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Red tattoo allergies after REACH regulation: a continuing problem

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Abstract

Despite new EU regulations, allergies to red ink tattoos remain an urgent public health problem. Red tattoo pigments continue to occur at a clinically relevant rate. This observation raises critical questions about the effectiveness, scope, and enforcement of the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation. We argue that current tattoo ink restrictions fail to sufficiently protect European consumers from known allergens and that regulatory revisions are urgently needed.

Key words: tattoo; cosmetic; adverse reaction; allergy; pigment; REACH; red.

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Tattoo complications in context

Tattoos are one of the most popular forms of body art, with approximately 10-20% of the population in Europe and the USA having at least one tattoo.[1] However, complications such as infections, allergic reactions, scars, and local activation of autoimmune skin diseases can occur. Among these, red pigment allergies are the most frequent tattoo-related complication in dermatologic practice.[2] These reactions cause chronic itching, pain, and swelling, and their clinical presentation varies from a plaque-like elevation to severe hyperkeratosis or ulceration (Figure 1).[3] Since January 4, 2022, the new Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation has restricted thousands of hazardous chemicals found in tattoo inks and permanent makeup within the European Union.[4] However, the regulation contains several insufficiencies and inconsistencies. Furthermore, despite the regulation's goal of enhancing tattoo safety, allergic tattoo complications continue to occur.

Clinical observations and epidemiological uncertainty

Between January 2022 and October 2024, our clinic recorded 220 tattoo-related complications. Of these, 41 were diagnosed as allergic reactions to red tattoo ink. Notably, 15 of those reactions occurred in tattoos applied after the REACH regulation came into force (Table 1), including cases involving inks labeled as "REACH-compliant".

The true incidence of red tattoo pigment allergy remains unknown due to a lack of large-scale epidemiological studies. In our current post-REACH dataset, red pigment reactions represent 19% of all tattoo complications. This contrasts with earlier findings from a previous study,[3] where red pigment allergies accounted for 50.2% of tattoo-related complications. This may indicate a decline, but data remain insufficient for firm conclusions, given differences in time frame, methodology, and clinical practice context. Moreover, our data originate from a single center and involve a relatively small sample size. These limitations reduce generalizability and emphasize the need for multicenter studies or national surveillance systems to better understand the epidemiology of tattoo-related allergies. Broader population-level surveillance will be essential to assess whether REACH has effectively reduced the burden of red ink allergies.

Regulatory gaps and inconsistencies

A key criticism of REACH has been its limited scope in addressing allergies to tattoo pigments.[5,6] While the regulation restricts certain hazardous chemicals, it does not comprehensively target all potential allergens. Chemical analysis of biopsies from tattoo reactions has identified several pigments linked to allergies, including Pigment Red (PR) 122, PR 170, PR 266, PR 22, Pigment Violet (PV) 19, PV 23, and Pigment Orange 13.[7,8] Table 2 provides a clear overview of the tattoo pigments identified in allergic reactions, along with their corresponding regulatory status under REACH and other EU regulations. While some of these pigments (*e.g.*, many naphthol AS pigments) are now prohibited under REACH, others (*e.g.*, PR 170 and PR 266) remain permitted, despite their frequent association with allergic reactions. This regulatory gap may explain the continued occurrence of tattoo-related allergies.

Furthermore, PR 210, a structurally related compound, is prohibited under REACH, while PR 170 and PR 266 are not. This inconsistency raises concerns about whether REACH sufficiently addresses allergenic tattoo pigments.

Another factor that may contribute to ongoing allergic reactions is the continued use of pre-REACH tattoo inks. These older

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formulations remain available through online retailers and may still be in use by tattoo artists. Regulatory oversight of ink stocks and enforcement of compliance in practice appear limited, raising concerns about the practical implementation of REACH.

Pigment authenticity and compliance discrepancies

Additionally, concerns have been raised about the authenticity of purportedly REACH-compliant inks, with studies indicating discrepancies between labeled and actual ink compositions.[9] Furthermore, multiple studies (including our own and others) have documented labeling inaccuracies, including inaccurate or overstated claims regarding REACH compliance, which undermine the effectiveness of current regulation.[7,8]

Regulatory oversight is further complicated by the lack of harmonized testing protocols for analyzing tattoo ink composition, including its various pigments. This lack of standardized methods poses a significant barrier to effective regulation and limits the feasibility of mandatory composition testing at this stage. Without harmonized analytical tools, both compliance verification and scientific reproducibility remain limited.

Pigment degradation and allergen formation

It is hypothesized that red tattoo allergies are not caused by the original pigment compounds themselves, but rather by their degradation products formed in the skin over time. These breakdown products may act as neo-antigens, triggering delayed-type IV allergic reactions. In a previous study, 32% of patients reported worsening symptoms after sun exposure, supporting the hypothesis that UV-induced degradation may play a critical role in allergen formation.[3] This concept is further supported by the predominantly negative patch test results found in prior studies, which suggest that the immune system is not responding to the intact pigment but to transformation products formed *in situ*.[10] Many of the red pigments implicated, particularly naphthol AS-based pigments such as PR 170 and PR 266, are chemically prone to photodegradation and cleavage, yet remain permitted under REACH. To improve both diagnostic accuracy and regulatory relevance, we propose that patch testing with known or simulated degradation products of red tattoo pigments be developed. Identifying the true allergens is essential for evidence-based restriction of the most reactive compounds.

Clinical and regulatory recommendations

Based on our findings and the current regulatory landscape, we recommend the following actions: i) adjust the REACH pigment ban list to better reflect clinical evidence of allergenicity; ii) promote the development and future implementation of standardized ink composition testing to ensure transparency and enable reliable regulatory oversight; iii) encourage dermatologists to systematically report post-REACH tattoo-related allergies, to improve epidemiological understanding and inform future regulation; and iv) support mechanistic research into pigment degradation and allergen formation, including patch testing with breakdown products.

Table 1. Clinical patient characteristics (n=15).

Parameter	n (%)
Age (years), mean (range)	43.2 (25-62)
Sex	
Male	3 (20)
Female	12 (80)
Tattoo location*	
Distal upper extremities	8 (53)
Proximal upper extremities	1 (7)
Distal lower extremities	4 (27)
Proximal lower extremities	0 (0)
Trunk	3 (20)
Face	1 (7)
Symptoms**	
Swelling	15 (100)
Itch	12 (80)
Pain	1 (7)
Histopathology	
Yes	6 (40)
No	9 (60)
Time to onset of symptoms, months, median (range)	4.5 (0.5-15)
Eliciting factors	
Sunlight	2 (13)
Q-switched laser	2 (13)
Unknown	11 (73)
Tattoo ink brand	
Intenze Bright Red	1
World Famous Tattoo ink JF Magenta***	1
World Famous Tattoo ink (type unknown)	1
Kuro Sumi Crusador Red***	1
Kuro Sumi (type unknown)	1
Quantum Peach Me***	1
Unknown	9

*The total is more than 15 because of patients with multiple tattoo reactions or a tattoo covering multiple anatomical locations; **the total is more than 15; ***labeled as REACH-compliant.



Figure 1. Allergic red tattoo reaction on the upper arm: erythematous plaques sharply confined to the red tattooed skin.

Table 2. Tattoo pigments in tattoo allergies and restrictions.

Tattoo pigment Abbr.	Name	CI number	CAS number	Annotation frequency Brungs *et al.*[7] (%)	Annotation frequency Serup *et al.*[8] (%)	Restricted in REACH annex XVII, entry 75 (Reg. 2020/2081) Annex VI Reg. 1272/2008	Annex II Reg. 1223/2009	Annex IV Reg. 1223/2009	Appendix 13 Entry 75, REACH	Concentration limit
PR 122	Pigment Red 122	73915	980-26-7	40	1	N	N	Y (Entry 103)	N	*
PR 170	Pigment Red 170	12475	2786-76-7	40	36	N	N	N	N	Not applicable
PV 19	Pigment Violet 19	73900	1047-16-1	31	1	N	N	Y (Entry 102)	N	*
PR 266	Pigment Red 266	12474	2786-76-7	28	24	N	N	N	N	Not applicable
PV 23	Pigment Violet 23	51319	6358-30-1	12	8	N	N	Y (Entry 85)	N	*
PO 13	Pigment Orange 13	21110	3520-72-7	4	12	N	N	N	Y	**
PR 22	Pigment Red 22	12315	6448-95-9	4	35	N	N	N	Y	**
PO 16	Pigment Orange 16	21160	6505-28-8	1	2	N	N	N	Y	**
PR 146	Pigment Red 146	12485	5280-68-2	1	0	N	N	N	Y	**
PR 184	Pigment Red 184	12487	99402-80-9	1	0	N	N	N	N	Not applicable
PR 112	Pigment Red 112	12370	6535-46-2	0	1	N	N	Y (Entry 11)	Y	*
PR 5	Pigment Red 5	12490	6410-41-9	0	1	N	N	N	N	Not applicable

In bold, tattoo pigments that are not restricted; CI, color index; CAS, chemical abstracts service; *maximum 0.00005% wt, based on REACH entry 75, column 2, paragraph 1(f), considering Annex IV to Regulation (EC) No 1223/2009; **maximum 0.1% wt, based on entry 75, column 2, paragraph 1(h), considering appendix 13 of this entry.

Conclusions

Although REACH is intended to make tattooing safer in Europe, current evidence suggests it does not sufficiently prevent allergic reactions to red tattoo pigments. Our post-REACH case series demonstrates that such allergic reactions continue to occur in clinical practice. Stronger collaboration is urgently needed between regulators, clinicians, scientists, tattoo professionals, and industry stakeholders to improve regulatory oversight, harmonize ink analysis, strengthen surveillance efforts, and advance safety research that reflects both clinical and chemical realities.

References

1. Kluger N. Epidemiology of tattoos in industrialized countries. Curr Probl Dermatol 2015;48:6-20.
2. van der Bent SAS, Rauwerdink D, Oyen EMM, et al. Complications of tattoos and permanent makeup: overview and analysis of 308 cases. J Cosmet Dermatol 2021;20:3630-1.
3. van der Bent SAS, de Winter RW, Wolkerstorfer A, Rustemeyer T. Red tattoo reactions: a prospective cohort on clinical aspects. J Eur Acad Dermatol Venereol 2019;33:e384-6.
4. Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up. OJEU 2020.
5. Serup J. Chaotic tattoo ink market and no improved customer safety after new EU regulation. Dermatology 2023;239:1-4.
6. Bäumler W, Hauri U, Liszewski W, et al. Alignment with toxicological and medical reality is urgently needed: A plea after more than one year of European regulation on tattoo and permanent make-up inks. J Eur Acad Dermatol Venereol 2024;38:e896-7.
7. Brungs C, Schmid R, Wolf C, et al. Tattoo pigment identification in inks and skin biopsies of adverse reactions by complementary elemental and molecular bioimaging with mass spectral library matching. Anal Chem 2022;94:3581-9.
8. Serup J, Hutton Carlsen K, Dommershausen N, et al. Identification of pigments related to allergic tattoo reactions in 104 human skin biopsies. Contact Dermatitis 2020;82:73-82.
9. Moseman K, Noble S, Sanders S, et al. Analysis of blue and green REACH compliant tattoo inks. Analyst 2024;149:5329-35.
10. Serup J, Hutton Carlsen K. Patch test study of 90 patients with tattoo reactions: negative outcome of allergy patch test to baseline batteries and culprit inks suggests allergen(s) are generated in the skin through haptenization. Contact Dermatitis 2014;71:255-63.

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Consent for publication: written consent was obtained from patients for their photographs and medical information to be published, with the understanding that this information may be publicly available.

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