



Programme & Abstracts

5th World Congress on Tattoo and Pigment Research

**24 - 26 August 2021
Amsterdam · The Netherlands**

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WCTP2021

5th World Congress of
Tattoo and Pigment Research



Organisation

WCTP 2021 Organizing Committee

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WCTP Congress Secretariat

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Welcome to WCTP 2021

Dear World Congress Participants, Dear ESTP members

This 5th congress in the Planetarium of Amsterdam is a window on the whole world. The previous European series of biannual congresses is this time and in future expanded and labelled a world congress framed as an open invitation to the entire planet. As part of this new strategy and in the shadow of the COVID-19 Pandemic, the 2021 congress includes speakers from far away presenting virtually. For the first time, we have attendees following the entire program of the congress over the internet. We use modern media to both speak to and listen to the whole world.

Previous congresses were organized in Copenhagen in Denmark 2013 with inauguration of the ESTP, Bruges in Belgium 2015, Regensburg in Germany 2017, and Bern in Switzerland 2019.

The WCTP2021 is an important scene where people working with tattoos can meet face-to-face and discuss, socialize and feel the vivid pulse of the tattoo world. People have backgrounds in research, ink manufacturing and tattoo practices, and in the regulatory business. In many countries, the tattoo industry faces a crossroad very difficult to pass exemplified by upfront strict regulation of tattoo inks in Europe under the EU REACH standard made for pure chemicals used in industry.

Besides the scientific programme, you will have the opportunity to network with colleagues and friends during the breaks and especially at the informal congress dinner. Finally, the congress would not be possible without your active participation and the economic support from sponsoring – so thank you very much!

Enjoy the congress and stay safe in the beautiful and dynamic city of Amsterdam!

On behalf of the congress organizers and the European Society of Tattoo and Pigment Research

Sebastiaan van der Bent, Congress President
Thijs Veenstra, Co-Host of Congress
Ines Schreiber, Co-Chairlady of ESTP
Jørgen Serup, Chairman of ESTP





Congress Themes

As you will see, the WCTP 2021 programme has two main themes:

- Upfront EU regulation of tattoo inks with profound change of the whole tattoo industry, success or failure with need for damage reduction
- The cutting edge of research on tattoos and tattooing including cosmetic tattoos

Other themes:

- Advances in experimental research, chemical characterization of inks and pigments and their fate in the body and effects on tissues and organs
- Epidemiology, clinical research and tattoo complications addressing tattoo allergy, potential carcinogenicity and other topics
- The many faces and aspects of tattooing; from decoration to permanent make-up, micropigmentation and microblading to medical use for corrective purposes
- Tattoo removal today and in the future, recent trends
- The voice of tattooists and PMU-artists
- The voice of the international tattoo ink manufacturers and resellers
- Corona, Tattooists' and Clients' safety in view of short-distance personal contact, with rehearsal of the new EU-CEN standard on tattoo hygiene



General information



Venue

Planetarium Meeting Center Amsterdam
Kromwijkdreef 11
1108 JA Amsterdam
The Netherlands

Certificate of attendance

Certificates of registered attendance can be downloaded from the congress website after the congress.

Lunch and coffee

Lunch and coffee are included in the registration fee. It is served in the foyer area.

Internet

Free Wi-Fi is available in the congress area. A Wi-Fi code can be collected at the registration desk.

Entitlements

Registration for the congress includes admission to the full congress programme, coffee breaks and lunch, programme and abstract book.

Information for speakers

Please bring your presentation on a USB stick. Please upload your presentation to the computer in the auditorium. An assistant will be present to help you if you have any problems. Please upload your presentation at least 30 minutes before your session starts.

Please note that we do not allow the use of personal laptops for presentations.

Information for poster presenters

Poster mounting:

Posters can be mounted 24 August from 12.00 when the registration starts. The Congress Secretariat will provide all necessary equipment to mount the posters.

Poster removal:

Posters can be removed after the last session on 26 August at 15.30.

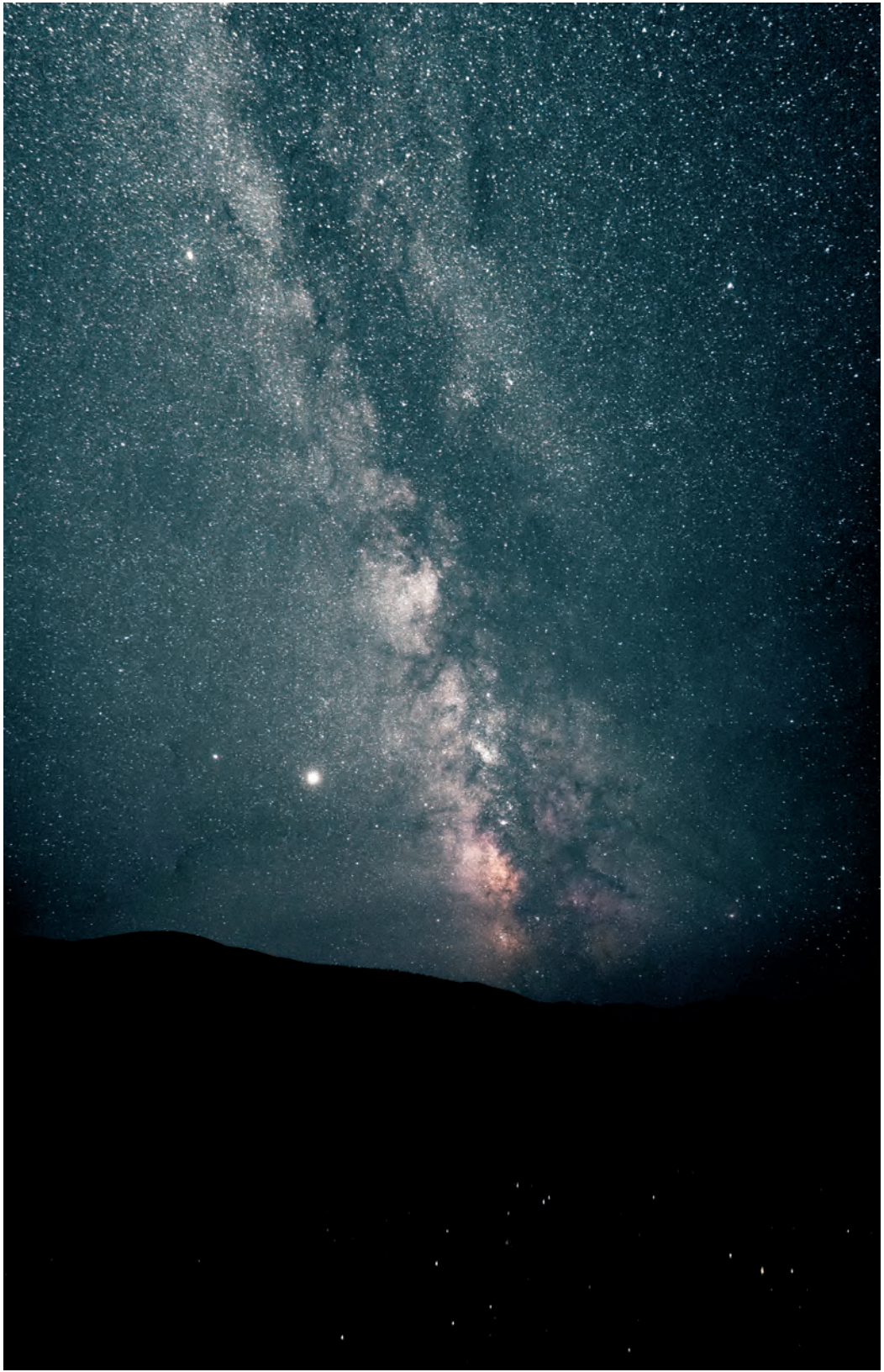
Visit the poster area:

Participants are encouraged to visit the poster area in the coffee and lunch breaks. Participants can attach their business card to the poster and expect to be contacted by the author during the congress or later as appropriate.

Social event

Congress dinner 25 August 18:30
Dinner tickets should be purchased in advance through the registration.

The congress dinner will take place at the congress venue (Planetarium). Participants will be served an informal BBQ Buffet with excellent wines, beer or soft drinks.



Sponsors

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Tuesday 24 August

12:00 - 13:00	Registration	
13:00 - 14:25	Session I: NEWS AND CURRENT CHALLENGES CHAIRS: Jørgen Serup, Sebastiaan van der Bent	
13:00-13:10		Opening - welcome from the conference chairs Sebastiaan van der Bent, Thijs Veenstra and Ines Schreiver
13:10-13:15		News from ESTP Jørgen Serup
13:15-13:40	01	Tattoo clinics around the world, the trends J. Serup & S. van der Bent, M. Leger & N. Kluger & W. Liszewski
13:40-13:55	02	The EU CEN hygiene guideline and the shift towards common standard Thijs Veenstra
13:55-14:10	03	How can tattooists tackle the challenge of the future and cope with the many new regulations? Andy Schmidt
14:10-14:25	04	Key aspects of vocational training for tattoo artists Olivier Laizé
14:25 - 14:55	Coffee break	
14:55 - 16:25	Session II: NEWS AND CURRENT CHALLENGES CHAIRS: Thijs Veenstra, Ines Schreiver	
14:55-15:10	05	Tattooing and the Corona pandemic: how do tattooists protect costumers and themselves against the virus? Dolores Murray
15:10-15:25	06	Tattoo Instruments and Regulation Andreas Pachten
15:25-15:35	07	The need for tattooist associations Gerrit Grootenhaar
15:35-15:45	08	The Australian Tattooists Guild Josh Roelink
15:45-15:55	09	Safe tattoo: an educational campaign in Poland Patrycja Rogowska
15:55-16:05	010	Swedish Tattoo Organization Rebecca Ryrberg (SRT)
16:05-16:15	011	Tattooing on the way to become a paramedical profession: adherence to rules clashing with artistic tradition Mel Dredd
16:15-16:25		Panel discussion: Views on the 2021 challenges tattooists are facing
16:25-16:45	Coffee break	
16:45 - 17:45	Session III: Arts & Skills of tattooing and PMU CHAIRS: Marie Leger, Walter Liszewski	
16:45-17:00	012	The Unique Aspects of Cover Up! Randy Engelhardt
17:00-17:15	013	Open our eyes: tattoo, prevention and risk in covid era? Rita Molinaro & Davide Allegrini
17:15-17:30	014	Scalp pigmentation, consideration for a growing phenomenon Ralph Moelker
17:30-17:45	015	Tattooing of the lips – what can go wrong Maya Ercegovac

Wednesday 25 August

8:30 - 09:15	Registration	
9:15-10:30	Session IV: Medical tattooing CHAIR: Paola Gateno, co-chair: Amelia Moreno	
9:15-9:30	016	Nipple- Areola reconstruction after breast cancer surgery: the importance of tattooist's empathy, insight and sympathy in the fulfillment of full emotional recovery Paola Gateno
9:30-9:45	017	Medical tattooing, challenges and risks Ellen Kuijper-Kuip and Nathalie Burger
9:45-10:00	018	Non-areola medical tattooing Brigitte Drost
10:00-10:15	019	Vitiligo: a challenge Amelia Moreno
10:15-10:30	020	Nipple-areolar complex tattooing for breast reconstruction: project, procedure, skills and patient satisfaction Antonia Pirrera
10:30 - 11:00	Coffee break	
11:00-12:00	Session V: REACH - Perspective of industry & artists CHARIS: Urs Hauri, Michael Dirks	
11:00-11:10	021	Which tattoo inks are used upfront the EU REACH registration: statistical benchmark based on Danish tattoo parlors and Inkbase™ registration of inks used in 39687 clients and 50604 sessions in 2018-1919 Jørgen Serup & Esben Hammershøj
11:10-11:20	022	Regulatory madness Jörn Elsenbruch
11:20-11:30	023	Are there realistic alternatives to blue and green pigments banned by EU REACH? Michael Dirks
11:30-11:40	024	Save the pigments-Initiative Erich Mähner
11:40-11:50	025	hmin(x)=1,2 mm - Understanding REACH and the consequences for manufacturers and importers Ralf Michael
11:50-12:00	026	Leading manufacturers' view on upcoming regulations on tattoo inks in EU and the US Sean Brown
12:00 - 13:00	Lunch break	
13:00-14:00	Session VI: REACH - Perspective of laboratories CHAIRS: Ines Schreiber, Wolfgang Bäumler	
13:00-13:15	027	Analytical results of regular tattoo inks sampled one year before REACH regulation Urs Hauri
13:15-13:30	028	Semi-quantitative analysis of organic pigments in tattoo inks with HPLC - work in progress Urs Hauri
13:30-13:45	029	REACH and analytics - a strategy to deal with the changes Veit Houben
13:45-14:00	030	Presentation on the functioning of the annexes of the Cosmetics Regulation and how they can be changed Gerald Renner, European Cosmetics
14:00 - 14:30	Coffee break	

14:30-16:30	Session VII: REACH - Perspective of legislative officials CHAIRS: Wolfgang Bäumlner, Jørgen Serup	
14:30-14:45	031	ECTP perspective of the REACH restriction, interventions, open questions Ines Schreiber
14:45-15:00	032	Risk Assessment of Tattoo Inks: Opportunities and Challenges Michael Giubudagian
15:00-15:15	033	Tattoo Pigments and Inks: Regulations and Challenges, Risks and Potential Complications Linda Katz, FDA
15:15-15:30	034	Color Additive Petition Process and Safety Assessments of Color Additives used in Tattoo Ink and Permanent Makeup in the US John Misock
15:30-15:45	035	Australia moves towards regulating cosmetic inks Tina Viney
15:45-16:30	Panel discussion: REACH, where to go from here? Moderator: Ines Schreiber	
18:30-22:00	Congress dinner at congress venue	

Thursday 26 August

8:30 - 09:00	Arrival	
9:00-10:15	Session VIII: RESEARCH: Late/Breaking Research CHAIR: Steffen Schubert, Co-Chair: Katrina Hutton Carlsen	
9:00-9:10	036	Encapsulation of azo- and xanthene-tattoo pigments in lipid microparticles: colorants photostabilization and retention by the particle matrix in excised porcine skin Scalia, Santo
9:10-9:20	037	Complementary imaging methods for the analysis of tattoo pigments in skin samples Carina Wolf
9:20-9:30	038	Comparative assessment of the long-term degradation of inorganic and mixed pigments (organic and inorganic) for permanent makeup (PMU) and microblading Andrea Martins
9:30-9:40	039	Visualization of in vivo tattoo particles using multiphoton tomography and fluorescence lifetime imaging Lyhnda Nguyen
9:40-9:50	040	Phototoxicity & 3D Skin Models Henrik Hering
9:50-10:10	041	Epidemiological studies on tattoo exposure, certain types of cancer and other health outcomes in the French and German national cohorts Milena Förster
10:15 - 10:45	Morning break	
10:45-12:00	Session IX: RESEARCH: Chemistry of tattoo inks CHAIR: Urs Hauri, Co-Chair: Ines Schreiber	
10:45-10:55	042	Preservatives in tattoo and PMU inks: Do the inks placed on the market comply with the new REACH restriction? Marco Famele
10:55-11:05	043	Simultaneous determination of 11 phthalates in tattoo and PMU inks by GC/MS as regulation (EU) 2020/2081 sets out Claudia Leoni
11:05-11:15	044	Inks for tattooing and microblading; difference, composition, dilution and mixing / or educational lecture on ink composition Michael Dirks
11:15-11:25	045	Analytical results of cheap inks from e-commerce stores Urs Hauri
11:25-11:35	046	Magnetic Inks: Responsible Iron Oxides Are Being Investigated Kasper Alsing and Jørgen Serup
11:35-11:45	047	A short-term human biokinetics study of soluble tattoo ink ingredients Susanne Kochs, BfR
11:45-11:55	048	Nano vs. Picosecond laser treatments of a green ink Marilena Carbone
12:00 - 13:00	Lunch break	
13.00-14.00	General Assembly ESTP (Members only)	

14:00-15:40	Session X: RESEARCH: TATTOO COMPLICATIONS CHAIR: Sebastiaan van der Bent, Co-Chair: Christa de Cuyper	
14:00-14:10	049	Overview of tattoo complications Sebastiaan van der Bent
14:10-14:20	050	Allergens in tattoo ink - first results of the IVDK patch test study Steffen Schubert
14:20-14:30	051	Tattoo complications seen in the Copenhagen tattoo clinic 2008-21: campaigns and impact on Danish national regulations Katrina Hutton Carlsen and Jørgen Serup
14:30-14:40	052	Relevant facts regarding complications in tattoos Jens Bergström
14:40-14:50	053	How frequent are tattoo complaints and complications according to published and unpublished data: the problem of measuring incidence and prevalence Jørgen Serup
14:50-15:00	054	Treatment of red tattoo reactions Sebastiaan van der Bent
15:00-15:10	055	Sarcoid granulomas in cosmetic tattoos and the association with systemic disease Grekova Ekaterina
15:10-15:20	056	Sarcoidosis and tattoo associated uveitis Nicolas Kluger
15:20-15:30	057	Tattoo-associated mycotic infections Ganiyat Adenike Adebajo
15:30-15:40	058	The Dermatologist's view on aftercare Christa deCuyper
15.40	Closing session	



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Join ESTP and support European Tattoo and Pigment Research

The most important aspect of becoming a member of ESTP is that you support the improvement and development of tattoo and pigment research in Europe.

Furthermore, a membership of ESTP will give you influence on this development. As an ESTP member you can vote for board members, and dependent on your membership category stand for election to the board.

How to apply for Membership

To apply for membership please go to the ESTP website; **estpresearch.org**, download the membership form, fill it in and send it by e-mail to the ESTP Secretariat: info@cap-partner.eu

On the ESTP website, you will also find more information about the society, it's activities and the latest news about tattoo complications, pigment research and other related topics.

Evaluations of new applicants will be undertaken by the ESTP board. Once your membership application has been evaluated you will be notified. If your application has been approved you will receive a link to follow for final subscription.

Benefits of your ESTP Membership

- You support the development and improvement of tattoo and pigment research in Europe
- Reduced congress fee at the annual congress
- Easy access to leading experts in the different fields of tattooing
- Free electronic subscription to the scientific journal DERMATOLOGY of Karger AG, Switzerland, official journal of ESTP with a special section for publications on tattoo and body art (J. Serup, Editor)
- Networking in Europe and worldwide on tattoo and pigment research



Oral Presentation Abstracts

[O1] TATTOO CLINICS AROUND THE WORLD, THE TRENDS: REPORT FROM BISPEBJERG UNIVERSITY HOSPITAL, THE TATTOO CLINIC, COPENHAGEN, DENMARK

Jørgen Serup¹

¹MD, Bispebjerg University Hospital, The Tattoo Clinic, 2400 Copenhagen NV, Denmark

Joergen.vedelskov.serup@regionh.dk

The Copenhagen tattoo clinic established in 2008 was the first clinic in the world specialized in tattoo complications. The clinic over the years received many serious adverse reactions. However, many mild complications particularly bacterial infections are treated by general practitioners. Mild complains such as sensitivity to sun are normally not seen by doctors.

Since the launch of the clinic the following trends have been noted:

Allergic reactions in red tattoos are declining, possibly as a results of public campaigns to avoid this colour due to higher risk of allergic sensitization

Papules and nodules in black tattoos e.g. granulomatous reactions with or without sarcoidosis in other organs (lung and eye) are clearly increasing, often with "rush phenomenon" and activation of granulomatous reaction in older hitherto tolerated tattoos

Bacterial infections may be declining as a result of improved hygiene in tattoo parlours

Cosmetic tattoo complications remain uncommon, however, increasing in prevalence along with increased popularity. The field is in rapid growth.

Trends in complications seem to follow increased public awareness about the risks of tattooing. New laws and many recent restrictions about tattooing have been launched in Denmark and stimulated public awareness. New Danish laws are briefly reviewed.

[O1] TATTOO CLINICS AROUND THE WORLD (THE NETHERLANDS): TATTOO CLINIC/TATTOO POLI ALRIJNE HOSPITAL LEIDEN

Sebastian van der Bent¹

¹Tattoo Clinic (Tattoo poli), Alrijne Ziekenhuis Leiden, Amsterdam, The Netherlands

In the Tattoo Clinic in the Netherlands (Tattoo poli, Alrijne Hospital Leiden) hundreds of patients with tattoo complications have been consulted. The Tattoo Clinic is currently regarded as a nationwide highly specialized referral center in The Netherlands. A great variety of complications in tattoos, including permanent makeup, is observed. These include allergic tattoo reactions, sarcoidosis, infections, manifestation of autoimmune dermatoses, blow-outs, scars and tattoo removal induced complications. Over the years, the clinical work at the Tattoo Clinic has been combined with medical research and several national and international collaborations have been established. The research focused on allergic red tattoo reactions and its clinical aspects, histopathology and treatment. Other research topics included tattoo related adverse events in sarcoidosis patients, tattoo associated uveitis and tattoo infections. All these studies finally resulted in a Phd thesis, with the aim of improving the safety of tattooing.* There is a strong and good collaboration with government organizations, media, and especially tattoo and permanent makeup artists. This is crucial in improving long term tattoo safety for clients.

* van der Bent SAS. Tattoo complications: Diagnosis and treatment. s.l.: s.n., 2021. 214 p. Available at: <https://research.vu.nl/en/publications/tattoo-complications-diagnosis-and-treatment>

[O2] THE EU CEN HYGIENE GUIDELINE AND THE SHIFT TOWARDS COMMON STANDARD

Thijs Veenstra¹

¹National Institute for Public Health and the Environment, Utrecht, Netherlands

After five years of intense work by many experts, the CEN standard EN 17169:2020, Tattooing - Safe and hygienic practice has been published. The path to a uniform level of safety in European tattoo studios is entering a new phase. What is to be done now?

Already at the very start of the creation of the standard in 2015, the inclusion of guidelines from both governmental and tattooist union origin illustrated the variety of standards and regulation in Europe. And still today, many standards are applied in many ways. Where in some countries authorities have established mandatory policy, in other countries tattooist unions have taken responsibility for safe practice of parlors. And more and more, vocational training of tattooists becomes common practice.

The CEN standard has potential to contribute to all of these strategies and policies. Containing guidance for practice as well as a detailed curriculum for training, it can be used to realize a comparable reality while applying different implementation strategies.

However, national standardization bodies must first adopt the standard and publish it nationally. Then, diffusion must take place within the countries. Standards are, although not free, available to anyone. Implementation however depends on the willingness and effort of national parties involved. It is crucial that leading parties in many countries apply the content standard in their policy and practice.

If this goal is reached in the upcoming years, clients as well as tattooists will benefit. Safe practice will be easier to recognize. Working abroad, at conventions, will become less complicated as uniform rules apply.

This situation would clear the way for new ambition. Mutual recognition of training certificates in European countries would certainly be one of them. And, who knows, this European standard may be the beginning of a version to be applied worldwide.

[O3] HOW CAN TATTOOISTS TACKLE THE CHALLENGE OF THE FUTURE AND COPE WITH THE MANY NEW REGULATIONS?

Andy Schmidt¹

¹Body Electric Tattoo Studio, Germany/Switzerland

The tattoo hygiene has always been a topic that the professional tattoo artists as well as the national and international organisations of professional artists took care of. The original paper of the new DIN EN17169 was a self-imposed hygiene standard of the German tattoo association D.O.T. If there's anybody saying that it's all new what the new European standard brought, it is nonsense. What the tattoo artist has to face, is a, let's say it positive...a paper that is really hard to come by as it is written in a typical „scientific“ way. But it's all in there, way better than it used to be. It's a question of some hours of reading and comparing and you're done.

For sure the Corona virus had some more challenges for the tattoo artists. Having a standard like the DIN EN17169 one might have expected that it should not be a problem at all to keep on working for the tattoo industry. Seeing that hairdressers with an almost not existing hygiene concept are allowed to work and the tattoo scene had to close the shops was frustrating as can be! It showed that all the participants, industry, science, health authorities, politicians didn't care too much about what happened to this industry, if they did care at all.

Being kind of neglected by all partners, it is hard for an artist to believe in the system, honestly. Over 120.000,-€ were invested by the D.O.T. and it didn't help at all.

Nevertheless, the task for the future will be to communicate, the tattoo artist/industry with health authorities, governments, REACH etc. etc. The artists are prepared to follow the self-imposed rules, but the other side must be prepared to talk and also make compromises. (Talking about pigments especially).

The tattoo industry must be strengthened and involved in the process of teaching, learning and education, as it is understandable that organizing an industry is not the business of authorities, it is their business to give help to the industry itself. But it must be a matter of give and take, the tattoo industry has already given a lot without getting something back....

[O4] KEY ASPECTS OF VOCATIONAL TRAINING FOR TATTOO ARTISTS

Olivier Laizé¹

¹Hygiene & Safety trainer - President of French délégation for EN17169 « Tattooing - Safe and hygienic practice », France

Since mid 2000's, thousands of tattoo artists followed a mandatory vocational training, as required by an increasing number of countries throughout the world. As a purpose of safety for both clients and tattoo artists, a vocational course based on infectious risks controls is more and more enforced as a legal requirement. As such, they are described today as the only "tattooing license" to officially achieve a professional status for tattooers.

On the field, safety trainings still show variations in format from a country to another. Harmonized such as in Europe in the EN17169 norm, and as they become today a standard on a worldwide scale, their efficiency relies on 3 major aspects:

- A well-balanced program between medical courses and tattooing techniques.
- The quality and experience of the trainer, being knowledgeable in both categories.
- Proper national regulations and adaptive enforcement processes for their authorities.

I'll present today the key aspects of vocational safety trainings for tattooing and a descriptive presentation of their technical requirements.

[O5] TATTOOING AND THE CORONA PANDEMIC: HOW DO TATTOOISTS PROTECT CUSTOMERS AND THEMSELVES AGAINST THE VIRUS?

Dolores Murray¹

¹Association of Body Modification Artists in Ireland (ABMAI)
Wildcat Ink Tattoo Studios-Dublin, Ireland

As there are no specific legislative texts relating to tattooing, General Health and Safety legislation, Work Safely Protocol - COVID-19 National Protocol for Employers and Workers published by the government of Ireland and NSAI standard I.S. EN 17169:2020&LC:2020 has been taken into consideration in the writing of this document.

This document will be revised and edited accordingly in line with any further recommendations set out by the Irish Government.

As Covid-19 tightened its grip on the world last year, industries that required physical closeness, including tattooing services were closed down to help to prevent the spread of the virus. Most countries have gone through several cycles of lock down and reopening. Social distancing became a way of life.

The recovery stage is now underway as society reopens and more people receive their COVID-19 vaccines. There has never been higher demand for tattooing services. Over the course of the pandemic tattooing services had changed. For the moment, the days of walk-in visits or in-person consultations are gone. Clients are no longer allowed to bring family members or friends into the studios for support.

But we should recognize that there are risks of infection associated with tattooing services in the context of the COVID-19 pandemic and adopt protocols to minimize the risks to the clients and the tattooist.

Due to the nature of the tattooing, most tattoo artists were already extremely diligent about cleaning and sanitizing workspaces between clients to prevent cross-contamination, using P.P.E. and client tracing. But an additional layer of safety precautions is required to adapt to the new challenges presented by COVID-19

[O6] PRESENTATION “TATTOO INSTRUMENTS AND REGULATION” AT THE UPCOMING WCTP 2021

Dr. Andreas Pachten ¹

¹Director QM/ Regulatory and PRRC at MT.DERM GmbH

Tattooing has a multicultural history and has been practiced across the globe since ancient times. However, complexity of tattoos as well as knowledge about associated risks have increased dramatically since historic times. Therefore, national and international regulatory requirements on tattoo machines and instruments are constantly increasing. The lecture explains the international regulative framework on equipment for medical and cosmetic tattooing (body tattooing, permanent makeup (PMU), and microblading). From a global perspective, regulation of equipment for cosmetic (decorative) tattooing is inconsistent and mainly based on a diversity of national laws. In contrast, regulation of equipment for medical tattooing is subjected to the internationally harmonized medical devices regulation. Even though, dermal invasiveness and biological mode of action are identical for cosmetic and medical tattooing, it is the intended use of the treatment which makes the difference, resulting in two different worlds of divergent regulatory framework.

[O7] THE NEED FOR TATTOOIST ASSOCIATIONS

Gerrit Grootenhaar ¹

¹Tattoo shop owner, vice-chairman NBTK

We, as tattoo artists, have left the regulation of the industry in the hands of the Dutch government since 2007. However, we see a huge rise in tattoo artists and tattoo shops in the Netherlands, where both the old school way of regulating (apprenticeship) and the current way (regulation) no longer works sufficiently. The industry is becoming polluted, which has a major impact on the image of the industry and public health, not to mention the aesthetic aspect.

Thus, the NBTK is in favor of regulation and legislation in consultation with the industry. New rules must be broadly supported by the industry. Working together means having respect for all aspects of the craft and the people within the industry. Artists, suppliers, manufacturers and shop owners must have a voice in order to collaborate with the government and other parties. The NBTK gives them that voice.

Gerrit has put a lot of effort into building and maintaining contacts within the industry and with the government. These forces have been joined with the NBTK. Which, during the most recent Covid crisis, has already paid off.

[O9] SAFE TATTOO: AN EDUCATIONAL CAMPAIGN IN POLAND

Patrycja Rogowska¹, Aneta Szczerkowska-Dobosz¹, Roman Nowicki¹

¹Medical University of Gdańsk

It is estimated that about 15-25% of the European population has at least one tattoo or more. According to the most recent available study about Poland, the CBOS (Polish Public Opinion Research Center) analysis published in 2017, this percentage was equal to 8%. Very limited literature can be found about the frequency and clinical manifestations of tattoo reactions in central and eastern European countries, where the popularity of tattooing is growing. Currently, Poland has not officially adopted any specific tattoo or permanent make-up regulations concerning the usage of pigments nor has set precise requirements regulating the profession of tattoo artists. In the Department of Dermatology, Venereology and Allergology of the Medical University of Gdańsk, we created a center for diagnosing and treating tattoo complications; we also run education campaigns on social media, maintain a dedicated website and hold direct meetings addressed to tattoo artists and future tattoo owners. We would like to present our achievements in increasing social awareness and strengthening cooperation between tattooists and dermatologists in our country.

[O10] SWEDISH TATTOO ORGANIZATION

Rebecca Ryrberg¹, Inge Norlin²

¹SRT (Sweden's registered tattooists), Kristinehamn, Sweden

²SRT (Sweden's Registered Tattooists), Nyköping, Sweden

Aim We aim to inspire other tattoo associations with the work our association has done in Sweden since we started in 2007.

Methods We have worked with authorities, not against. We try to be one step ahead and have a serious approach towards the media and our members.

Results Swedish tattooists are now able to get official journeyman certificates and mastership diplomas in our trade. We also have our own insurance that only members are allowed to get and we have written a book to help guide the teacher and apprentice through the education.

Conclusions SRT have put in a lot of time and energy creating an understanding and cooperation regarding related governmental issues. SRTs main objectives have always been to further the understanding and importance of a safe way of practice. Our model has been very beneficial for both the practitioners, the general health and the consumers.

Sweden's Registered Tattooists have come a long way in the work to become a force to be reckoned with.

[O11] TATTOOING ON THE WAY TO BECOME A PARAMEDICAL PROFESSION: ADHERENCE TO RULES CLASHING WITH ARTISTIC TRADITION

Mel Dredd, Copenhagen, Denmark

The idea behind this subject is to have a look at the approach to tattooing from a less technical angle and more of an ethical view. If we consider all the new regulations coming to the tattooing profession, we notice a trend towards treating it more as a paramedical profession than what it is now, and as tattooists, and medical professionals working in this field, we must adjust accordingly our behavior, clients treatment and follow up. As the medical profession's credo promises, we should do no harm, even at the cost of a little pain.

In this subject I propose an idea: what if we were more than just tattooists, but actual paramedical professionals, therefore able to help our clients with more than a design on their skin? What do we need to learn to make this happen? How can we be better? How can doctors and tattooists work together to preserve both the rich history of tattooing, and ensure a safe and scientifically sound experience to our clients?

[O13] OPEN OUR EYES: TATTOO, PREVENTION AND RISK IN COVID ERA?

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The systemic ophthalmological and pathological anamnesis has a fundamental importance. Auto-immune disorders such as Sjogren's Syndrome or metabolic disorders such as diabetes can cause eyes tearing changes.

Regarding ocular pathologies, treatment with IOP therapy for glaucoma is one of the main causes of conjunctival hyperaemia and dry eye syndrome.

Eyelashes growth and eyelid changes need to be included in the causes responsible for dry eye syndrome and corneal lesions.

In all these cases, an ophthalmological evaluation is required before any aesthetic treatment.

Therefore, the collaboration between doctor and professional is important, throughout a collaborative synergy to safeguard the customer with the application of particular technical attention in the executive practice to preserve eyes health state, preventing irritation or other complication, sometimes even serious.

It should be emphasized that for tattoos in the periocular area, the professionalism and knowledge of the executor must be extensive and precise.

In addition, the Covid 19 pandemic highlighted the importance of hygiene protocols and contagion connected risks between customer and operators. The eye as a sensitive organ to be protected and preserved.

[O14] SCALP PIGMENTATION, CONSIDERATION FOR A GROWING PHENOMENON

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¹Tattoo Bob & TB Medical, Germany

Baldness, alopecia, thin hair or suffering from (a lot of) hair loss has a huge impact in everyday life on men and women. People have always been looking for ways to deal with this and in recent years it was mainly hair transplantation that predominated the hair solutions spectrum. That has now changed with scalp pigmentation. Micro Hair Pigmentation (MHP) or scalp pigmentation is NOT a surgical procedure but is in fact a “stubble tattoo”. It creates the image of a shaved hairstyle or will camouflage hair loss or scars from earlier hair transplantation treatments.

We, at Tattoo Bob, believe that the MHP technique which is used by most clinics in the Netherlands and the rest of the world, does not provide the ultimate result. Therefore, we have developed a special MHP technique at Tattoo Bob; the so-called Ultra Fine Technique (UFT). With specially made needles & machines we can tattoo real-life stubbles that give an even more realistic look, close by. With this special MHP technique we distinguish ourselves from our competitors and we deliver the best result against baldness or hair loss.

In this presentation, I will provide some background on Tattoo Bob, scalp pigmentation, and explain how we can achieve convincing stubbles with our special method and the ink that we use. I will also briefly explain how the use of ink, different skin types and certain skin problems can affect the healing process, and what qualifies a good stubble tattoo.

[O15] TATTOOING OF THE LIPS – WHAT CAN GO WRONG

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¹Holo Academy, Melbourne Australia

Aim Symmetrically shaped, fuller lips align to attractive qualities. These principles serve as the biological indicators of a woman’s health, attraction and fertility. Cosmetic tattooing, also known as permanent make or micropigmentation is performed as an enduring aesthetic replacement of conventional make-up as well as or for remedial purposes. Cosmetic lip tattoo proves to produce a natural and realistic appearance in comparison to conventional lipsticks especially when it is applied properly by an experienced cosmetic tattoo artist using updated techniques. Complications with cosmetic tattooing procedure are common, including infections and allergic reactions.

Introduction Lip tattooing is a cosmetic tattooing modality, an aesthetic tattoo art process used for beautification or remedial enhancement of lip mucosa. This long-lasting procedure embeds pigment (ink) when performed properly, right below the dermal labial membrane. Resulting in enhancing the natural beauty shape or to add decorative pigment to the skin lip areas. The lip tattoo procedure’s main purpose is to give shape, balance, symmetry, camouflage or definition that naturally lacked or was diminished with time. Currently more natural looking results are desired rather than the outdated pigmentation alternative finish of conventional make up.

Risks and complications Alongside infections and allergic reactions some other complications commonly seen include mild to severe scarring, pigment fading, blurring and dissatisfaction with colour and shape outcomes. With dissatisfied results common solutions for the removal of unwanted cosmetic tattoos include lasers, saline and acid-based suspensions, though complications due to the removal treatment are common and extreme such as titanium dioxide resulting in reversal darkening and severe scarring. Incorrect aftercare follow-ups can result in temporary or permanent infections and reactions.

[O17] MEDICAL TATTOOING, CHALLENGES AND RISKS

Ellen Kuijper-Kuip and Nathalie Burger

Materials and Methods 16 years of personal hands on experience in cosmetic tattooing application and educational delivery is used to update the audience with commonly seen complications within the cosmetic tattoo settings.

Conclusion With upcoming new pigment regulations in place, technical updates and research on gentler, less invasive cosmetic tattoo applications and cutting-edge machinery and auxiliary developments, strict occupational and hygiene measures and prolonged educational deliveries that are readily available online and face to face will help in preventing and managing complications associated with lip tattooing.

In the early 1990s, physicians started to use tattoos for medical purposes, to hide scars, trauma, skin diseases like alopecia, wine stains and vitiligo, or surgery on eyebrows or lips. Not much later nipple/areola reconstruction followed using tattoos. Medical tattooing is all about restoring nature instead of enhancing or beautification. In performing medical tattoos, you have to take in consideration that skin reactions may be worse and healing processes can be challenging.

In the literature, various complications are described after the application of cosmetic tattoos. Skin infections, HIV infection and tuberculosis are reported, but also allergic reactions, formation of granuloma and even keloid. Ex-(breast) cancer patients for example can be vulnerable, their skin can be thin and damaged after radiation and often these patients have lymph nodes removed. Skin- and edema-therapists are medically trained and are especially aware of possible skin reactions and infections. For that a special dressing code was developed as after treatment. With over 30 years of experience between them, authors performed many medical tattoos like areolas, scars and more. No infections were reported. In n=12 the dressing had to be changed once due to copious exudate production. One patient with a known history of psoriasis had a flare under the dressing. The patients reported the dressing regime to be comfortable and were allowed to shower with the dressing in place. In this presentation we will show various cases of medical tattooing.

[O19] VITILIGO: A CHALLENGE

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Medical tattooing procedures in vitiligo consist in repigmenting the skin to make the white patches less

Noticeable. Though it is not always easy to treat vitiligo, there is much to be gained by clearly understanding the diagnosis, the future implications, treatment options and their outcomes.

Abstract: Vitiligo is an acquired depigmenting disorder that affects 0.5% to 2% of the world population, characterized by depigmenting disorder of the skin: clinically by totally white “spots” on the skin and microscopically with total absence of melanocytes in the epidermis.

The change in appearance caused by vitiligo can affect a person’s emotional and psychological wellbeing and may cause them to alter their lifestyle.

The aim of the medical tattooing procedure in vitiligo is to repigment the skin to make the white patches less noticeable.

Methods: A descriptive and comparative study of data obtained from 30 patients with non-segmental generalize vitiligo subtype. Micropigmentation procedures with different types of needles and techniques were performed on these patients.

Results: the average age of patients requiring the procedure is between 23 and 46 years. We found that 78.4% of patients obtained satisfactory results, performing an average of 3 to 4 sessions

Conclusions: -Though it is not always easy to treat vitiligo, there is much to be gained by clearly understanding the diagnosis, the future implications, treatment options and their outcome.

[O20] NIPPLE-AREOLAR COMPLEX TATTOOING FOR BREAST RECONSTRUCTION: PROJECT, PROCEDURE, SKILLS AND PATIENT SATISFACTION

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⁴ LILT Treviso, Treviso, Italy

Aim: Medical tattooing is now widely performed as the final step in nipple-areolar complex (NAC) reconstruction, as well as being an adjuvant procedure to improve colour mismatch in patients treated for breast cancer. This study describes specific application of the technique, to complement breast reconstruction at hospital of Northern Italy.

The aims of the project were to: design a specific procedure in cooperation with Italian Anti-Cancer League (LILT); ensure the complete safety of the patient, assess the usefulness of NAC dermopigmentation for patients; and measure the degree of patient satisfaction with the results of the treatment received.

Methods: From 2010 to 2016, 169 patients underwent dermopigmentation treatments. Tattooing was evaluated after the completion of reconstructive surgery; the hospital Breast Centre laid down a detailed procedure that established when to intervene. Patients were selected by the hospital’s plastic and breast surgeons. An expert medical tattooist performed the treatments, following a specific procedure to ensure safety. A sterile, disposable surgical set was used.

Results: Of 169 patients treated in 309 treatment sessions, no serious complications were reported, with only three cases seen of minor complications. Patients expressed high level of satisfaction with the aesthetic results achieved (90%).

Conclusions: NAC tattooing remains a simple and safe procedure, providing benefits to the patients and to the hospital. It is a nonsurgical technique that reduces hospital time for patients, which translates into a saving both for society and for the health system itself.

[O21] WHICH TATTOO INKS ARE USED UPFRONT THE EU REACH REGISTRATION: STATISTICAL BENCHMARK BASED ON DANISH TATTOO PARLORS AND INKBASE™ REGISTRATION OF INKS USED IN 39687 CLIENTS AND 50604 SESSIONS IN 2018-2019

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²Miks Tattoo and InkBase™, Copenhagen, Denmark

Background/aim: The use of safe tattoo ink products is important for client's safety. New restrictions on safer inks of postulated less risk are coming up in Europe, US and other countries. First result of a large-scale tattooist-operated electronic system for ink registration is presented.

Method: A local data base in the studios refers to a central data base. Clients and sessions are registered. Tattoo ink bottles are barcode labelled. Product brand, name, manufacturer, distributor, color index (CI), and Lot/batch number are systematically registered. These routine registrations are required by Danish law.

Results: 108 tattoo studios in Denmark reported to the central InkBase™ system. Data from March 2018 through 2019 were collected. 39687 clients were tattooed in 50604 sessions, using colors from in total 109720 ink bottles (some reused). Details on brands and labelled pigments are presented. Black and titanium oxide followed by red were the commonest pigments. Pigment blue-15 was the only blue pigment in use, having no registered alternative. 10833 of bottles were CI-labelled identifying the pigment. 98.1% of inks were manufactured in USA. The range of pigments and brands are presented.

Findings referenced to surveillance systems: 126 (0.32%) clients were tattooed with 32 tattoo inks (0.029% of ink bottles) notified in the EU rapid alert system (RAPEX) due to any kind of concern being independent or dependent on the pigment. Only one ink measured in use, with bacterial contamination, had been disclaimed by the Food and Drug Administration (FDA), USA.

Discussion/Conclusion: The registration system allows large scale real-time surveillance of tattoo inks used in studios. Tracing labelled potentially or known unsafe pigments and brands down to the individual client is possible. The system can rapidly communicate observed inks of risk to tattooists and authorities, and authority alerts back to tattooists with tracing of those clients who were exposed. However, authority alerts and warnings are with the already established systems obviously dysfunctional and cannot depict clinical events reliably when referenced to present knowledge about the prevalence and diagnostic spectrum of clinical adverse reactions.

[O22] REGULATORY MADNESS

Jörn Elsenbruch¹

¹*Magic Moon Tattooing GmbH, Germany*

One can perhaps still understand the intention of the various laws and regulations, but none of the desired effects will occur and the tattoo industry will react completely different from expectations. A well-functioning infrastructure with a more than acceptable level of security will be destroyed, and an entire industry will be driven back underground. I will present my perspective as a tattoo artist, supplier and petitioner with 151,679 supporters in Germany.

[O23] ARE THERE REALISTIC ALTERNATIVES TO BLUE AND GREEN PIGMENTS BANNED BY EU REACH?

Michael Dirks

Rien ne va plus. The decisions have been made and the ECHA restriction proposal is already being implemented. Blue 15 and Green 36 are prohibited. Now that the die has been cast, the question arises whether there are alternative pigments to the prohibited ones or not.

[O24] SAVE THE PIGMENTS-INITIATIVE

Erich Mähner¹

¹Deputy Guild Master of the Vienna Chamber of Commerce, Austria

European Petition No. 1072/2020, submitted by Erich Mähner and Dipl. Ing. (FH) Michael Dirks, for the preservation of the two pigments Blue 15:3 & Green 7 in Regulation (EC) No. 1907/2006 (REACH). As is well known, on 23.03.2021 the hearing of petition no. 1072/2020) took place in the EU Petitions Committee. The result of the hearing was that the EU Petitions Committee decided to keep the petition open.

In addition, the Petitions Committee decided to refer the petition to the European Parliament's Committee on the Environment, Public Health and Food Safety.

- Why a European Petition?
- Status quo of the petition
- The next steps of the petitioners
- What is the aim of the petition?

[O25] $HMIN(X)=1,2\text{ MM}$ - UNDERSTANDING REACH AND THE CONSEQUENCES FOR MANUFACTURERS AND IMPORTERS

Ralf Michael¹

¹TIME – Tattoo Ink, European Manufacturer

My lecture shows the complexity of REACH regulations, consisting of the main Regulation (EC) No 1907/2006, the CLP Regulation with additional demands and the Biocide Product Regulation. I want to demonstrate step by step, how a REACH assessment for tattoo inks is made. It points out its main difficulty: to reduce a mixture in its basic ingredients. Therefore, a secondary problem occurs if mixtures in mixtures are used.

Furthermore, I'd like to explain necessary steps, how a product is placed on the market according to current regulations.

I would like to guide the audience through the process of REACH assessment, including placing on market, by using practical examples.



[O26] LEADING MANUFACTURERS' VIEW ON UPCOMING REGULATIONS ON TATTOO INKS IN E.U. AND THE U.S.

Sean Brown¹

¹General Manager, Eternal Ink

This presentation will take a detailed look at leading manufacturers view on upcoming Tattoo Ink regulations. We will explore current regulations and discuss the ideologies behind them and how they have influenced the upcoming ones.

You will get to experience these views from the eyes of restorative tattoo artist Sean Brown. Sean is the current General Manager of Eternal Ink, LLC. He has a background in pre-hospital emergency medicine, occupational safety and health and environmental health. He has been tattooing since 1999 and for the last decade has focused on medical applications of tattoos. He has lobbied United States Congress to educate law makers on perspectives of industry experts over proposed legislation. Sean is passionate about closing the knowledge gap between physicians, scientist, industry professionals, law makers and regulators to ensure tattooing is safely enjoyed for generations to come.

Sean will share and explain steps taken by manufacturers to ensure safety and to assist in proposed regulations. He will discuss multiple points of view and what the industry and tradespeople are doing to keep tattooing safe and to maintain integrity of the craft.

During this presentation you will have a unique opportunity to learn the perspective of multiple manufacturers who fiercely compete within the industry but who have banned together to share a cohesive and unified voice.

We will discuss:

Why have these upcoming regulations been developed?

What are the consequences should they be enforced?

What are Regulatory Agencies doing to involve Industry Experts?

What are the responsibilities of the agencies, industry, and the consumer?

[O27] ANALYTICAL RESULTS OF REGULAR TATTOO INKS SAMPLED ONE YEAR BEFORE REACH REGULATION

Urs Hauri¹

¹Gesundheitsdepartement Basel-Stadt, Kantonales Laboratorium, Switzerland

Aim: Current requirements for colorants in tattoo inks are based on negative lists. The REACH regulation sets limits for these and new substances. This investigation should reveal how well this regulation was met at the time of publication of the new requirements and give some clues for producers and legislators alike to improve products and legislation.

Methods: Twenty tattoo inks of ten brands were bought in fall 2020. Samples were analysed for preservatives, pigments and contaminants (nitrosamines, polyaromatic hydrocarbons, primary aromatic amines, formaldehyde and many others).

Results: The composition of all investigated inks was non-compliant with the new REACH regulation. Every ink contained between two and seven substances above the legal limits:

Forbidden pigments (70%), Acetaldehyde (>65%, Limit of quantitation (LOQ): 2 mg/kg), Isopropyl alcohol (50% according to declaration), Benzisothiazolinone (40%), Diethanolamine (>35%, LOQ: 10 mg/kg), Formaldehyde (>30%, LOQ: of the used method 3 mg/kg), o-Toluidine (25%), Phenoxyethanol (25%), Benzoic acid (15%), Benz(a)pyrene (10%), Methylisothiazolinone (10%), N-Methylpyrrolidone (10%), Phenol (5%).

Conclusion: REACH is a much higher barrier for tattoo ink producers than was ResAP(2008). This was expected. While the composition of 35% of the investigated samples was judged compliant with the Swiss legislation, no inks were compliant with REACH. Producers will have problems to resolve all issues until REACH gets into force. Surely, pigments and solvents can be adapted and aromatic amines and polyaromatic hydrocarbons avoided by choosing the right pigments. However, some substances like Acetaldehyde, Formaldehyde, Diethanolamine, Benzoic acid, Isopropyl alcohol or Phenoxyethanol can hardly be avoided completely or might be useful ingredients and should therefore be evaluated toxicologically and specific limits set as was done for other substances like aromatic amines or methanol.

[O28] SEMI-QUANTITATIVE ANALYSIS OF ORGANIC PIGMENTS IN TATTOO INKS WITH HPLC - WORK IN PROGRESS

Urs Hauri¹

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Aim: Qualitative methods have been successfully used in our laboratory to identify forbidden pigments in tattoo inks. REACH regulation has now set legal limits for pigments which demands quantitative methods for the supervision.

Methods: Samples are extracted with different solvents depending on the result of the screening methods. The suspensions are diluted and re-extracted until clear solutions result. Extracts are then analysed with at least two different HPLC/DAD methods.

Results: Mono-azo-pigments like C.I. 11741, 11767, 12315 or 12477 are extracted with Dimethylformamide and quantified with the same HPLC method that is also used for the forbidden dyes. Other regulated pigments are more difficult to deal with. For extraction, chloronaphthalene (e.g. C.I. 21095, 21110, 51319 or 74160) or N-Methylpyrrolidone (NMP; 73915) are used. Analysis is performed with RP-HPLC methods using NMP at elevated temperature. For some of these pigments the solubility in the solvent and/or in the eluent and thus the linear range is very limited. Method validation still needs to show the reliability of the results.

Conclusion: A major obstacle is the lack of quantitative references for most pigments. Without such references, analytical methods are at best semi-quantitative. Apart from that, the quantitative determination of most mono-azo-pigments is possible and there are or will be solutions for other pigments, maybe with other methods like e.g. LC/MS where a higher dilution is possible due to higher sensitivity. Still, the need for quantitative references, development, validation and testing requires a much higher effort than before without an appropriate benefit.

[O29] REACH AND ANALYTICS - A STRATEGY TO DEAL WITH THE CHANGES

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Tattoo- and PMU-colours are now regulated via Reach (Regulation 1272/2008). Compared to the ResAP(2008)¹, new links to the CLP regulation (1272/2008) are established. Simultaneously, the links to the cosmetics regulation (1223/2009) are still valid. The impact of these links for analytical services is tremendous. The examples of isopropyl alcohol, formaldehyde and primary aromatic amines thoroughly demonstrate the resulting impacts.

- Isopropyl alcohol
 - widely used in tattoo and PMU inks (formerly)
 - widely used in other applications (still)
 - Example how useful and harmless substances are restricted.
- Formaldehyde
 - banned as being carcinogenic with 0.5 ppm
 - Example how the respective limit can be its own challenge.
- Primary aromatic amines
 - restricted as free amines but three of them are not restricted as “soluble”
 - Example how the concept that one analytical group has one testing method is jeopardised.

The combination of these examples and impacts can easily become a never-ending analytical narrative. A new and smart approach in handling this analytical dilemma is necessary. When using the advantages of Reach, many sources of impurities can be identified, and unnecessary testing can be avoided. Combining Reach with an internal database from various screening methods reduces ‘surprises’ during testing and offers a stable and calculable testing method. A start has been made by bringing tattoo testing to the future and providing necessary safety to ink-producers and artists alike, even in the face of a Reach regulation that is vividly discussed.

[O30] PRESENTATION ON THE FUNCTIONING OF THE ANNEXES OF THE COSMETICS REGULATION AND HOW THEY CAN BE CHANGED

Gerald Renner¹

¹European Cosmetics

The EU approach on ingredient regulation arises from the principle of 'Responsible Person' and safety assessment. The choice of safe ingredients and use levels is in the primary responsibility of the Responsible Person (advised by his safety assessor, and subject to in-market control by the national authorities). For some classes of substances, however, the legislator has identified the need to introduce EU-harmonised restrictions. This includes a positive list of colouring agents. The process for modifying restrictions or adding new cosmetic ingredients to a positive list is the following:

- Call for safety data by the EU Commission or request for addition of a material to a positive list by an industry applicant
- Preparation by industry of a complete toxicological dossier and safety assessment (typically done in a consortium managed by Cosmetics Europe)
- Submission to the European Commission (DG GROW)
- Mandate for dossier evaluation to the Scientific Committee for Consumer Safety (SCCS)
- SCCS evaluation and publication of preliminary opinion for public comments
- SCCS review of comments and transmission of final opinion to the Commission (DG GROW)
- DG GROW proposal for change to the respective Annex
- Risk management discussion at the Cosmetic Products Working Group (EU Commission, Member States, Industry and consumer associations)
- Refined proposal voted by the Member States Standing Committee
- WTO consultation of the draft and internal approval procedure in the Commission
- 3-month scrutiny period for the European Parliament
- Publication in the Official Journal of the European Communities (OJEC) with appropriate transition times.

[O31] ESTP PERSPECTIVE OF THE REACH RESTRICTION: INTERVENTIONS AND OPEN QUESTIONS

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As from January 2021, the new REACH restriction on substances in tattoo inks and permanent make-up went into action. During the public hearings, the ESTP raised several points that were not properly answered or acknowledged by the committees in charge. In addition, the ESTP send out open letters to the committee and placed a complaint to the Ombudsman of the European Commission.

In this talk, we will explain the main points raised by the ESTP during the legislative process and try to look into a possible future: What is the positive we get out of REACH? How to live and tattoo with the current restriction and which possibilities may still exist to change the restriction.

[O32] RISK ASSESSMENT OF TATTOO INKS: OPPORTUNITIES AND CHALLENGES

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Tattooing is the insertion of pigment formulations into the skin or mucous membranes to affect appearance. For the protection of consumers, tattooing products are regulated. The REACH restriction (entry 75 of Annex XVII of the REACH Regulation (Regulation (EC) No. 1907/2006)) on hazardous substances in tattooing products and permanent make-up has been adopted at the European level on December 14, 2020. This regulation restricts the use of substances with known and suspected adverse health effects. It sets maximum concentrations for substances in tattooing products.

At the same time, little is known about undesirable health effects that may be associated with the injection of tattooing substances into the human dermis. It cannot be excluded that at a later stage, as a consequence of exposure to the substances in tattooing products, effects may occur in organs other than the skin. Hence, the safety assessment of pigment, being the main components in tattoo inks, is inevitable. The basis of this assessment should be an analytical characterization and a hazard characterization. Therefore, the German Federal Institute for Risk Assessment has compiled a set of requirements and testing methods for tattoo pigments as a first step for their risk assessment.

[O33] TATTOO PIGMENTS AND INKS: REGULATIONS AND CHALLENGES, RISKS AND POTENTIAL COMPLICATIONS

Linda M. Katz¹

¹MD, MPH, Director Office of Cosmetics and Colors,
Center for Food Safety and Applied Nutrition, Food and
Drug Administration

Tattoos and permanent makeup have greatly increased in popularity over the past several decades both in the United States and globally. US polling indicates that the percentage of adults with at least one tattoo rose from 16% in 2003 to 37% in 2019. These types of body art are produced by injecting tattoo inks containing various pigments through the epidermis into the dermis of the skin. Globally, the safety of tattoo inks has been a subject of interest and has prompted the consideration of regulatory requirements for the tattoo inks as well as their pigment components. Development of analytical methods to determine the composition of the many types of tattoo inks available in the global marketplace, and risk assessment for potential adverse reactions, has been challenging and complex. This presentation will address some of the key issues on both the regulatory and analytical fronts.

[O34] COLOR ADDITIVE PETITION PROCESS AND SAFETY ASSESSMENTS OF COLOR ADDITIVES USED IN TATTOO INK AND PERMANENT MAKEUP IN THE US

John Misock¹

¹Senior Consultant with Ceutical Labs, Inc, USA (retired from FDA's Office of Cosmetics and Colors in June 2019)

In the United States color additives are regulated under the Color Additive Amendments of 1960. This amendment to the Food, Drugs and Cosmetic Act is unique in that it places the responsibility for proving the safety of color additives on the user of the color additive. FDA does not take any action on its own to approve color additives. FDA reviews color additive petitions (CAP) submitted by users (color manufacturers). There are four primary categories of CAP approvals, which are listed in FDA regulations: Foods, Drugs, Medical Devices and Cosmetics. The FDA classifies tattoo ink and permanent makeup (ink) as cosmetics. Does that mean any colors approved for cosmetics are also approved for inks? ABSOLUTELY NOT! There is a little known or followed rule (21 CFR 70.5(b)) requiring color additives that are "injected" to obtain a separate approval specifically for that use. Since the growth in popularity of tattoos and reports of health-related adverse events linked to tattooing and permanent makeup, FDA has taken the position that pigments used in tattoo ink and permanent makeup must be approved for injection. Even though this regulation has been on the books since the 1960's, NO COLOR ADDITIVES HAVE RECEIVED APPROVAL FOR INJECTION. Keep in mind many color additives used in injectable drugs and medical devices have been given approval through other parts of the FD&C Act. However, none of these ingredients, including carbon black, TiO₂, zink and barium, have been approved under the color additive amendments. When pressed for a reason for the apparent abandonment of legal responsibilities under The FD&C Act, FDA has stated that although the use of any color additive in a tattoo ink or permanent makeup is not approved, they have taken a position of "enforcement discretion". As long as FDA maintains this position there will be little change in tattoo ink and permanent makeup regulation.

How long this enforcement discretion stays in place is anybody's guess. Will the US Congress enact new legislation? Unlikely. For years there has been attempts to change the FD&C Act regulation of Cosmetics, but it keeps stalling when industry cannot agree on specific elements. The issue of tattoo ink, permanent makeup and injected color additives has

not been mentioned in proposed legislation. Similar to other major changes to the FD&C Act it may take a major catastrophe or a push by interested NGO's to move the dial.

Another complication in the US is the fact that tattooing and permanent makeup artistry is regulated by each state. Without clear FDA regulation of color additives, the industry is left to decipher a myriad of state regulations meant to control the safety of ink.

Considering all of the forces working against any change in ink regulation, the Body Art Committee (BAC) of the Association of Food and Drug Officials (<http://www.afdo.org/about>) has taken on the task of proposing a pathway for approval of pigments used in tattoo ink and permanent makeup. The BAC has submitted a Color Additive Petition (CAP) aimed at getting approval for TiO₂ under 21 CFR 70.5(b). The goal is to develop a model for how a CAP should be submitted for any color additive. FDA has never published guidance on how to obtain approval under this regulation, therefore whatever is gained from the process will become defacto regulation for any future submissions. We decided to start with TiO₂ because it is allowed for use in all FDA products (Food, Drugs, Medical Devices and Cosmetics) with only minor restrictions. TiO₂ is also one of the most common pigments used in inks. Once we have succeeded with TiO₂ the next pigment to tackle is carbon black which adds additional dimensions to the equation.

AFDO's CAP request resulted in FDA stating four distinct areas that need to be addressed:

- The results from a literature search for all relevant published toxicology data on the proposed color additive and its impurities.
- Acute sensitization bioassays in tattooed animals addressing the sensitization, phototoxicity, and allergenicity through intradermal exposure.
- Genotoxicity testing from a battery of bacterial and mammalian testing to assist in evaluating the carcinogenicity potential of the color additive.
- Long term (life-time) bioassay in tattooed animals with UV light to evaluate chronic sensitization, photosensitization, and dermal carcinogenic potential.

[O35] AUSTRALIA MOVES TOWARDS REGULATING COSMETIC INKS

Tina Viney¹

¹APAN - Aesthetics Practitioners Advisory Network, Austria

A literature search (Number 1.) has been completed and submitted to the CAP. Addressing the other three points on FDA's list are more troublesome. In a subsequent meeting with FDA the necessity of filling in data gaps became apparent. There is an opportunity to make a scientific case for what data is possible to obtain from the studies FDA is requesting and how they should be applied to an approval process. There is no model to emulate that even comes close to addressing the issues FDA wants answered. Obviously, there are many obstacles that need to be overcome. One thing is for certain. The best minds available to address the situation need to be involved in the process. There is an opportunity to write the next chapter in tattoo ink and permanent makeup regulation. Your participation is paramount! The effort to create a sound regulatory framework for acceptable use of pigments in ink will require input from many voices. Unlike color additive approvals for food, drugs, etc. there is no organization with a sizable economic interest to fund efforts to fill the research gap. Piecing together this effort will be most important to achieve success.

Since August 2019 Australia moved to investigate the potential risks of certain tattoo inks for the purpose of restricting their use through a regulatory initiative. This activity was undertaken by the Queensland Health Department. The **Departmental Standards – Tattoo Inks** has been made pursuant to section 233 of Medicines and Poisons Act 2019 by the Chief Executive of Queensland Health, and establishes procedures and requirements of use of the products. The standard also prescribes the requirements for a **Compliant Analysis Certificate** under section 48A of the Act.

Representing the PMU industry, the Aesthetics Practitioners Advisory Network (APAN) being the largest industry standards body/association, while the body tattoo art was represented by the Australian Tattooist Guild and the Professional Tattooing Association of Australia.

This Standard must be followed where it is referenced by the Act or Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (Poisons Regulation) or when it is required as a condition of an authority.

Supporting the move for introducing the Departmental Standards included the Australian Medical Association, however, the new laws were opposed by the two tattoo industry bodies who did not support the proposed Compliance Analysis Certificate stating that it would "place an unnecessary and unfair burden on suppliers". This led to section 48A of the Act to be deferred pending a further investigation by the Health Department.

This presentation will report on:

- The outcome of this investigation.
- Australia's position in aligning its regulatory decision to EU Commission Regulation (EU) 2020/2081
- The debate of safety as it affects the process of tattoo removal and other considerations.

[O36] ENCAPSULATION OF AZO- AND XANTHENE-TATTOO PIGMENTS IN LIPID MICROPARTICLES: COLORANTS PHOTOSTABILIZATION AND RETENTION BY THE PARTICLE MATRIX IN EXCISED PORCINE SKIN

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Aim: The light-induced degradation of tattoo pigments is a critical issue for the stability and safety of tattoo inks, since the colorant photodecomposition not only results in tattoo fading but also in the formation of potentially hazardous photoproducts. In the present study, the photo-protective effect of lipid microparticles (LMs) on encapsulated azo- and xanthene-tattoo colorants (C.I. 15865, C.I.19140 and C.I. 45380) was investigated. Moreover, for C.I. 45380, the capacity of the LMs to retain the incorporated dye after intradermal injection in excised porcine skin was evaluated.

Methods: LMs loaded with the colorants were prepared using tristearin as lipidic material. Photolysis experiments were performed by irradiation of the samples with a solar simulator and the extent of photodegradation was measured by HPLC. For stability evaluation, the LMs were introduced in excised porcine skin mounted in Franz diffusion cells.

Results: The light-induced degradation of C.I. 45380, C.I. 19140 and C.I. 15865 was significantly decreased by their incorporation into the LMs (particle size 30-75 nm) from 20.2±5.8 to 1.9±2.1%, 4.2±2.6 to 0.6±1.6% and 13.1±2.7 to 0.6±0.8%, respectively. Moreover, only 1.5±1.7 % of microencapsulated C.I. 45380 was lost from tattooed excised porcine skin, indicating that the LMs did not degrade in the dermal tissue.

Conclusions: The obtained results indicated that incorporation in LMs of the examined tattoo colorants enhanced their photostability. The triglyceride based LMs exhibit the additional advantages of excellent tolerability combined with good stability, as no significant release of the encapsulated colorant was detected in the dermal region of isolated pig skin.

[O37] COMPLEMENTARY IMAGING METHODS FOR THE ANALYSIS OF TATTOO PIGMENTS IN SKIN SAMPLES

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Aim: Adverse reactions in tattooed skin regions are a widely described issue, even several years after the injection. The used tattoo inks consist of a complex variety of pigment classes, which were not designed for long-term intradermal exposure. The diversity of chemical properties of inorganic and organic pigments and their low purity poses an outstanding analytical challenge when searching for possible triggers of adverse skin reactions. Our bioimaging workflow introduces open mass spectral libraries and methods to identify pigments and their impurities in tattooed skin thin sections without extensive sample preparation.

Methods: Results from two analytical techniques are combined to confidently identify the present pigments. Micro-X-ray fluorescence (μ XRF) is used to screen for inorganic pigments, metallic impurities, and heteroatoms of organic pigments. A laser desorption/ionization-mass spectrometry (LDI-MS)-based approach is utilized to provide molecular information and to characterize organic pigments. Both methods lead to spatially resolved images that allow localization of pigments in the skin sections. The combination provides a straightforward workflow for elemental and molecular bioimaging.

Results: We extended open-source software to streamline the data evaluation and applied this workflow to over 60 skin samples that were removed after adverse reactions.

Conclusions: All samples resulted in matches to either organic or inorganic pigments with trends of co-occurrence. Especially mixtures of organic pigments were found and identified based on matches against mass spectral fingerprints that were acquired from commercial pigments.

[O38] COMPARATIVE ASSESSMENT OF THE LONG-TERM DEGRADATION OF INORGANIC AND MIXED PIGMENTS (ORGANIC AND INORGANIC) FOR PERMANENT MAKEUP (PMU) AND MICROBLADING

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Aim: COMPARATIVE ASSESSMENT OF THE LONG-TERM DEGRADATION OF INORGANIC AND MIXED PIGMENTS (ORGANIC AND INORGANIC) FOR PERMANENT MAKEUP (PMU) AND MICROBLADING

Methods: Pigments for PMU and microblading manufactured in Brazil were selected and analyzed for the study. Information was compiled about its composition and manufacture, according to its manufacturers, as well as the results obtained by professionals/expertise in PMU/microblading in eyebrows. The selection of pigments followed the following requirements:

- Manufacturing of National Origin;
- Available Registration at the Ministry of Health - ANVISA;
- Present user manual.

Results: We evaluated the work of 4 different artists, using PMU and Microblading techniques, with the use of pigments of inorganic and mixed compositions (organic and inorganic): For the evaluation of the results, the technical work was divided into:

Each artist performed 2 (two) procedures of each technique, totaling 32 (thirty-two) results for evaluation. The Evaluation was carried out as follows: After immediate, after 30 days and after 180 days.

From the analysis of the results, we can conclude that the inorganic compositions of yellow, red and black iron oxide, generate more lasting results in relation to their degradation, presenting a preserved, opaque and natural brown in the long term.

Conclusions: This conclusion is based on its best industrial processing condition for dispersion, due to the chemical and physical integration of pigment particles, where the composition has greater chemical stability than iron oxides with extrinsic factors, thus guaranteeing fidelity in color degradation.

[O39] VISUALIZATION OF IN VIVO TATTOO PARTICLES USING MULTIPHOTON TOMOGRAPHY AND FLUORESCENCE LIFETIME IMAGING

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Aim: In the last decades, numerous reports on tattoo complications raised awareness of health problems related to tattoo components. These tattoo reactions comprise a broad spectrum, including allergies, granulomatous inflammation and carcinogenic skin lesions. To diagnose and monitor the course of tattoo-based skin changes sufficiently, high-resolution non-invasive imaging techniques are necessary. This first preliminary study introduced the multiphoton tomography with fluorescence lifetime imaging (MPT-FLIM) into the assessment of in vivo tattoo particles in human skin.

Methods: Black and colored tattoos in three volunteers were studied using the multiphoton tomographic system MPTflex with fluorescence lifetime imaging (JenLab GmbH, Jena, Germany).

Results: In MPT-FLIM images tattoo pigments appear as different sized particles with clustered or diffused organization, depending on the pigments used. Distribution of the particles may vary throughout the papillary dermis. Morphologic and metabolic changes of living cells and extracellular matrix in healthy skin and tattoo complications can be visualized and analyzed by high-resolution optical biopsies.

Conclusions: MPT-FLIM may be a qualified non-invasive method in daily clinical practice to analyze in vivo tattoo particles and investigate the morphological alterations and metabolic activities of the surrounding tissue. This diagnostic tool may add an essential benefit to plan following therapeutical procedures and predict their outcome.

[O40] PHOTOTOXICITY & 3D SKIN MODELS

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Recently, the popularity of tattooing has skyrocketed with more people tattooed than ever before. Not only the awareness of tattoo-related side effects, but also the research interest in tattoo toxicology grew with the number of tattooed people. Yet, there are few viable test systems for tattoo toxicology due to the three-dimensional structure of the skin and the unique route of application of tattoo pigments. Here, we present TatS, a novel in vitro tattooed human skin model for improved pigment phototoxicity research.

We compared key skin homeostasis markers (occludin, tenascin C, filaggrin, collagen IV, and E-cadherin), general skin morphology, uptake of tattoo pigments by fibroblasts, cytokine release, and viability of TatS with and without tattoo pigments. In addition, we assessed the effects of UVA and UVB on TatS and on monolayer cell cultures as done in traditional phototoxicity studies. We compared cell viability and cytokine release and examined the effects of tattoo pigments on UVB-induced DNA damage (TatS only). In all tests, the tattoo pigments carbon black, titanium dioxide and Pigment Orange 13 were used.

All markers for skin/TatS homeostasis and viability were unaffected by tattoo pigments. While some tattoo pigments induced phototoxicity in monolayer culture, no phototoxicity was observed in TatS. Contrary, all tattoo pigments reduced the induction of UVB-induced DNA damages in underlying cells.

In summary, TatS proofed to be a promising tool for tattoo research revealing effects that cannot be seen in traditional phototoxicity testing.

[O41] EPIDEMIOLOGICAL STUDIES ON TATTOO EXPOSURE, CERTAIN TYPES OF CANCER AND OTHER HEALTH OUTCOMES IN THE FRENCH AND GERMAN NATIONAL COHORTS

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As more and more people get tattooed, public concern about adverse effects of tattooing is growing. Systemic health effects of tattoos, and in particular certain types of cancer, would not necessarily appear on the tattoo itself or in its vicinity. Thus, such an association may not have been detected by dermatologists nor other clinicians so far as only epidemiological studies can answer these questions. However, due to the recent rise of tattoo popularity and certain characteristics of cancer outcomes (e.g. lag-time, mortality) epidemiological designs need to be planned carefully to be informative and not only premature.

We elaborated an efficient and timely epidemiological design in collaboration with the ongoing French and German national population-based cohort studies “Constances” and “NAKO”. Scheduled for 2022, approximately 35,000 tattooed individuals of both cohorts will fill in a detailed retrospective tattoo exposure questionnaire. Non-Hodgkin Lymphomas, Melanoma and Non-Melanoma skin cancer, and other outcomes of interest will be assessed prospectively to avoid biased information. Relevant information on demographic factors, confounder and effect modifier were routinely collected by both cohorts.

Here, the proposed epidemiological design will be explained in detail, its pros and cons are discussed, and the preliminary version of the tattoo exposure questionnaire will be presented.

[O42] PRESERVATIVES IN TATTOO AND PMU INKS: DO THE INKS PLACED ON THE MARKET COMPLY WITH THE NEW REACH RESTRICTION?

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Aim: According to the new REACH restriction (Reg. EU 2020/2081) mixtures for tattoos and PMUs placed on the EU market after 4th January 2022 shall not contain methylisothiazolinone (MIT), benzisothiazolinone (BIT), octylisothiazolinone (OIT) and other skin sensitisers category 1, 1A or 1B in concentrations $\geq 0.001\%$ w/w and phenoxyethanol (PE), o-phenylphenol (o-PP) and other skin/eye irritants category 2 in concentrations $\geq 0.01\%$ w/w. Quantification of preservatives in inks placed on the Italian market was performed to assess whether these mixtures meet the new REACH requirements.

Methods: Methods based on liquid-chromatography tandem-mass-spectrometry and diode-array detector for quantification of fourteen preservatives including MIT, BIT, OIT, PE and o-PP were developed and validated. Thirty-seven tattoo and eighteen PMU inks of different colours and brands were selected and analysed.

Results: BIT was the most used preservative in both tattoo and PMU ink formulations. About 26.0% and 4.0% of the analysed samples contained BIT and OIT respectively in concentrations $\geq 0.001\%$; PE was present in 13.0% of samples at concentrations $\geq 0.01\%$. Parabens and o-PP were not found. The number for non-compliant tattoo inks were significantly greater than for PMUs. Only two inks reported on their labels a preservative as ingredient.

Conclusions: About 42.0% of the overall samples were non-compliant with the new REACH restriction for the presence of a preservative above the permitted level. Our results suggest that stakeholders need to get ready to take appropriate measures to lower preservatives concentrations in their inks. Nevertheless, official controls on these products will ensure consumers' safety.

[O43] SIMULTANEOUS DETERMINATION OF 11 PHTHALATES IN TATTOO AND PMU INKS BY GC/MS AS REGULATION (EU) 2020/2081 SETS OUT

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Aim: Regulation (EU) 2020/2081, amending Annex XVII to REACH, lays down concentration limits on certain substances in tattoo and permanent make-up (PMU) inks. A study was undertaken to assess the content of eight phthalates, namely, dibutyl phthalate, bis(2-ethylhexyl) phthalate, bis(2-methoxyethyl) phthalate, dipentyl phthalate, diisopentyl phthalate, benzyl butyl phthalate, diisobutyl phthalate and dihexyl phthalate, being these substances subjected to the restriction limit of 0.00005 % w/w in these matrices after 4th January 2022. The study was extended to three other phthalates not included in the REACH restriction: dioctyl phthalate, diisononyl phthalate and diisodecyl phthalate.

Methods: To this aim, an analytical method based on gas chromatography/mass spectroscopy for the analysis of phthalates in tattoo and PMU inks was developed. Validation studies were conducted in accordance with the requirements of ISO/IEC 17025 and measurement uncertainty was evaluated by bottom-up approach. The validated method was applied to the analysis of forty-two tattoo and PMU ink samples of different brands and colours collected from the Italian market.

Results: For all substances, Limits of detection and Limits of quantification ranged between 0,0000003 - 0,000002 % w/w and 0,000001 - 0,000003 % w/w, respectively. Intermediate Precision and Recovery at the permitted level were 2.0 - 9.8 % and 70 - 109 % respectively. Results obtained from the analysis of collected samples showed that 43% of inks wouldn't be compliant to the new regulation.

Conclusions: Validation studies demonstrated that this method is accurate and sensitive, and could represent an effective work tool in the context of official control analysis.

[O44] EDUCATIONAL LECTURE ON INK COMPOSITION

Michael Dirks

The lecture provides insights into the composition of tattoo inks, briefly explains the ingredients and their contamination profiles and shows the difficulties in connection with the future Regulation.

[O45] ANALYTICAL RESULTS OF CHEAP INKS FROM E-COMMERCE STORES

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Aim: Tattoo inks are available at a very low cost from internet-providers like alibaba or e-bay. Little is known about the composition and legal compliance of these inks. The aim of this investigation was to investigate ingredients and impurities in these inks and to compare them with regular inks.

Methods: 9 sets of tattoo inks comprising 94 inks were purchased in December 2018 from e-bay and alibaba. Two sets were obviously fake products of wellknown American ink brands. Pigments, primary aromatic amines, preservatives, polyaromatic hydrocarbons and N-nitrosamines were analysed in representative samples and compared to the results of regular samples between 2018 and 2021.

Results: Pigments in the cheap inks differed remarkably from those found in regular inks, the most frequent being C.I. 21090 (29% vs. 1%). Other pigments with a remarkably higher incidence were C.I. 11741, 12315, 11710, 15850 and three not identified pigments. Noteworthy was also the frequent finding of rhodamines.

Cheap inks contained mainly cosmetic preservatives (Phenoxyethanol (41%), Methylisothiazolinone (17%) and Methylparaben (14%). Benzisothiazolinone, the most frequent preservative in regular inks, was only detected in 5% of the samples.

O-anisidine was the most often found aromatic amine compared to o-toluidine in regular inks. 20% of the samples contained the sensitiser Naphthol AS. Nitrosodiethanolamine was present more frequently in cheap inks (16 vs. 8% @ > 10 ug/kg). Cheap black inks contained higher amounts of polyaromatic hydrocarbons than regular inks.

Conclusions: Cheap inks were mostly preserved with cosmetic preservatives and pigment composition differed remarkably from regular inks. They were more often contaminated with polyaromatic hydrocarbons and nitrosamines but comparably so with aromatic amines. Labelling of ingredients was so obviously wrong or incomplete that any tattoo artist is expected to notice the implausible information.

[O46] MAGNETIC INKS: RESPONSIBLE IRON OXIDES ARE BEING INVESTIGATED

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Until the introduction of modern organic pigments, ferro oxides were used to produce a spectrum of tattoo colours. Iron oxide pigments have duller colour tones matching facial complexions, and thus remain popular in permanent make-up tattooing.

It is not an uncommon routine of MRI physicians to caution tattooed individuals of possible burning sensations before entering the magnetic field of a clinical MRI scanner, and this problem is expected to be underreported in the literature. Most patients report stinging burning pain in the tattooed skin with transient oedema and erythema, recurrently leading to termination of the MR-procedures.

Iron oxide pigments are rock minerals originating from natural sources and therefore invariably contaminated with other metals and minerals, including nickel, cobalt, chromium, and copper. Iron oxides may have paramagnetic or ferromagnetic properties.

However, an increasing concentration of metals in tattoo pigment does not correlate with a higher level of ink magnetisation, as the magnetic properties of the metallic compounds depend on factors such as oxidation level and crystallographic configuration. For instance, hematite and maghemite are both iron oxides, but represent distinct crystal classes with particular magnetic properties. Hematite is a hexagonal mineral and a so-called spin-canted antiferromagnet leading to a feeble magnetization, whereas maghemite is a tetragonal mineral and a ferrimagnet with a magnetization hundred times stronger. These minerals behave very differently when exposed to MRI conditions and can vary significantly from MRI procedure to procedure.

So, what iron oxides minerals can be held responsible for reported magnetization of tattoo pigment? The results of an ongoing project are presented.

[O47] A SHORT-TERM HUMAN BIOKINETICS STUDY OF SOLUBLE TATTOO INK INGREDIENTS

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Aim

When applied by tattooing, soluble substances can enter the bloodstream due to injury of dermal blood vessels. Depending on the substance, renal or biliary excretion occurs. The bioavailability of these soluble substances depends on their physicochemical properties, the tattooed area and the ink applied per tattooed area. The aim of this study is to determine the true range of exposure with tattoo ink per cm² in vivo and the quantification of selected tracer substances in blood and urinary samples.

Methods

Three primarily renally excreted tracer substances are added to black or red tattoo ink that is used to tattoo voluntary study participants: 4-aminobenzoic acid as representative for an aryl with primary amino-group, 2-phenoxyethanol as representative for alcoholic preservatives and potassium iodide to determine the actual amount of used ink. Blood and urinary samples are drawn before, during and after the tattooing process to quantify the tracers and their metabolites. 4-Aminobenzoic acid and 2-phenoxyethanol are quantified with liquid chromatography coupled to a time-of-flight mass spectrometer (HPLC-QToF). Potassium iodide is quantified via inductively coupled plasma mass spectrometry (ICP-MS). Additionally, an untargeted screening of substances is carried out to identify other ink ingredients and their metabolites in blood and urine.

Outlook

This study will contribute to the estimation of safety limits for soluble tattoo ink ingredients. Gained biokinetics data of the tracers might be transferable to substances of high concern (e.g. carcinogenic aromatic amines) by computer-assisted pharmacokinetic modeling, allowing exposure estimations of these substances without in vivo testing.

[O48] NANO VS. PICOSECOND LASER TREATMENTS OF A GREEN INK

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Aim

The removal of green tattoos is considered among the most difficult ones. The aim of this study is at determining efficiency and toxicity of treatments of a green ink performed with Ruby vs. Nd:YAG laser where the latter is operated in 4 different modalities: nanosecond single beam, picosecond single beam, nanosecond array, picosecond array.

Methods

Water dispersions of a green ink, based on a single pigment, i.e. the hexadecachloro copper phthalocyanine (PG7) have been treated with the different lasers in the different modalities, using an equal total power in all cases. Subsequently, the treated samples were, subjected to UV-Vis spectroscopy, GC-mass spectroscopy, Dynamic Light Scattering measurements and SEM microscopy.

Results

Tattoo inks consist of pigments and a complex envelope of components labelled as vehicle, which include the pigments additives. The different laser treatments influence the type of fragments that are produced, especially as far as the additives are concerned, thus affecting the associated risks. In addition, sizes and shapes of the solid residues largely change, depending on the treatments, as well as the dispersions discoloration.

Conclusions

The choice of the laser for removal purposes is usually evaluated in terms of bleaching efficacy. In this regard, picosecond lasers appear to be more efficient. The potential toxicity should be taken into account and the best combination of parameters pondered. In general, none of the probed laser treatments can be considered risk-free.

[O49] OVERVIEW OF TATTOO COMPLICATIONS

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Aim: To describe the types and clinical aspects of complications in tattoos.

Methods: A selection of representative cases of the Tattoo Clinic (Tattoo poli, Alrijne Hospital Leiden) is made to describe and illustrate the most frequent and important complications in tattoos, including permanent makeup.

Results: Tattoo complications can be categorized into inflammatory tattoo reactions, infections, neoplasms and miscellaneous reactions. In our Tattoo Clinic, inflammatory tattoo complications are the most frequently observed by the dermatologist. The majority of these reactions are chronic and include allergic tattoo (pigment) reactions, chronic inflammatory black tattoo reactions and manifestations of autoimmune dermatoses such as psoriasis, lichen planus, non-segmental vitiligo and lupus erythematosus. In a recent Dutch study, 308 tattoo complications in 301 patients were analyzed. Allergic red tattoo reactions and chronic inflammatory black tattoo reactions accounted for 50,2% and 18,2% respectively. Although bacterial infections are the most frequent tattoo complication, they only present a minority of the total of tattoo complications in the Tattoo Clinic as they are generally treated by the general practitioner. Other more rare infections include mycobacterial or fungal infections and manifestations of the herpes simplex virus, human papilloma virus and molluscipox virus. Neoplasms in tattoos, such as basal cell carcinoma, are rarely observed. Miscellaneous complications include blow-outs, scars, keloids, neurosensoric and photosensitive tattoo reactions. The last decade, a (renewed) trend of alternative tattoo removal has emerged including caustic removal cremes. For this reason, tattoo removal induced complications are increasingly observed in the Tattoo Clinic.

Conclusions: A wide variety of complications can occur in tattooing. The vast majority of reactions in the dermatological clinic is chronic and mainly include allergic red tattoo reactions and chronic inflammatory black tattoo reactions.

[O50] ALLERGENS IN TATTOO INK - FIRST RESULTS OF THE IVDK PATCH TEST STUDY

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Aim: The Information Network of Departments of Dermatology (IVDK) is an association of dermatological departments in Germany, Austria and Switzerland dedicated to the epidemiology of contact allergy. Between September 2016 and July 2020, 90 of 1976 (4.6%) tattooed patients reported non-infectious tattoo reactions (incl. permanent make-up). In July 2018, the German Contact Dermatitis Research Group (DKG) established a novel tattoo patch test recommendation. First results will be presented.

Methods: 57 patients (40 women, 17 men) were patch tested between August 2018 and July 2020 in 23 of 58 dermatological centers of the IVDK. Allergic contact dermatitis was suspected in n=35 (61.4%) of these patients, n=16 (28.1%) were tested for exclusion. Patch testing focused on commercially available substances, i.e. the baseline series, preservatives, disperse dyes as potential markers for pigment allergy and the DKG tattoo series.

Results: Considering positive reactions on D3 (72h), 69 positive reactions to 27 test preparations were documented. Most frequently, Nickel sulfate (n = 12; 25%), p-Phenyldiamine (PPD, n=7; 15%), and Cobalt chloride (n= 6; 12%) were patch tested positively as well as eight preservatives, three other metals and three binder materials.

Conclusions: Seven patients in our cohort reacted to PPD, five of them extremely strong (+++) and additionally to disperse dyes. These patients were sensitized by black henna. Two patients with complications in red permanent tattoos had weak positive reactions (+) to PPD. Usually, clinical relevance of positive patch test reactions for the etiology of tattoo reactions remains elusive. The IVDK tattoo study goes on (<https://ivdk.org/en/activity/tattoo-study/>).

[O51] TATTOO COMPLICATIONS SEEN IN THE COPENHAGEN TATTOO CLINIC 2008-21: CAMPAIGNS AND IMPACT ON DANISH NATIONAL REGULATIONS

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Background: Today tattoos have become ubiquitous. As the number of tattooed people rose, the number of tattoo reactions increased. National regulations were until recently much behind.

Aim: In 2008, the "Tattoo Clinic" was created to help sufferers with tattoo complications.

Method: In total, 883 patients with more than 1000 tattoo complications have been referred, diagnosed and treated. Infections, allergic and papulo-nodular reactions remain commonest followed by a broad range of unusual adverse events.

Results: Through the years, research conducted at the "Tattoo Clinic" has been reported in the media including Danish television and medical journals and opened debate. Public campaigns have been launched. Politicians have implemented several restrictions, regulations and legislations concerning the practise of tattooing in Denmark. Examples include; mandatory hygiene courses for tattooists, digital registration of parlours, tattooists, inks and costumers to trace complications; technical training course for cosmetic tattooists, requirements on laser equipment used for tattoo removal and ban of parlours use of caustics for removal. Tattooists are now obliged to provide standard written and oral information before tattooing is started. The preventive instruments involving politicians and the public are paralleled by decreasing referrals to the "Tattoo Clinic" in recent years despite the continued upgoing trend of the popularity of tattoos. This positive development took place before the EU REACH regulation of inks was launched.

Conclusion: Several restrictions have been implemented on the Danish tattoo industry concerning permanent tattoos, cosmetic tattoos and tattoo removal. The public awareness about complications has increased as a result of campaigns and exposures on media. The number of tattoo reactions have declined markedly despite the still upgoing tattoo trend. This positive development took place before the EU REACH regulation of inks was launched.

[O52] RELEVANT FACTS REGARDING COMPLICATIONS IN TATTOOS

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Aim: The aim is to be able to stand by Associations and the related governmental issues thru out the EU with relevant statistics regarding the practice of tattooing. The initiative is based on the need for a larger scale of information then what we can see today. Laws and legislations must be based on facts and large-scale statistics, not speculations and questioners.

Methods: Tascc is a tool easy applied thru our social media channels where it can spread and collect the statistics we need. We ask questions of related issues, topics and current problems and save the results in a data base. Any question asked, delivers a statistic result.

Results: We are currently creating a new Survey to send out. The first survey in Swedish rendered almost 10.000 answers and covered approximately 50 questions regarding tattoos and complications. We also did an English version that was lounged simultaneously in Denmark, Norway and other countries thru out EU, this rendered around 2000 answers.

Conclusions: We can see the need for this type of tool to get the right type of information out to the research community as well as tattoo Associations around Europe. We as a trade and as practitioners are worried that the future legislations and laws are based on loose facts and speculation. Offering information based on large scale surveys will in the future hopefully help to create laws using actual facts and relevant statistics.

[O53] HOW FREQUENT ARE TATTOO COMPLAINTS AND COMPLICATIONS ACCORDING TO PUBLISHED AND UNPUBLISHED DATA: THE PROBLEM OF MEASUREING INCIDENCE AND PREVALENCE

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Complaints are defined as typically intermitten and mild adverse events with the tattooed not seeking medical service. Complications are defined as more serious, recalcitrant and chronic adverse events needing diagnosis and treatment by a doctor or clinic. Obviously, the threshold of seeking medical advice is individual and variable. Questionnaire based studies in the vast majority involves some important degree of selection bias. Studies when medical staffs systematically and with no special selection examine populations provide more reliable data, exemplified by studies performed on the beach (naked skin exposed) or in a hospital outpatient clinic exemplified by a STD clinic. The observer shall be unbiased, which tattooists are not positioned to be particularly if they ask their own customers. It requires special education to assess if an event is a complaint or truly a medical event.

In larger studies the simple question "did you ever consult a clinic or a doctor for a complication in your tattoo" answered by yes or no appears the best objective measure of medical complication.

A population study performed in Denmark in 2017 (under publication) among 52,000 individuals with response rate 62% found 5,205 with tattoo(s). Detailed findings are presented. More tattoos and tattoos more than six years had more complications (OR >2, and >1.95). Other colours than black had 4 times increased risk. 2% of individuals sought help from a clinic or medical provider. This large study is accordant with previous studies and qualifies previous more uncertain observations that about 2% of tattooed individuals have a medical complication, early infection not considered (1-7).

General conclusion: Self reported long-term medical complication to tattooing measured as contact to the medical service is in the magnitude of order of 2%. Mild complaints are indicated to be much more frequent (reaction to sun in 1:5), however, the range of complaints are difficult to measure reliably and influenced by many variables such as geography, culture and social environment.

[O54] TREATMENT OF RED TATTOO REACTIONS

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Allergic reactions to tattoo pigments cause itch, pain or swelling, generally confined to one tattoo color. The vast majority is caused by red tattoo pigments. The average time of onset of symptoms is 12 months.* These reactions are chronic and can result in a significantly reduced quality of life. Clinical subtypes include plaque type elevation, excessive hyperkeratosis and ulcero-necrosis.

Treatment of these allergic reactions is difficult, as tattoo pigments are permanently located in the dermis. Topical or intralesional corticosteroids are its first line treatment but effects are often temporary or unsatisfactory. Other reported treatment options include conventional full-thickness excision, dermatome shaving, Q-switched laser and ablative CO₂ laser therapy. Furthermore, cases of systemic therapies with allopurinol and hydroxychloroquine are described. Removal of the culprit tattoo pigments is thought to be the best approach for a permanent treatment result. Treatment with CO₂ laser ablation (either fractional or full surface ablation) improves itching, burning and impact on daily life in tattoo allergy.** Nonetheless, each therapy has its advantages and disadvantages, such as potential scarring, infections, risk of generalized allergic reactions and treatment imprecision.

* van der Bent SAS, de Winter RW, Wolkerstorfer A, Rustemeyer T. Red tattoo reactions, a prospective cohort on clinical aspects. *JEADV. Journal of the European Academy of Dermatology and Venereology.* 2019 Oct 1;33(10):e384-e386.

** van der Bent SAS, Huisman S, Rustemeyer T, Wolkerstorfer A. Ablative laser surgery for allergic tattoo reactions: a retrospective study. *Lasers in Medical Science.* 2020.

[O55] SARCOID GRANULOMAS IN COSMETIC TATTOOS AND THE ASSOCIATION WITH SYSTEMIC DISEASE

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Nowadays tattooing is a fashionable trend, which is used increasingly for cosmetic purposes. However, even the small cosmetic tattoos may provoke severe complications in predisposed individuals and provoke systemic disease.

Sarcoidosis is a chronic multiorgan inflammatory disease characterized by the development of non-caseating epithelioid granulomas. Cutaneous lesions in known sarcoidosis are observed in approximately one third of patients and may develop months to even 10 years after tattooing. Patients with known sarcoidosis have increased risk of granuloma formation in any tattoo including cosmetic tattoos; vice versa and importantly a tattoo can in predisposed individuals trigger systemic activity with debut of classical sarcoidosis in the lungs, eyes, joints and other organs.

In this presentation seven illustrative cases are demonstrated. Cosmetic tattooists and decorative tattooists as well as dermatologists and internists treating such patients should be aware of this special complication of tattooing.

[O56] SARCOIDOSIS AND TATTOO ASSOCIATED UVEITIS

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Sarcoidosis is a granulomatous systemic disease that can affect the skin in 25% of the patients, including scars and tattoos. Patients with sarcoidosis may get tattooed, and most of tattoo-related sarcoidosis occur in patients with no past history of sarcoidosis at presentation. Granulomatous tattoo reactions may also be associated with other granulomatous conditions, making clinical and patho-logical correlation warranted. Lastly, tattoo Granuloma with Uveitis (TAGU) is an exclusion diagnosis that encompasses patients for whom extensive investigation fails to evidence any specific etiology including sarcoidosis.

[O57] TATTOO-ASSOCIATED MYCOTIC INFECTIONS

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Aim: Although there are numerous reports in the literature about bacterial and viral infections, there are a few works that discuss the mycotic ones. The purpose of this review is to evaluate the impact of mycotic infections in tattoo practice.

Methods: We carried out a search on PubMed using the keywords “fungal”, “infection”, “tattoo” and “tinea”, examining the period of time between 2009 and 2020 with no language restriction.

Results: We identified 10 patients affected by tattoo-related fungal infections. Most of the evidence identified consists in case reports describing the development of tinea on tattooed skin: the culprit agents were *Microsporum canis*, *Microsporum gypseum*, *Trichophyton rubrum* and *Epidermophyton floccosum*. Interestingly, a case of aspergillosis has been described: a 24-year-old male patient started complaining of nodular purpuric lesions on the tattoo area 2 weeks after the execution. One case of *Purpureocillium lilacinum* infection was described.

Conclusions: Given the increasingly frequent practice of tattooing, it is critical to consider all the risks related to it, with infections being no exception. All hygienic practices must be implemented in order to reduce the risk of contamination both during the execution of the tattoo and during the healing phase and subsequent care.

Specifically, although mycotic infections account for a small percentage of tattoo adverse effects, they should be taken into account, especially when the clinical features are suggestive and previous anti-inflammatory therapies have failed, in order to begin effective treatment as soon as possible and tackle the condition.

[O58] THE DERMATOLOGIST'S VIEW ON TATTOO AFTERCARE

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Aim

Good aftercare instructions are helpful for optimal wound healing and to avoid complications.

Summary

The healing phase is extremely important to obtain a perfect tattoo. After the procedure the tattooist will treat the fresh tattoo and provide the client with aftercare instructions and give information about normal and abnormal healing. Different aspects such as the skin type, the size and the site of the tattoo can be taken into account. In the first days after the procedure the risk of infection is still high. The customer should understand the importance of good hygiene and will be informed about activities to avoid during the healing process. As a basic principle all aftercare procedures shall be performed with clean hands. Scratching can lead to scarring; sun protection is recommended to avoid pigmentary changes.

There are different treatment modalities of good wound care. They can be adapted depending on the experience of the tattooist, and the preference of the customer.

More information: <https://eadv.org/cms-admin/showfile/Tattoo%20Aftercare.pdf>



Poster Presentation Abstracts

[P1] REACH ANNEX XVII - A LONG WAY TO GO: 0% COMPLIANCE IN CURRENTLY AVAILABLE TATTOO INKS

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Aim: Quantify how many of the currently available tattoo inks will be in compliance with the new REACH annex, assuming no changes will be made to label and (chemical) composition prior to 4-1-'22. This information will be used for risk-based market surveillance by the Netherlands Food and Consumer Product Safety (NVWA) and the Office for Risk Assessment & Research (BuRO).

Methods: 53 inks (33 samples, 9 brands of tattoo inks and 20 samples, 5 brands of permanent makeup pigments) were purchased from Dutch tattoo suppliers.

The labels of these inks and pigments were assessed based on national legislation and the new REACH annex.

The chemical composition (PAH, PAA, VOC, Azo, heavy metals, preservatives) was investigated by the NVWA laboratory.

Results: Labelling: None of the sample products were in compliance. There were problems with the legibility and durability, however there were also incidents of wrong ingredient declarations, the absence of an address or the presence of multiple addresses. Formal requirements such as the presence of allergens were also absent. Composition: Chemical analysis not yet finished, however presence of IPA in 34 of the 53 sampled problems will be an issue due to the H319 classification of IPA. This means that these products will have to be reformulated.

Conclusions: If the new REACH annex was in effect today, none of the inks would be in compliance. It is not feasible to assume that compliance will significantly improve before 01-2021. European market surveillance authorities should prepare for (joint) action.

[P2] TWO CASES OF ANAPHYLAXIS PRESUMABLY PROVOKED BY TATTOOING

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Aim: Only a few examples of immediate IgE-mediated reactions emerging after tattooing can be found in the literature, although during the tattooing process, a person is exposed to a great number of potential allergens, like disinfectants, anesthetics, latex gloves, nickel needles, or wound dressings.

Methods: We report two cases of type I hypersensitivity reactions, with the presence of potentially life-threatening symptoms, which had occurred immediately after tattooing. The causative allergen was not identified, however, in both cases the procedure of tattooing was the most suspicious factor that could trigger the reaction.

Results: A 35-year-old male patient presented shortness of breath, tongue numbness, and difficulty swallowing about two hours after getting a black tattoo on the scapular area. Concomitant flushing of the skin in the upper back, cleavage, and neck was observed. In the second case, tachycardia, dyspnea, and a sensation of heat and weakness with the presence of erythema and swelling of the eyelids appeared in a 42-year-old woman immediately after the procedure of permanent make-up of the upper eyelids. Both patients were treated at the emergency department with systemic glucocorticoids and antihistaminic medications and none of them developed anaphylactic shock.

Conclusions: We suggest that tattooists should receive first aid training in case of potential anaphylactic reaction provoked by tattooing procedure in sensitized individuals.

[P3] COLOR THEORY APPLIED TO TATTOO PIGMENTS

Michaela Dahlgren, Finland

Choosing the right pigment to fulfil a client's expectations is challenging without first having a good understanding of the properties of colors and pigments and how they may affect the final result of the healed tattoo.

All colors are made up of different combinations of the three primary colors, red, blue and yellow, as well as two non-colors, namely black and white. These colors can be mixed to create additional hues, as well as adjusting their tint, shade, tone, temperature and saturation.

Perceived colors can also be greatly affected by the presence of other colors around it, this is called simultaneous contrast. The actual colors themselves don't change, but we see them as altered.

The Fitzpatrick Scale is a numerical classification for human skin color and is used to estimate the response of different types of skin to ultraviolet light. The skin's undertone, as defined in the Fitzpatrick Scale, can influence the perception of the healed tattoo. For example, when brighter colored pigments are used, the undertone will have a minor influence over the healed result, but as the color starts to fade, the undertone will become more apparent. Skin color, combined with the color of the ink, results in a new color.

The properties of organic and inorganic pigments can also influence the perceived colors and affects their strength and longevity. Ultimately, different pigments can yield unexpected results as their properties and particle sizes can impact the colors of the healed tattoo.

[P4] TATTOO INK MARKET IN FRANCE: A FIELD STUDY AMONG 598 PROFESSIONAL TATTOOISTS

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Aim: We performed an observational self-reported internet survey with the French Tattoo Union (Syndicat National des Artistes Tatoueurs) to evaluate what were the most popular inks and how professional tattooists used them in daily practice.

Methods: All active professional tattooists in France were invited to take part in a six-question Internet survey regarding their habits of use of tattoo inks.

Results: 598 tattooists reported 36 different brands of black inks and 44 of colored inks. However, six brands of black inks were used by 14.2 to 44% of the tattooists and, for colored inks, five manufacturers were favored by 11.2 to 55.7% of the tattooists. The majority of tattooists mixed two different colors or more to obtain a new shade (68.9%), while 21.7% would try to find the adequate shade within the assortment provided by a manufacturer. 54.4% had between 10 and 40 references, 31.9% had less than 10 references, 11.5% had 40 to 100 references and 2.2% had > 100 references.

Conclusions: The market of tattoo inks in France is dominated only by a fistful of brands. Controls by official authorities should target those popular brands, even though all brands should respect the law. Toxicological studies should always precise from which market and what brands are tested, so we can assess their impact in real life. Tattooists also should also try to lower the number of ready-made colors they need.

[P5] STUDY OF THE IMPACT OF NATURAL DISCOLORING MEDIA ON BODY TATTOO AND PERMANENT MAKE UP (PMU) COLORANTS

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Aim: The aim of this work was the assessment of natural origin discoloring media on the alteration of color intensity of tattoo and PMU colorants.

Methods: Body tattoo and PMU colorants (Table 1a) dispersed in water in concentration 1mg/30ml were incubated with natural origin extracts (Table 1b) in 1/10 (v/v) ratio and incubated at 37°C. A commercial tattoo discoloring product was used as control. The spectra of the colorants dispersed in water and their mixture with the discoloration media was obtained by ultraviolet-visible (UV/Vis) spectrophotometry (UV-1800 UV-Vis Spectrophotometer, SHIMADZU, Kyoto, Japan). The discoloration potential of each media was assessed by calculating the alteration of absorption (A) maximum in the visible range (400 nm – 800 nm) of each colorant before and after incubation with each discoloration media.

Results: The results (Table 2) showed a good discoloration of 810 (85,47%) and 702 (93,18%). Although 712 and 710 have the same colorant composition the performance of the discoloration media differed. This results is an indication of the significance of the presence of other ingredients in the colorant formula.

Conclusions: Natural origin discoloring media may act as efficient alternatives of laser tattoo removal.

a		b
Body tattoo and PMU colorants	Colorant ingredients (CI)	Discoloration media
DB	CI77891, CI77492, CI77266	Malva infusion
TI	CI77266	
152	CI77499, CI77492, CI77491	Geranium infusion
712	CI77891, CI56300, CI56110, CI77266	
702	CI77891, CI56300, CI56110, CI 77266	Malva/geranium infusion
Sunset	CI77891, CI56110, CI77491	
810	CI 77891, CI56300, CI77491, CI77288, CI77499	Agaricus infusion
816	CI 77891, CI77288, CI77499, CI77492, CI77266	Commercial discoloration product
288	CI 77891, CI77499, CI77491, CI77492	

Table 2. UV absorption of colorant dilutions in water and their mixtures with discoloration media

Colorant	A max (nm)	Ink diluted in water	Ink diluted in water incubated with discoloring media				
			malva	geranium	malva / geranium	Agaricus	Control
DB	566	0.085	0.166	0.108	0.12	0.186	0.176
TI	440	0.167	0.166	0.082	0.085	0.096	0.153
152	780	0.171	0.252	0.073	0.139	0.199	0.402
712	600	0.341	0.708	0.273	1.647	0.853	0.705
702	600	0.425	0.743	0.029	0.421	0.492	0.77
sunset	476	0.422	0.31	0.407	0.314	0.612	0.348
810	800	0.289	0.264	0.042	0.292	0.392	0.481
816	735	0.684	0.839	0.05	0.612	0.771	0.984
288	790	0.1448	0.264	0.042	0.292	0.392	0.481



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