with liver cirrhosis and hepatocellular carcinoma, but also lymphoma. Vaccination for hepatitis-B-virus (HBV) is available, but not for hepatitis-C-virus (HCV). Infected individuals have often a late onset of symptoms making it difficult to identify the disease. The World Health Organization (WHO) aims to reduce hepatitis transmission by 90% by 2030. Tattoo needles might be a potential transmission route. In recent years, no studies investigated specific tattoo circumstances and hepatitis transmissions were conducted despite the high tattooing popularity in HICs. Preliminary data from the CRABAT cohort shows an increased risk of HCV infections in individuals that got their tattoo outside a tattoo studio with smaller increases for HBV. Approximately 11,000 cases of HCV in the age group 45-70 due to unsafe tattoo practice were identified. To date it remains unknown whether HCV rates are rising again in the tattooed population, as surveillance in this population is scare.. Because of the low hepatitis rates in most parts of Europe and other High-Income Countries (HICs) in general and the public awareness of the importance of tattoo hygiene, such an increase seems however more relevant in Low- and Middle-Income Countries (LMICs) with emerging and poorly controlled tattoo markets. Still, there is a risk in HICs due

to the increasing popularity of home tattooing, because tattoo studios close for economic reasons.

### BfR – A short review of recent epidemiological studies in the tattoo field

Epidemiological studies on lymphoma and skin cancer for the risk assessment of tattoo inks were summarized by a member of the BfR. Difficulties in the interpretation and comparability of the results of the studies are highlighted.

The following studies on the risk of lymphoma were reviewed by the BfR:

| Publication | Entity | Result | Comment |
|---|---|---|---|
| Warner et al., 2020[3] | Non-Hodgkin-Lymphoma and Multiple myeloma | No significant effects (Odds-Ratio) | Population-based case-control study |
| Nielsen et al., 2024[1] | Lymphoma general | Increased Incidence Rate Ratio | Retrospective case-control study |
| Clemmensen et al., 2025[4] | Lymphoma general | Increased Hazard-Ratio for larger tattoos | Retrospective case-cotwin study |

The following studies on the risk of skin cancer were reviewed by the BfR:

| Publication | Entity | Result | Comment |
|---|---|---|---|
| Barton al., 2020[6] | Basal cell carcinoma | No significant effects (Odds-Ratio) | Population-based case–control study |
| Liljedahl et al., 2024[5] | Squamous-cell carcinoma | No significant effects (Odds-Ratio) | Retrospective case-control study |
| Clemmensen et al., 2025[4] | 1. Skin cancer general<br>2. Basal cell carcinoma | 1. Increased Hazard Ratio (Hazard-Ratio)<br>2. Increased Hazard Ratio (Hazard-Ratio) | 1. Retrospective case-cotwin study and twin cohort study<br>2. Twin cohort study |

A commission member suggests that studies on permanent makeup might be also interesting to evaluate.

## Item 5 BfR - Integrated Risk Assessment of Tattoo Pigment Impurities: From Literature-Based Composition Investigation to *In Silico* Toxicology via Lhasa Tools

BfR presents a comprehensive approach that included gathering data from regulatory databases (e.g. ECHA, IUCLID), laboratory analyses, and literature, followed by *in silico* toxicological assessment using Lhasa QSAR tools. Specifically, the software tool METEOR by Lhasa Limited was employed for metabolism prediction and identifying potential bioactive

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metabolites (with scores of 700-900+ indicating higher likelihood of toxic metabolites), while the software tools DEREK and SARAH by Lhasa Limited were used for genotoxicity and mutagenicity evaluation, respectively. Compounds were subsequently categorized into low, medium, or high risk based on these *in silico* predictions, with an example workflow suggesting that chemicals with high METEOR scores and positive DEREK/SARAH predictions should be avoided in tattoo inks. The presentation also provided details on industrial synthetic procedures, starting materials, and potential impurities for various pigments such as Pigment Blue 15:3 & 15:1, Pigment Yellow 138, Pigment Red 254 and Pigment Red 170. During the discussion, a commission member inquires whether the analysis included mechanistic pathways, emphasizing the value of incorporating Mode of Action (MoA) for *in silico* pigment toxicology analysis in future assessments, noting that METEOR already contributes to understanding metabolic pathways relevant to such insights.

## Item 6 Update minimum requirements

The BfR has announced that the minimum requirements are currently being revised for retrofitting. The revision process is intended to take into account the latest state of the art in testing tattoo ink ingredients. Within this framework, annexes to the minimum requirements will be compiled providing specific testing strategies, recommended adjustments to existing guidelines, and new standard operating procedures (SOPs). The experts of the Tattoo Commission will have the opportunity to comment on these documents and contribute their expertise. The aim is to develop SOPs on the specific topics covered by the minimum requirements. These will serve as guidance for tattoo ink manufacturers in assessing the safety of their products. Although they are not binding, tattoo ink manufacturers are encouraged to fulfil these requirements as they are considered essential for the safety assessment of tattoo inks. Overall, the initiative was supported by the Commission members, although concerns were expressed regarding requirements in addition to those imposed by the REACH restriction.

## Item 7 BfR – Discussion round: follow up from the WCTP

The members of the Commission are asked by the BfR to summarize the most important points from the WCTP conference. According to ink manufacturers low limits for some chemicals that are defined in the REACH restriction, cannot be realized in the production process. As an example, low limits for aldehydes are contrary to the sterilization process for inks that is necessary to comply with the biological safety. Aldehyde formation is intrinsic for gamma radiation and alternative preservation methods are restricted since no biocidal product was approved for the use in tattoo inks. In the opinion of the ink manufacturers, the limits for formaldehyde according to the entry 75 of the REACH restriction are too low and are even lower than the requirements for medical products.

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A manufacturer announces that according to Schreiver et al, 2024[7] the exposure to chemicals in tattoo inks might be lower than assumed during their evaluation for the REACH restriction.

According to ink manufactures alternatives to Pigment Blue 15 and Pigment Green 7 are missing because other blue and green pigments are not REACH compliant and might be even worse for the health of consumers.

The question was raised on how it is technically possible to adopt the REACH restriction according to the points mentioned above. A member state or ECHA can request an amendment of a restriction by submitting an Annex XV dossier, if risks are not adequately controlled.

At the WCTP the sensitising potential of different chemicals, for instance of azo pigments, has been a discussion topic. These are only partially restricted under REACH. The collection of clinically relevant pigments is currently observed in the tattoo study by the Information Network of Departments of Dermatology (IVDK). Besides data collections and opinions on risk assessment, a joint opinion or regulatory position from the manufactures with concrete points what needs to be changed in the restriction and for what reasons would be helpful.

## Item 8 Any other business

Dr. Milena Carbone suggests to build up a national registry of tattoo artists for Italy. She asks if such a registry exists in Germany. One commission member points out that in Germany tattoo artist is not a recognised training occupation with a job description. Nevertheless, because tattoo studios are small businesses, hygienic requirements are implemented on the state level. A contact to Austrian regulatory bodies might be helpful because tattoo artist is a recognised training occupation there.

Regarding reference material for tattoo pigments, the BfR has approached the German BAM (Federal Institute for Materials Research and Testing), which regularly develops analytical reference standards. The BfR is asking if similar institutions in other countries could be contacted to establish an international joint project on the development of such standards.

## Item 9 Planning of the next meeting

Possible dates for the next meeting of the BfR Commission on Tattoo Inks are discussed and it is decided that the next meeting of the BfR Tattoo Commission for Tattoo Inks should be scheduled for October or November, 2025. BfR will sent out a poll to all members to determine the exact dates.

[7] DOI: 10.1007/s00204-025-03959-8

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