DRAFT

Minutes | 20 April 2026

6th 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 members appointed for a four-year term through an open tender and application procedure. They are distinguished by their scientific expertise in their respective fields. 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.

Preliminary note

The 6th Meeting of the BfR Commission on Tattoo Inks was conducted as a hybrid event.

Item 1 BfR - Welcome and approval of agenda

The meeting is opened and welcome remarks are made by the appointed head of the BfR Commission for Tattoo Inks. In particular, commission members are thanked for their contribution in the previous term of office. Eight newly appointed members for the current term of office are warmly welcomed.

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Item 2 Department of Chemical and Product Safety

The head of the department of Chemical and Product Safety, thanks members for past and continued contribution and emphasises the complexity of tattoo ink safety.

Strategic priorities for the current term:

- Ink composition & Identity database: Developing a comprehensive repository of substances for inks in collaboration with manufacturers and surveillance authorities.
- Analytical methods development: Refinement of standard operation procedure (SOPs), establishment of laboratory reference materials (RM).
- Epidemiological causality evaluation: Investigation of the alleged public and clinical linkage between tattoo inks and human malignancies (e.g., skin cancer and lymphoma) as well as the understanding of molecular mechanisms to improve risk assessment.
- Refining Minimum Requirements: Continuous iterations of the BfR Minimum Requirement document.

Item 3 Introduction to BfR Commissions and Conflicts of Interest

A BfR representative from the Unit for Crisis Prevention and Commission Coordination outlines the procedural guidelines governing the honorary, personal appointments for the commission members:

- Scientific Independence: Members represent themselves strictly as individual scientific experts, not their employers or institutional affiliations.
- Conflict of Interest (CoI) Protocol: Declaration of Interest forms are strictly required upon appointment. Additionally, contextual of specific agenda items will be queried at the opening of every meeting. Affected members will be temporary excluded from voting in those distinct topics, with the exclusion documented in the public record.
- Freedom of Information Act (Informationsfreiheitsgesetz): All official documentation and communications received by the BfR are subject to public access inquired. One single meeting protocol is generated and published online.
- Emergency Risk Detection Network: Members are requested to utilise the dedicated channel (risikofrueherkennung@bfr.bund.de or via direct notification to the head of the commission) to flag potential emerging hazards, consumer trends or market anomalies.

Item 4 Introduction of the Commission Members – Tour de Table

All members introduce themselves and present their professional background and the relevance to tattoo inks safety assessment. The list of the appointed experts for the

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commission term 2026-2029 including their affiliation can be found at the dedicated website[1].

Item 5 Election of the chairperson and vice chairperson – All

Report on first term (Mar 2023 - Dec 2025): 23 experts from 7 nations were appointed, five commission meetings and three sub-committees (Analytics; Toxicology; Hygiene & Technology) took place. Emphasis is given on the need for well-characterised reference materials for pigments (for analytics, enforcement, *in vitro* testing), development and validation of analytical methods (HPLC, Raman, MALDI-TOF, etc.), application and limitations of *in silico* methods, hygiene/sterilisation topics, and review of recent epidemiological and immunotoxicological findings.

Current (second) term: runs until Dec 2029, 22 experts from 9 nations are appointed; two active working groups established (Analytics; Technology and Hygiene); balanced representation across industry, research and governmental organisations is reached; inclusion of tattoo artists' representation and certification laboratory representation is achieved.

The members of the BfR Commission shall elect a chairperson and at least one deputy chairperson by closed ballot. The election shall be decided by a majority of the members present. In the event of a tie after the second ballot, the decision shall be made by lot. The chairperson presides over the meeting of the BfR Commission. If both the chairperson and their deputy are unable to attend the meeting, the members of the BfR Commission shall elect another member on an ad hoc basis to act as chairperson and preside over the BfR Commission during the meeting in question.

Emphasis on efficient meeting schedule is given: Maximum two plenary meetings per year; working groups to meet on demand. Election procedure is explained.

Two members raise their candidacy. Dr Marilena Carbone is elected as chairperson and Dr Marco Famele as vice chairperson.

Item 6 Tattoo ink research and regulation in Australia: Recent developments – Robert McGowan, Think Aesthetics

Mr. Robert McGowen gives an overview about Australian regulatory history: Australia has a population of approx. 28 million people. Much of the research has been going on in Australia during the last 3 years. As in other countries, the amount of people that are getting tattooed in Australia is increasing; accordingly, complications raise as well. 20 % of the Australian population are tattooed. A publication[2] recommended already in 2016 that information on potential hazards is needed for medical professionals, tattoo artists and the general public. It was suggested that Australian legislators regulate the industries because of the rising

[1] https://www.bfr.bund.de/ueber-uns/einrichtungen-am-bfr/bfr-kommissionen/kommission-fuer-taetowiermittel/kommission-taetowiermittel-2026-2029/
[2] Matsika et al.,2016: https://www.researchgate.net/publication/321274157_A_review_of_tattoo-related_medical_complications_why_the_Australian_tattoo_industry_should_be_regulated

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trend of tattooing. Activities in regulation from Queensland "Characteristics of tattoo inks used in Australia" released by the National Industrial Chemical Notification & Assessment Scheme (NICNAS now AICIS - Australian Industrial Chemicals Introduction Scheme) recognised inks non-compliant with Australian poison standards and recommended a risk assessment of eight pigments in common use[3]. Between 2019 to 2022, a Departmental Standard by Queensland Health (state regulator) with the industry was drafted to follow REACH regulations but was blocked by the ATG (Australian Tattoo Guild).

Nevertheless, new publications from Australia raise concerns about risks related to tattoo inks. The University of New South Wales has recently published on toxic metals and carcinogens in tattoo inks[4]. Fifteen inks on Australia's market were analysed using ICP-MS and untargeted LC-MS. Eight of thirteen exceeded EU limits for one or more substances like antimony, arsenic, cadmium, chromium, copper, lead, selenium, and tin. Toluidine and sulphanilic acid were detected. All inks tested would be prohibited under EU regulation, revealing a clear gap in Australian oversight. Another study from Flinders University (South Australia) on tattoo inks that used multiple analysis techniques revealed discrepancies in ingredient composition and elemental content when compared against label claims[5]. Reference pigments PY14, PY65, PB15, PO13 and white pigments titanium dioxide and barium sulphate were used with reported purity of 97 to 99.5% for PY14, PY65, TiO2 and BaSO4, while PB15 and PO13 were reported as technical grade (85 to 95% purity). (for more information see article [5]) Analytical spectroscopy techniques including FTIR, NMR, XRD, Raman, EDX and ICP-OES were used.

The speaker introduces another publication investigating challenges in laser tattoo removal, especially the impact of titanium dioxide on photodegradation of yellow inks. Yellow pigments are difficult to be removed by laser treatment[6]. The degradation process is significantly influenced by the presence of TiO_2, including the formation of aggregates and possible limited pigment degradation due to reduced laser effectiveness. Several toxicological relevant substances could be detected after laser irradiation.

A study of 40 cases of tattoo-associated uveitis (TAU) is presented[7]. 25 of them were tattooed with black ink, one with red, one with pink and 14 with "unknown". All cases showed inflamed tattoos, indicating a connection between uveitis and the tattoo. In the discussion it is mentioned that ophthalmologists are often not aware of the connection between uveitis and tattooing. The number of total cases is not known for Australia nor for other countries. But cases have been also reported in Europe. The mechanism is unknown. In is proposed in the discussion that the German Information Network of Dermatology Clinics (Informationsverbund Dermatologischer Kliniken (IVDK)) may contribute to informing physicians and monitoring cases of TAU.

[3] https://www.industrialchemicals.gov.au/sites/default/files/2020-05/Characterisation%20of%20tattoo%20inks%20used%20in%20Australia%20%5BPDF%20456KB%5D.pdf
[4] Violi et al., 2026: https://doi.org/10.1016/j.jhazmat.2025.140874
[5] Aljubran et al., 2025: https://doi.org/10.70387/001c.143999
[6] Aljubran et al., 2025: https://doi.org/10.1007/s00204-025-03989-2
[7] Siebert et al., 2025: https://doi.org/10.1111/ceo.70012

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Item 7 Tattoo ink regulation – perspectives from New Zealand – Dr Shaun Presow, Environmental Protection Authority, Wellington, New Zealand

Hazardous substances are regulated in New Zealand by the "Hazardous Substances and New Organisms Act" from 1996[8]. This act regulates the import and manufacture of hazardous substances. In New Zealand, the cultural context is important due to the Māori and Pasifika people who use traditional tattooing, which needs to be respected. Regulation can be divided into two parts. Firstly, individual approval for high-risk substances, that usually are published within Environmental Protection Authority (EPA) documents setting the legal classification and rules of use. And secondly, bulk approval for grouped chemicals based on use and classification, with fixed group standards. Importers/Manufacturers can self-assign substances and mixtures, but must keep record. Tattoo inks are regulated as bulks under the Tattoo and Permanent Makeup Substances Group Standard 2020[9]. Recommendations for impurity and component limits are available which were last updated in 2020.

Health New Zealand has commissioned testing of 110 inks from various sources and the results are due in May 2026. According to the results of this study a proposal will be formulated on amending the Group Standard followed by a public consultation, determining whether new rules need to be implemented.

The discussion is on traditional inks, which are usually produced from burned plants. The group standard for tattoo and Permanent Makeup does not include hygiene regulations of inks. Substances of higher classifications are completely banned in inks, but less severe substances, for instance, classified as eye irritants, are still allowed. Numbers and frequency of tattoo complication in New Zealand are unknown.

Item 8 Tattoo inks: minimum requirements and test methods, BfR

A BfR speaker outlines the framework to assess the safety of tattoo ink substances that are currently not restricted under the EU REACH regulation. While the EU REACH regulation restricts over 4.000 hazardous chemicals in tattoo inks based on the CLP (Classification, Labelling, Packaging) and cosmetic regulations, a safety gap exists for unregulated substances. The intention is to communicate practical, action-oriented annexes to the minimum requirements and test methods - specifically SOPs - for manufacturers and surveillance authorities.

Tiered Approach

The BfR briefly reports on the work of planned annex 1 for BfR "Tattoo inks: minimum requirements and test methods", which focusses on the analytics of tattoo pigments and

[8] https://www.legislation.govt.nz/act/public/1996/30/en/latest/#DLM381222

[9] https://www.legislation.govt.nz/secondary-legislation/agency-drafted/~2025/~340435/en/latest/

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inks[10]. The previously introduced Tiered Approach as guidance for the identification and quantification of pigments in tattoo inks is explained and consists of 3 tiers:

Tier 1: a label check purely based on observable or declared information (e.g., label, colour, data sheets),

Tier 2: a pigment screening with different methods giving tentative pigment identity information,

Tier 3: providing confirmation of pigment identification and (semi)quantitative assessment based on HPLC analysis.

At the moment, a real quantitative assessment is not possible for most pigments due to the lack of reference materials. Based on the general design of the Tiered Approach, the BfR is drafting a decision tree, while providing decision nodes intended for the determination of pigments in ink products.

Tier 1 consists of 3 nodes: conformity of the label, whether all declared pigments are legally allowed; consistency of given information, whether the declared information is coherent (e.g., CAS and C.I. number match); and the plausibility, whether all available information at that level make sense.

Depending on the outcome and gathered information more detailed nodes would then suggest further analytical methods. For example, in case of a blue ink, UV-vis or FTIR analysis would be suggested to distinguish Pigment Blue 15 from Pigment Blue 60.

Finally, Tier 3, which at the moment only encompasses HPLC, aims to confirm identity of the pigments, which are hypothesised bases on the screening results from tier 2, as well as to provide quantitative information. Quantification depends on the availability of respective reference materials.

In addition to the decision tree and method suggestion, the Tiered Approach annex to the BfR Minimum Requirements document will also provide further information on these methods like parameters, limitations, and for which pigments each can be applied. This includes also appropriate protocols for each method, either by providing a SOP or by referencing to respective publications.

In conjunction with the Tiered Approach, the BfR mentions the continuing Working Group Analytics. The Working Group advises the BfR regarding the decision tree as well as for additional input to the method collection.

Besides the work on the Tiered Approach, the BfR addresses the low solubility of the pigments and introduces a novel approach to determine it. Starting with a dispersion (in NMP or DMSO), the method makes use of a stepwise dilution procedure and records corresponding UV-vis spectra until the excitonic features of the particle fraction disappear and the spectrum becomes invariant upon further dilution. The crucial transition point then indicates the solubility of the pigment in that given solvent irrespective of the crystal structure or polymorph used. Furthermore, pp-LFER modeling is used to transfer the

[10] https://www.bfr.bund.de/cm/349/tattoo-inks-minimum-requirements-and-test-methods.pdf

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experimental solubilities to solubilities in water[11] and cytosol[12] respectively, employing Abraham-type solvation models.[13] The BfR addresses that these cytosolic solubilities can be compared with literature-known sensitisation thresholds for strong sensitisers which are typically at 2-3 µM (derived from *in vitro* assays), above the majority of the modelled pigment cytosolic concentrations. Based on these results, most common tattoo pigments should not reach concentrations high enough to trigger a sensitisation event in human tissue except for some exceptions.[14] In addition to information of possible sensitising effects this approach also provides UV-vis reference spectra and recommended pigment concentrations for sample preparations.

Epidemiologic studies

Many case studies were published raising the question if there is a connection between tattooing and cancer [15,16,17]. Tattoo inks may contain polycyclic aromatic hydrocarbons (PAHs), primary aromatic amines (PAAs) or heavy metals (cadmium, chromium, nickel) [18]. Therefore, epidemiological studies have been demanded with skin cancer and lymphoma of most interest [19]. The analysis of epidemiological data has been suggested in the Minimum Requirements document in the sequential testing scheme under Step 1. A BfR member gives an overview of studies describing the risk of skin cancer from tattoos. Seven studies were reviewed. Two studies showed a sample size, which was too small to draw conclusions. The studies focused on different types of skin cancer: only one study investigated Squamous cell carcinoma (SCC). No increased risk of SCC was found in tattooed individuals compared to non-tattooed individuals[20]. Three studies investigated malignant melanoma, one case-control study suggest a link between tattoos and an increased risk of skin melanoma, although no dose-response relationship was identified[21]. In another case-control study the presence of a tattoo was not clearly associated with an increased risk of melanoma; however, higher exposure was linked to a reduced risk. Confounding factors such as sun exposure and immune response could not be ruled out[22]. The overall risk of skin cancer, as well as the risk of melanoma and non-melanoma skin cancer individually, was not increased[23]. One study, providing data from case-control and cohort type on twins showed an increased risk of skin cancer in general and basal cell carcinoma in particular[24].

[11] Endo, S.; Goss, K.-U. Applications of Polyparameter Linear Free Energy Relationships in Environmental Chemistry. *Environ. Sci. Technol.* **2014**, *48* (21), 12477−12491.
[12] Endo, S.; Brown, T. N.; Goss, K.-U. General Model for Estimating Partition Coefficients to Organisms and Their Tissues Using the Biological Compositions and Polyparameter Linear Free Energy Relationships. *Environ. Sci. Technol.* **2013**, *47* (12), 6630−6639.
[13] Chung, Y.; Vermeire, F. H.; Wu, H.; Walker, P. J.; Abraham, M.; Green, W. H. Group Contribution and Machine Learning Approaches to Predict Abraham Solute Parameters, Solvation Free Energy, and Solvation Enthalpy. *J. Chem. Inf. Model.* **2022**, *62* (3), 433−446.
[14] Patalag, L. J. Quantifying Ultra-Low Pigment Solubilities by UV-Vis Spectroscopy: Implications for Toxicological Assessment. *ACS Meas. Sci. Au* **2026**, https://doi.org/10.1021/acsmeasuresciau.5c00214.
[15] Kluger and Koljonen, 2012: https://doi.org/10.1016/S1470-2045(11)70340-0
[16] Kluger et al., 2019: https://doi.org/10.1111/jdv.15808
[17] Paprottka et al., 2018: https://doi.org/10.1007/s00266-017-1002-0
[18] Fels et al., 2020: https://doi.org/10.3390/cosmetics10050141
[19] RAC/SEAC, 2019: https://consultations.hse.gov.uk/crd-reach/restriction-proposals-003/user_uploads/opinion-on-annex-xv.pdf
[20] Liljedahl et al., 2025: https://doi.org/10.1007/s10654-025-01230-z
[21] Rietz Liljedahl et al. 2025: https://doi.org/10.1007/s10654-025-01326-6
[22] McCarty et al.,2025: https://doi.org/10.1093/jnci/djaf235
[23] Mo et al., 2025: https://doi.org/10.1093/jnci/djaf332
[24] Clemmensen et al. 2025: https://doi.org/10.1101/2024.07.05.24309993

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Furthermore, an overview of studies describing the risk of blood cancer from tattoos is presented. Four studies were reviewed. One case-control study did not show enough data to draw a conclusion. Large-scale analyses from Northern Europe and the US suggested an increased risk of non-Hodgkin lymphoma (NHL) of B-cell type. [25,26,27] The current epidemiological data on the risk of developing haematopoietic cancer as a result of tattooing is contradictory and is currently the subject of intense debate.

Taken together there might be an increased risk for some skin cancer types and NHL. Uncertainties due to the retrospective study design have been discussed intensively[28, 29,30]. All studies investigated cancer cases before the REACH restriction of tattoo inks and not all confounders (for example, sun exposure or infections) have been taken into account.

Epidemiological studies alone do not allow to draw conclusions on the carcinogenicity of tattoo ink ingrediencies. However, additional evidence from *in vivo* and *in vitro* studies suggests that ongoing inflammation due to tattoo ink ingredients (e.g., pigments) might be a mechanism for cancer development. Associated confounding factors such as viral infections (particularly hepatitis C) must be considered as triggers for an increased risk of non-Hodgkin's lymphoma in tattooed individuals[31].

In the discussion it is asked if death rates should be an endpoint to investigate in the future, instead of single endpoints like skin cancer, because it is known that tattooing may have multiple health effects as, for instance, the uveitis cases have shown. Single endpoints might be more difficult to observe especially if internal organs are affected.

Intensive investigations were done on confounding factors and it is known that tattooed people show a different lifestyle. If one looks at death rates, it needs to be death after a specific condition and not earlier death in total. It could rather be that tattoos through this inflammation route affect diagnosis or therapy.

On the other hand, lifestyle is also influencing the way of skin cancer development and progression. It is argued that statistics on death may be easier to acquire from official statistics. Of course, it would still be a challenge to find out what the frequency of tattooing in these deceased people was.

In-silico methods

The BfR presents another planned annex draft to the BfR Minimum Requirements document, proposing the integration of artificial intelligence (AI) and *in silico* computational methods into next-generation risk assessment (NGRA) frameworks for tattoo ink

[25] Nielsen et al., 2024: https://doi.org/10.1016/j.eclinm.2024.102649
[26] Clemmensen et al., 2025: https://doi.org/10.1101/2024.07.05.24309993
[27] McCarty et al., 2024: https://doi.org/10.1002/cam4.70260
[28] Kluger, 2026: https://doi.org/10.1007/s10654-026-01370-w
[29] Faheem, 2026: https://doi.org/10.1007/s10654-025-01345-3
[30] Rietz Liljedahl et al., 2026: https://doi.org/10.1007/s10654-026-01381-7
[31] Foerster et al., 2026: https://doi.org/10.1101/2024.10.25.24316096

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ingredients. The rationale is to align with the growing international regulatory momentum towards non-animal testing, recognising that classical *in vivo* data (predominantly rodent-derived) are of limited relevance to human dermal physiology and that conventional toxicological testing is resource- and time-intensive. The annex builds on outcomes of the 3rd International Expert Meeting on Tattooing that took place in 2022 at the BfR, which had already identified the integration of Quantitative Structure-Activity Relationship (QSAR) and physiologically based pharmacokinetic (PBPK) modelling as priority areas.

Proposed In-Silico Tools and Scope

The annex foresees use of QSAR modelling, supported by regulatory-grade databases and tools (OECD QSAR Toolbox, ECHA EUCLID, EPA ToxCast/Tox21) and by expert knowledge-based systems (LHASA Derek Nexus, Sarah Nexus, Meteor) to predict skin sensitisation, genotoxicity, mutagenicity and carcinogenicity endpoints. PBPK modelling (e.g., SimCyp, PK-Sim, MoBi) is proposed to characterise systemic absorption, distribution, metabolism and clearance, supplemented by *in vitro* to *in vivo* extrapolation (IVIVE) to translate *in vitro* IC_{50} values into *in vivo* dose equivalents, consistent with EPA/OECD guidance. The EU Commission noted that these tools were originally developed for soluble small-molecule chemicals and require adaptation to the nanoparticulate-chemical nature of tattoo pigments, including consideration of biopersistence, dissolution behaviour, agglomeration/dispersion status and particle size distribution per established nanomaterial characterisation guidance. Available toxicological data for tattoo inks remain sparse and predominantly concern insoluble species, constraining PBPK parameterisation.

The annex also includes the Threshold of Toxicological Concern (TTC) concept as a potential screening approach for categorising low-level tattoo ink impurities and degradation products by concern level. The TTC does not adequately translate to the tattoo toxicology context: the underlying threshold (0.15 µg/day; EFSA, 2019) was derived for oral dietary exposure to trace food impurities, whereas the exposure route, biological fate, tissue persistence and systemic bioavailability of dermally deposited, biopersistent tattoo ink constituents differ fundamentally. Hence, the application of the TTC concept to tattoo ink risk assessment is scientifically inappropriate without substantial methodological adaptation.

Item 9 Risk assessment of tattoo inks in the Netherlands – Dr Krista Bouma, NVWA, Netherlands

The Office for Risk Assessment & Research is a part of the Netherlands Food and Product Safety Authority and provides independent advice to the Inspector-General of the NVWA, Ministry of Health, Welfare and Sport and Ministry of Agriculture, Fisheries, Food Security and Nature. Its main task are science-based risk assessments in the field of food safety, consumer product safety, animal health & animal welfare, plant health and nature. A Dutch Survey on tattoos with 3,273 respondents between 18 and 80 years was carried out in

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2024[32]. 3 out of 10 Dutch people have a tattoo or permanent make-up and the average age at which people get a tattoo is 27 years. Arms and hands are the most popular sites of a tattoo. The median tattoo size is 150 cm² (average 530 cm²). The questionnaire also included rating for the amount of shading/filling of the tattoos allowing to calculate the median tattoo skin area coverage of 75 cm² (average 350 cm²). These data are informative for a more accurate exposure by means of body surface tattooed - similar to the EpiTAT questionnaire[33]. Hence, they can be used to inform exposure scenarios in risk assessment in the future. Concerning colour, black and shades of grey are the most popular (85 %). Followed by dark blue/dark green (19 %) and bright red (16 %) colours. 37 % did not inform themselves about possible health risks. 39 % experienced health complaints. For future tattoos, 80 % have no regret. Two out of five plan to get a tattoo within five years. One in ten considers removing their tattoo, while 16 % had a tattoo removed. Laser removal is the most popular method. Health effects that may occur are chemical hazards (target organ toxins, irritation, carcinogenicity, mutagenicity), infections (bacterial, viral, fungal), allergic reactions and foreign body reactions (granuloma, sarcoidosis). Other complications such as pain, itching, reactions to cold and heat were reported. Complications can occur immediately or after a few decades.

In 2024, an EU enforcement action coordinated by the NVWA was carried out regarding the composition of tattoo inks[34]. 14 EU market surveillance authorities participated investigating 52 tattoo inks of 26 different brands. For 27 samples, the composition was found to be non-compliant. PAHs were found in 13 %, PAAs in 8 %, heavy metals/elements in 33 %, preservatives in 29 %, volatile organic compounds (VOCs) in 92 % and microbiological contamination in 8 % of the inks.

RAC and SEAC derived DNELs and DMELs specifically for substances in tattoo inks, but such health-based guidance values are available only for a limited number of substances, due to the unique route of exposure. If not available, values from different routes of exposure could be used. These limit values could be drawn from ECHA, EFSA, SCCS and literature documents, but it is uncertain if other exposure routes can be extrapolated to intradermal injection. For the exposure estimate parameters the background document REACH restriction (RAC & SEAC, 2019) was used: Size of tattoo per session was 300 cm^2, amount of ink per cm^2 was 14,36 mg, amount of ink per session was 4308 mg, bioavailability was 100 % and body weight 60 kg.

Substances with systemic effects were identified by calculating the ratio of exposure and a health-based guidance value. Increased risk has been identified for some PAAs, metals/metalloids, preservatives. For micro-organisms the requirement in Dutch national legislation of tattoo inks is sterility. Aerobic bacteria were found in an EU survey, but infections may have occurred as the skin was pierced.

Uncertainties are due to toxicity data based on other routes (primarily oral exposure), comparison of one tattoo session to lifelong health-based guidance value, and limited information on toxicokinetics. Substances of concern for systemic effects are PAHs, PAKs, As,

[32] https://www.nvwa.nl/site/binaries/site-content/collections/documents/consumentenartikelen/non-food/tatoeages/onderzoek-tatoeages-in-nederland/onderzoek-tatoeages-in-Nederland.pdf
[33] https://www.sciencedirect.com/org/science/article/pii/S2561326X23006601
[34] https://english.nvwa.nl/topics/product-safety/tattoo/supervision-of-tattoo-inks-and-dyes

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Cu, Pb, benzoic acid and phenoxyethanol. Substances of concern for skin sensitisation are Cr, Ni, formaldehyde and isothiazolinones. The labelling is often incorrect, therefore displays unreliable information. The analysis is mainly focused on 'usual suspects' and a screening method for non-volatiles is needed.

Data gaps are due to incomplete knowledge of the composition of the tattoo ink. Furthermore, screening methods for non-volatiles and pigments are missing. Analysis of anaerobic bacteria should be included in testing for microbial ink contamination. Also, there is a lag of data on toxicokinetics. Not all substances have toxicity data and not all endpoints are covered (such as endocrine disruptors).

Dr Bouma stresses that a harmonised approach on risk assessment of tattoo inks is needed. In particular, the exposure scenario, the transfer of oral hazard data to intradermal application and the use of life-long health-based guidance values [daily intake] despite irregular application of tattoos.

Item 10 Results of the market surveillance study 2025 of Tattoo and PMU inks from Northwestern Switzerland and Geneva – Dr Urs Hauri, Official Laboratory of Canton of Basel-City, Switzerland

Dr Hauri reports on the results of a market surveillance study from 2025 in Switzerland. The samples, 50 tattoo inks and 35 permanent make-up inks, were sampled in tattoo studios in Northwestern Switzerland and Geneva as well as from an importer in Switzerland and Swiss internet stores. Of the samples from studios about 15 % were not REACH compliant. Here, it is also stated that there are still ink products on the market that have not changed since REACH came into force and where the label already shows that.

Many analytical methods mainly (U)HPLC-based employing different extraction and sample preparation techniques were used to assess several analytes such as preservatives, PAAs, nitrosamines, PAHs and aldehydes. Additionally, a metal analysis and GC screening was conducted. As the limit values for several substances differ between Switzerland and EU, often both were used for reference and discussed.

The PAH analysis showed that two samples (12 %) exhibited PAH (i.e., Naphthalene and Bez(a)pyrene) concentration above the legal limits. For the PAAs four samples (6 %) were above the legal limit (5 mg/kg) and 11 (15 %) above the toxicologically derived limit (0.5 mg/kg). Only two samples which did not incorporate forbidden pigments exceeded the toxicologically derived limit. Furthermore, Dr Hauri showes results of the assessment of synthesis educts from so far unregulated pigments in these ink samples. Depending on the pigments the synthesis may include previously reported educts but also new educts, including amines or naphthols, which may not have a harmonised classification as carcinogenic or sensitising substances. Some educts from the synthesis of the now commonly used Pigment Yellow 138 were found in high concentration.

Analysis of formaldehydes, acetaldehydes and glyoxals showed that 67 % of the samples were above the legal limit of 0.5 mg/kg. Dr Hauri points out that for practical reasons the

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limit for PAAs (5 mg/kg) was chosen to act upon for these substances, which was still exceeded by about one third of the samples. He raises the point that for formaldehyde, acetaldehyde and glyoxal a risk assessment by ECHA would be favourable and would enable an adaptation of the limit. Similarly, the analysis of nitrosamines showed that 2 % and 31 % were above the legal limit for *N*-nitrosodiethanolamine and for diethanolamine, respectively. Even applying the CLP-based concentration limit for diethanolamine due to its irritative effect 19 % were still above this limit. The use of triethanolamine during synthesis will often result in to high diethonalamine concentration and is therefore not recommended. In regard to phenol, about 24 % of the tested samples showed concentrations above the legal limit (0.5 mg/kg) and 8 % were still above 5 mg/kg. Several substances toxic for reproduction like styrene and phthalates were found above the legal limit of 0.5 mg/kg in 15% and 28 % of the samples, respectively.

Dr Hauri also shows the results for the analysis of preservatives and it is discussed that as of now no preservatives are allowed to be used functioning as preservatives in tattoo inks. Thus, REACH concentration limits were used when available. Several preservatives were found above the legal limit (e.g., benzisothiazolinone). Almost in all cases when preservatives were found, they were not disclosed on the label, independent if they were present in high or low concentrations (e.g., benzoic acid, methylchloroisothiazolinone/methylisothiazolinone).

Heavy metal analysis showed that inks declared REACH-compliant were less likely to show concentration above the respective legal limits than inks not declared REACH-compliant (16 % vs 43 %). The heavy metals found most often were cobalt followed by arsenic, nickel and lead (15 %, 7 %, 5 %, 1.5 %). Additionally, barium was present in several samples at sometimes very high concentrations and was not declared. Furthermore, the rosin (classified as skin sensitiser) content within the samples was tested and it was found in 15 %. Interestingly, it could not be detected in samples which were not declared REACH-compliant, but it was detected in inks declared REACH-compliant (14 out of 76, 18 %). Also, it was found in inks without azo pigments and in inks containing Pigment Blue 60 (now substituting the banned Pigment Blue 15).

Regarding the assessment of the regulated pigments, preliminary results indicate that many were to be found above the respective limits. Pigment Blue 15 and Pigment Green 7 were only detected in one sample each, but at high concentrations, despite their recent ban. Another change observed now was the occurrence of Pigment Red 48 and Pigment Red 266 which were less common in the past. The unfortunate differences in concentration limits of pigments (0.1% or 0.00005%, depending on the covered annexes they are listed in) pose difficulties in the already challenging quantification of pigments.

In summary, the REACH requirements are difficult to meet for a majority of inks. Changes of pigments used after the REACH restriction on inks also lead to a change of contaminants in the inks. It is called for a re-evaluation of aldehydes by ECHA and lastly, the situation of the absence of legal use of preservatives is highlighted.

Subsequent questions focus on toxicological derived ECHA limits, which are based on lead substances, like aniline, and then applied to all substances with the same harmonised classification. Secondly, a short discussion takes place regarding the occurrence and disclosure of preservatives in the analysed inks. It is asked if the discrepancy between

disclosed and found preservatives could stem from the used raw materials. Dr Hauri explains that this may be possible for cases with very low detected preservative concentrations, while for other cases the found concentrations are identical for several ink products of the same manufacturer or are too high to assume an unintentional inclusion.

Item 11 Detection of anaerobic and aerobic bacteria from commercial tattoo and permanent makeup inks – Dr Goran Periz, US Food and Drug Administration (FDA), USA

Dr Periz presents a study by researchers at the U.S. Food and Drug Administration (FDA) investigating the presence of aerobic and anaerobic bacterial contamination in commercial tattoo and permanent make-up (PMU) inks available on the U.S. market[36].

The presentation begins with a brief overview of tattoo-related health risks. While immunological reactions are among the most commonly reported complications, infectious complications also occur. Dr Periz notes that recent findings identify tattoo inks themselves as a potential source of infection, combined with insufficient hygiene during application and inadequate aftercare. As the tattooing process breaches the skin barrier, contaminated inks may introduce microorganisms into the dermal layer, increasing the risk of infection by anaerobic bacteria in the low-oxygen environment.

The study intended to assess the prevalence of aerobic and anaerobic microbial contaminants in commercial tattoo and PMU inks. A total of 75 products from 14 manufacturers were purchased and analysed using microbiological methods in accordance with the FDA Bacteriological Analytical Manual Chapter 23. Bacterial isolates were identified by 16S rRNA gene sequencing and subsequent database analysis.

Of the 75 ink samples analysed, 26 (35%) were contaminated. A total of 34 bacterial isolates were recovered and identified as belonging to 14 genera and 22 species; 19 isolates were identified as potentially pathogenic. *Staphylococcus* species were the most frequently detected, followed by *Sphingomonas*, *Cutibacterium*, *Stenotrophomonas*, *Pseudomonas* and *Bacillus* species. Eight additional genera were identified at lower frequencies.

Among the 22 identified bacterial species, 8 were classified as potentially pathogenic, including strains of *Staphylococcus saprophyticus*, *Staphylococcus epidermidis*, *Staphylococcus warneri*, *Staphylococcus xylosus*, *Cutibacterium acnes*, *Stenotrophomonas maltophilia*, *Nocardiopsis dassonvillei* and *Pseudomonas putida*.

The presentation further reports that PMU inks showed a higher contamination rate than tattoo inks. Contamination was detected in 17 of 35 PMU inks (49%) compared with 9 of 40 tattoo inks (22.5%).

The 34 bacterial isolates recovered from 26 contaminated ink samples were grouped based on their growth patterns across different culture conditions. Four strains of *Cutibacterium acnes*, an obligate anaerobe, and two strains of *Staphylococcus epidermidis*, facultative

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anaerobes, were isolated under anaerobic growth conditions. According to Dr Periz, this is the first report of obligate anaerobic *C. acnes* isolated from commercial PMU inks[35].

The relationship between sterility claims and bacterial contamination was also evaluated. No significant association was found between a sterility claim on the product label and the absence of bacterial contamination. Contamination was detected in 33% of inks labelled as sterile and in 38.5% of inks without a sterility claim. According to Dr Periz, this may indicate that sterilisation procedures are not always effective or that sterility claims may not accurately reflect the microbiological status of the product.

In conclusion, Dr Periz states that this is the first study to investigate both aerobic and anaerobic bacteria in commercial tattoo and PMU inks under aerobic and anaerobic conditions. The results show that unopened, sealed products may contain both aerobic and anaerobic bacteria, including potentially pathogenic microorganisms. The data emphasises the need to monitor tattoo and PMU inks for both bacterial groups and to improve quality control and sterilisation procedures.

A question from the audience addresses the cut off colony forming units (CFU, being the number of bacteria growing per g ink) from which on onwards the FDA or laboratories would normally regard an ink as unsafe. The FDA would consider inks with 100 CFU or more per gram ink as violation for tattoo inks [similar to leave-on cosmetics in the EU]. In addition, the presence of certain pathogenic microorganisms might be considered as violation despite low CFU counts.

Item 12 SAILOR – Development of analytical assays for tattoo removal products and metabolomic profiling of blood samples from human volunteers in conjunction with food supplement intake – Prof. Dr Marilena Carbone, University of Rome Tor Vergata, Italy

Dr Marilena Carbone introduces and explains the upcoming SAILOR project which is planned as collaboration between the University of Rome Tor Vergata and the University of Barcelona. It will be focussed on tattoo removal of red, black and green tattoos with q-switched nano- and picosecond lasers on human volunteers. The volunteers will be split up in two groups. One group will be given food supplements during the study while the others will only receive placebos, while body fluids (i.e., blood) will be collected at several timepoints before and after the tattoo removal session. The aim is to detect the removal fragments, oxidative and inflammatory processes, and metabolic parameters to correlate the body response to the produced fragments. Thus, the project stands on three pillars: the fragment analysis, the assessment of inflammatory reactions and oxidative stress, and the determination metabolic reactions. These require different approaches in regards to sample treatment and preparation. For example, regarding the use of anti-coagulant, the standard EDTA is not compatible for all three areas. Furthermore, the fragment detection poses a challenge. Especially for carbon black, as is it unclear whether it will accumulate in the sediment or the plasma fraction during the centrifugation step of the sample preparation or if it will dependent on the fragments' sizes or their physical-chemical properties. To

[35] Yoon *et al.*, 2024: https://doi.org/10.1128/aem.00276-24

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establish the analytical method surrogate substrates are planned to be used first and their complexity is to be increased stepwise until plasma is used. Overall different analytical approaches will be employed and validated to assess the carbon black using Raman, electrophoresis, thermal analysis, or through the determination of the oxidation of carbon black to benzene polycarboxylic acids.

For the fragment analysis in the plasma samples using HPLC-MS or GC-MS several unknowns have to be dealt with. Firstly, the identity of pigments used originally for the tattooing and, secondly, the fragmentation pattern during laser tattoo removal and possible metabolism of the fragments. Additionally, the protocol and sample treatment have to be established. Analysing the oxidative stress and inflammatory process markers will be conducted using already established essays and give indication whether the processes progress towards a chronic systemic inflammation. The metabolomics parameters will also include the inflammatory as well as the anti-oxidation and oxidation marker parameters. Additionally, NMR will be used to investigate amino acids, derivatives of amino acids, or specific proteins and identify correlations by using unsupervised power analysis. It is discussed that the fragment analysis will be very complex and the methods need to validated for the individual fragments. Unfortunately, there will be no information of the tattoo ink that were used for tattooing the volunteers in the past and no skin biopsies of the tattooed area for pigment identification can be done. It is further discussed that the fragmentation pattern during laser tattoo removal will be investigated in *in vitro* studies using for instance water as media.

The discussion following the presentation briefly touches questions of the analytical difficulties of detecting pigment fragments and potential metabolites. While the specific inks and pigments used during the previous tattooing of the volunteers may not be known, the identification of pigment fragments created by laser radiation for tattoo removal will be supported by developing an *in vitro*-based fragment database.

Item 13 Tattoo inks in practice under REACH: insights from a BVT survey of German tattoo artists – Stefanie Lamm, Bundesverband Tattoo e. V., Germany

Stefanie Lamm presents results from a survey conducted by the Bundesverband Tattoo e.V. (BVT), the German federal association for tattooing and tattoo professionals, among German tattoo artists between January and March 2025. The dataset comprised 727 respondents, all of whom were actively working as tattoo artists. In addition, selected observations from long-term studio documentation and feedback from BVT members were included.

More than half of respondents (53.4%) had worked in the tattoo industry for over ten years, while only 7.0% had been tattooing for three years or less. According to Ms. Lamm, this allows to compare working conditions before and after the implementation of the REACH restriction based on their own professional experience.

Key findings are highlighted: a majority of respondents (67.4%) rated the quality of currently available tattoo inks as worse than before REACH. Furthermore, 60.8% reported using fewer coloured inks than before or having abandoned colour work entirely. In addition, 59.8%

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rated the price-performance ratio of currently available inks as bad or very bad, while 56.1% stated that REACH had affected their work moderately to very strongly.

The survey results are presented in the context of the current economic situation of the tattoo sector. According to the survey, 66.4% of respondents rated the overall economic situation of the sector as bad or very bad, and 65.1% reported lower demand for tattoo services than before the COVID-19 pandemic and the introduction of REACH restriction. Economic uncertainty, competitive pressure, increasing material costs, and a lack of bookings were identified as the main challenges currently faced by tattoo artists. Ms. Lamm notes that these economic pressures may influence reporting behavior, as artists have less time and capacity to systematically document and report product-related issues.

Attitudes towards REACH compliance were also addressed. While 61.1% of respondents considered compliance with REACH requirements very important, 38.9% stated that compliance was less relevant than practical usability, or that they prioritised products that perform reliably under everyday working conditions. Ms. Lamm describes this as a tension between regulatory compliance, practical usability, and economic viability rather than a simple division between compliant and non-compliant actors.

Beyond the survey results, additional observations from tattoo practice are presented. These include repeated changes in declared formulations between production batches, including apparent variations in auxiliary substances and, in some cases, pigments and their relative proportions. In some cases, colour appearance was reported to differ between batches despite unchanged declarations. According to the presentation, such variability reduces predictability and makes it more difficult to achieve consistent tattoo results. Furthermore, some products were reported to have narrower storage temperature requirements and shorter shelf lives after opening.

In her concluding remarks, Ms. Lamm emphasises that practice-based observations can complement laboratory-generated and regulatory data when evaluating tattoo inks under real-life conditions.

Item 14 Polystone Chemical @ BfR Commission for Tattoo Inks – Dr Maximilian Bogner, Polystone Chemical GmbH, Germany

Dr Maximilian Bogner briefly introduces his professional background as a chemist working in regulatory affairs and presents Polystone Chemical GmbH. Polystone Chemical GmbH was founded in 1989, initially producing UV gels for nails, and has been active in the field of permanent make-up and tattoo inks since 2002. The company operates as a private-label manufacturer with sites in Germany and France.

The presentation discusses tattoo ink regulation and consumer safety from a manufacturer's perspective. Dr Bogner emphasises the importance of professional exchange within the BfR Commission for Tattoo Inks among representatives from research, medicine, analytics, regulatory authorities, and industry, with the shared goal of developing safer tattoo inks.

Several topics relevant to manufacturers and the work of BfR Commission are presented. These include toxicological conclusions on ingredients, promising alternatives to substances of concern, and the toxicological effects of ingredients. Dr Bogner also highlights trends,

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such as the increasing demand for tattoo removal procedures. In this context, he discusses the need to consider both removability and the longevity of tattoos by finding suitable pigments.

Manufacturing and quality standards are presented as another topic of interest for manufacturers. Dr Bogner refers to the German Tattoo Ink Ordinance (TätoV), which requires manufacturers to observe the principles of Good Manufacturing Practice (GMP).

The presentation further addresses conflicts between European and national legislation. Examples discussed include national labelling requirements for period after opening & best before date (Germany) and the sterilisation of tattoo inks. Dr Bogner notes that some countries require sterile tattoo inks (Spain and the Netherlands) and refers to gamma irradiation as a sterilisation method that may release formaldehyde in ink formulations. He suggests that recommendations developed by the Tattoo Commission could support a more harmonised approach to such issues.

Another topic concerns the notification of tattoo ink formulations. Dr Bogner presents the Poison Center Notification (PCN) system as a potential model for a harmonised European notification scheme for tattoo inks. Such a system could provide a standardised format for manufacturers and facilitate access to product information in emergency situations by Unique Formula Identifiers (UFI) on the ink labels.

Dr Bogner also discusses mandatory risk and hazard communication. He highlights the need for further standardisation of instructions for use under REACH, noting that manufacturers' information currently varies considerably. According to Dr Bogner, additional communication and guidance may improve studio hygiene and help prevent tattooing complications. The presentation also addresses the communication of product compliance and the use of claims such as “REACH compliant” on product labels. Here, discrepancies exist due to the non-compliance of such statements also leading to unfair competitive practices.

A comparison between tattoo ink regulation and cosmetic product regulation is also presented Dr. Bogner notes that tattoo ink regulation is largely based on hazard classifications, analytical limits, and blacklists, whereas cosmetic products are additionally subject to risk assessments, qualified assessors, and product-specific safety reports. He discusses the difference between hazard classification and risk assessment, noting that risk assessments also account for exposure. In this context, the role of the Scientific Committee on Consumer Safety in cosmetic product regulation is presented, and the possibility of a similar scientific assessment approach for tattoo inks is discussed. Dr Bogner further discusses the advantages and limitations of blacklist-based approaches and suggests that scientific review of ingredient restrictions could support future regulatory developments.

In the final part of the presentation, Dr Bogner discusses an example of a manufacturer applying safety measures beyond existing legal requirements. He suggests that selected aspects of such approaches could be considered in future regulatory developments.

In conclusion, Dr Bogner states that currently available tattoo inks are generally safe, although not entirely risk-free. Topics identified for future discussion include labelling, notification and documentation requirements, harmonisation of European and national legislation, and regulatory and assessment approaches.

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