

JOINT CONTROL OF TATTOO INKS

Nordic Enforcement Group,
2023–2024



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Preface

Enforcement of the new tattoo ink restriction in Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach) is important for consumers' health and to ensure a fair level playing field for competition. The restriction applies to tattoo inks and permanent make-up (both here after referred to simply as tattoo inks). The project has focused on controlling whether economic operators comply with the new Reach restriction on tattoo inks. In addition, such joint projects contribute to effective cooperation by exchanging experience, discussing common challenges, and ensuring harmonised enforcement this new restriction with the participating Nordic countries.

The significance of tattoo ink control

Tattoo ink safety is important for European and Nordic consumers since the popularity of tattoos continues to rise, so does the need for regulations and enforcement of these regulations. A joint Nordic enforcement project is useful to ensure compliance of the new restriction in the Nordic market.

A joint Nordic enforcement project

The goal has been to ensure compliance with the new restrictions in the Nordic market by using our collective expertise and resources. This joint project aimed to enhance the distribution of safe chemicals throughout the supply chain and to promote responsible tattoo practices that complies with the applicable European legislation on chemicals. The project contributes to fulfilling UNs Agenda 2030 by ensuring better Nordic cooperation regarding enforcement on chemical content in goods. Thereby reducing potentially negative impacts of chemicals on health, which are hazardous for human health, and increasing safe use of chemicals.

Summary

A new Reach restriction came into force January 4th, 2022. Thousands of hazardous chemicals potentially used in tattoo inks became restricted in the EU under the Reach regulation (specifically, Reach Annex XVII entry 75).

This project "Joint Control of Tattoo Inks," has been a collaborative enforcement effort by market surveillance authorities within the Nordic Enforcement Group, including Finland, Sweden, Denmark, and Norway.

The primary objectives of this project have been to ensure compliance of tattoo inks with the new Reach restriction, raise awareness about the regulation, identify non-compliant products in the Nordic market, follow up deviances with enforcement actions. The results of this project will also be used to inform consumers about their rights and the lack of implementation of the new requirements in this segment.

Results

Inspection methods varied across the participating countries. A total of 211 tattoo inks from 64 different enterprises were controlled.

Over half of the inks controlled in the project originated from the US, about a quarter from the EU, and the rest from China, the UK, and other non-EU countries. A few inks had unknown origin.

Out of the 211 controlled inks, 46 inks (22%) contained one or more restricted substances. Among the detected substances both carcinogenic and skin corrosive/irritating substances were found. There were also detected substances restricted by the cosmetics regulation (Regulation (EC) No 1223/2009) and substances listed in Annex XVII to Reach (Regulation (EC) No 1907/2006). Sweden and Finland performed chemical analysis of the inks, and the results showed that approximately one third of the analysed inks (34%) contained one or more substance above the permitted concentration limits. The highest percentage of inks with restricted substances originated from outside of the EU.

Regarding labelling, over half of the controlled inks were marked with reference numbers, a list of ingredients, and safety instructions. About only a quarter had the obligatory statement "Mixture for use in tattoos or permanent make-up" correctly labelled. In total, only 17 out of 211 controlled inks (8%) were correctly labelled. None of the inks from China and the UK had the correct labelling.

Overall, only 14 inks (7%) were found to be compliant for the items that were controlled in this project. The results indicate that there will be a need to further monitor the industry going forward.

1. Introduction

1.1 The Nordic Enforcement Group

Nordic enforcement projects are run by the Nordic Enforcement Group, a subgroup of the Nordic Chemicals Group, under the Nordic Council of Ministers. The main purpose of the Nordic Enforcement Group is to exchange experience on control, discussing common challenges as well as enforcing the European chemical legislations through joint enforcement projects.

The Joint Control of Tattoo Inks project was launched in 2023 and completed in 2024. The Norwegian Environment Agency leaded the project (through project managers Alexander Kristiansen and Bjørg Bergheim). Participants from other Nordic countries included Anna Vuori and Petteri Talasniemi from the Finnish Safety and Chemicals Agency, Elmira Tavoosi and Charlotte Björkbäck from the Swedish Medical Products Agency and Ida Lundstein Scharff, Anna Magdalene Brun Hansen and Mette Arnecke from the Danish Environmental Protection Agency.

The project was funded by Nordic Council of Ministers, as part of the program for Nordic co-operation on the Environment and Climate 2019–2024 and the Nordic working group for chemicals, environment and health (NKE) 2023.

1.2 Objectives of the project

The overall objective of this project has been to control compliance of tattoo inks with the requirements of the new Reach restriction (in Annex XVII, entry 75), to raise awareness about the restriction, to identify non-compliant products in the Nordic market and to follow up with enforcement actions.

In addition, a goal of the project was to ensure close cooperation between Nordic enforcement authorities to increase the efficiency of enforcement and ensuring a uniform interpretation of the applicable restriction between the Nordic countries and to harmonize enforcement.

Regarding the enforcement, the project had focus on the following sub-objectives:

- the new regulation is known by economic operators in the supply chain
- the language requirements are followed
- the mandatory statements are correctly applied
- the reference/batch number is applied
- the list of substances of tattoo inks is including in the marking

- the tattoo artists (professional user) fulfil the requirement to provide information to consumers
- the tattoo inks do not contain selected restricted substances

Furthermore, we wanted to:

- compare the legal differences between each country in the follow-up of non-compliant companies;
- investigate if there are differences in non-compliance-rate between the different participating countries; and
- investigate if there are differences in the type and/or frequency of non-compliances due to country of origin.

2. Chemical regulations in scope

To protect European citizens, thousands of hazardous chemicals that could potentially be used in tattoo inks and permanent make-up (both here after referred to simply as tattoo inks) are restricted in the EU under the Reach regulation, Reach Annex XVII entry 75. Entry 75 in Annex XVII came into force January 4th, 2022. For Pigment Blue 15:3 and Pigment Green 7 entry 75 no. 1 applied from January 5th, 2023.

The restriction covers different categories of substances that are considered to pose risks to human health if they are used for tattooing purposes.

The restriction covers substances that are classified according to the CLP Regulation (EC) No 1272/2008 as causing or suspected of causing cancer, genetic mutations, and adverse effects to human reproductive function, fertility, or foetal development and growth as well as skin sensitizers, skin corrosives, skin and eye irritants, and eye damagers. The restriction also covers substances listed in Annex II (a list of forbidden substances) and substances with specific restrictions according to Annex IV (colourants) to Regulation 1223/2009 (EC) as well as substances listed in appendix 13 to Reach annex XVII entry 75.

Beyond restrictions on the inclusion of hazardous substances above limit values, there are also labelling requirements for tattoo inks and for the user of the tattoo ink (the professional carrying out the tattoo) to provide information to the person receiving treatment with the tattoo ink.

The labelling elements to be placed on the mixture are:

- The mandatory statement "Mixture for use in tattoos or permanent make-up"
- A reference number to uniquely identify the batch
- A list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number, by decreasing order (weight or volume)
- Special labelling for compliant levels of Ni, Cr (VI) and pH regulators
- Instructions for safe use.

Where necessary because of the size of the package, the information listed above, except for the mandatory statement, shall be included instead in the instructions for use. The label shall be in the national language(s) unless the Member State decide otherwise.

3. Inspection procedures

The framework for the Joint Control of Tattoo Inks project, along with the project plan, was established during a group meeting held in Oslo in February 2023. Prior to this meeting, each country had developed its own plan for controlling tattoo inks, drawing advantage of the fact that Sweden had already initiated their controls. However, the group collectively agreed on a set of common checklist items that were controlled and reported on. Subsequent communication in the group occurred through an online communication platform, and several digital meetings.

3.1 Norway

The Norwegian Environment Agency performed 18 controls at selected stores and tattoo shops. The controlled stores are the two largest suppliers of tattoo inks in Norway. The tattoo shops mainly consisted of two or more tattoo artists who shared shop space but run their own separate enterprises. The tattoo artists were all users according to the Reach definition.

The control objects were chosen based on information from the Norwegian Food Safety Authority's registry of tattoo ink importers, internet research and general knowledge of the inspectors. Most of the control objects were located in the greater Oslo area.

A press release about the controls along with information about the new regulation, was announced at the Norwegian Environment Agency's web page prior to the inspections: [Tatoveringskemikalier kontrolleres - miljodirektoratet.no](https://miljodirektoratet.no/tema/tatoveringskemikalier-kontrolleres)

A press release with inspections results was announced after the completion of the inspections: [Informerer ikkje godt nok om innhald i tatoveringsblekk - miljodirektoratet.no](https://miljodirektoratet.no/tema/informerer-ikkje-godt-nok-om-innhald-i-tatoveringsblekk)

Controls

Two to seven inks were selected for control at each controlled economic operator. The inks were selected from different brands/suppliers and in a variety of colours. The ink labels were inspected according to the requirements in points 7 a-g to Annex XVII, entry 75 of Reach and pictures were taken for documentation. The lists of ingredients were controlled for legal content according to point 1 a-h back at the office.

No analyses of the inks were performed. The requirement for inks users (tattoo artist) to give the information on the ink label to their customers was also controlled.

Any non-compliance regarding labelling or content was followed up with the suppliers.

3.2 Sweden

The Swedish Medical Product Agency (the Swedish MPA) performed a risk-based selection of 46 tattoo inks (incl. permanent make up) for the market surveillance. Out of these 46 inks, 31 inks were from traditional economic operators^[1] and 15 were from online marketplaces (CDON.se, Amazon.se, Fruugo.com and Fyndiq.se). The selection of economic operators was based on information in the Agency's product registry over tattoo inks^[2] and was based on tattoo inks that were available on the Swedish market, either by webpages or online marketplaces.

The 46 inks were chemically analysed by the Netherlands Food and Consumer Product Safety Authority (NVWA) with focus on a selection of aromatic amines, polycyclic aromatic hydrocarbons (PAH) and heavy metals.

The labelling of the 46 inks was also controlled in regard to points 7 a-g to Annex XVII, entry 75 of Reach and 7 § points a-c to the Swedish MPA's provision (HSLF-FS 2022:16) for tattoo inks.

Suppliers placing a tattoo ink on the market is responsible for ensuring that their ink(s) have all the mandatory labelling, while tattoo artist who only use the inks (neither import, sell or otherwise supply the products to third parties) do not have the same extensive requirements. However, the lack of certain information can prevent the tattoo artist to fulfil the obligation under point 8 to Annex XVII, entry 75 of Reach (the information to be provided to the customer before tattooing). Where applicable, the Swedish MPA has informed the user of tattoo inks about deficiencies in the labelling.

A list of the included substances in the analysis and a list of selected tattoo inks in the Swedish project can be found in the published report on the Swedish MPA's webpage (see Annex 1 and 2, referred as "bilaga 1" and "bilaga 2"): [Kontroll av tatueringsfärger på den svenska marknaden 2022–2023 | Läkemedelsverket \(lakemedelsverket.se\)](#)

1. Traditional economic operator means a natural or legal person subject to obligations regarding the content, labeling and/or use of tattoo inks (e.g. manufacturer, importer, distributor or professional user of an ink).

2. According to the Swedish regulation (2012:503) on tattoo inks, anyone who professionally manufactures a tattoo ink or brings such an ink into Sweden shall notify the Swedish Medical Products Agency for registration in the product register referred to in section 4. The notifier shall provide the information required for registration. If the information changes, the notifier shall inform the Agency of this.

3.3 Denmark

The Danish Chemical Inspection Service performed a nationwide control which consisted of a combination of physical inspections and border controls.

The Danish Chemical Inspection Service performed five physical inspections located all over the country. Two inspections were carried out at tattoo shops (downstream users), one inspection at the manufacturer of PMU-colours (permanent makeup) and two inspections were located at the largest distributors in Denmark.

In cooperation with The Danish Customs Controls shipments were detained. The Inspection had prepared a fact sheet for The Danish Customs Controls to clarify the rules of restriction nr 75. This initiative was taken to support The Danish Customs Controls in which products should be detained for further inspection. We consider the factsheet being particular useful, as mostly non-compliance products have been taken out for inspection.

The physical inspections were notified in advance and the companies were selected based on the following criteria:

- Prior knowledge of the company,
- physical location combined with a
- general search on the Internet.

August 2023, an inspector from The Danish Chemical Inspection Service participated in a stakeholders' meeting from the tattoo business and gave a presentation on the project as well as the requirements for labelling and ingredients. Examples of some non-compliant products were also shown.

The Danish Chemicals Inspection Service primary found compliant products during the physical inspections. All physical inspections had focus on guidance. It seems that the industry was familiar with the new restriction.

During collaboration with The Danish Customs, 13 shipments were taken out for inspection. Three of these shipments were released with a guidance paper. A total of 86 products were detained by the border, and 71 products turned out as non-compliant and were seized and destroyed.

The majority of the products were imported from outside the EU.

Only labelling on the ink was controlled, none of the inks were analysed.

3.4 Finland

The Finnish Safety and Chemicals Agency (Tukes) selected 7 tattoo inks and 14 permanent make up pigments for the market surveillance. 19 of these samples from traditional online web shops and two of the samples were from online marketplaces.

The selection of economic operators was based on information in the Agency's product registry (KemiDigi) and was based on information on the tattoo inks that were available on the Finnish market either by webpages or online webstores.

The inspected products were purchased from online stores. The inks were chemically analysed by the Netherlands Food and Consumer Product Safety Authority (NVWA) with regards to a selection of aromatic amines, polycyclic aromatic hydrocarbons (PAH) and heavy metals. 10 of the inks were also microbiologically analysed by the Finnish Customs laboratory.

The labelling of the inks was controlled in regard to points 7 a-g to Annex XVII, entry 75 of Reach regulation.

Upon observation of a non-compliance, the economic operators which were controlled were made aware of the non-compliances with the law and requested to give their opinion on the issue. In all cases, the economic operators took the necessary corrective actions without coercive actions.

The agency organized a webinar for industry stakeholders about the content of the new restriction before launching the monitoring project and updated its website regarding the restriction. A press release about the results was published after agency's web page after the inspections: [Tukes testautti tatuointi- ja kestopigmentointivärejä: tulokset parantuneet merkittävästi | Turvallisuus- ja kemikaalivirasto \(Tukes\)](#).

Seven of the samples were compliant by the chemical analysis and labelling. Three of the inks exceeded the concentration limits of the Reach restriction. One of the inks included restricted PAHs and two of the inks included heavy metals such as copper and lead over the concentration limits. One of these three also contained a significant amount of microbes.

All the inks which had exceeded the concentration limits were voluntary withdrawn from the market by the economic operator.

12 inks didn't contain all the labelling required. Most of the non-compliance with labelling requirements were missing frames in Swedish which is required to have in the inks placed on the market in Finland since Finland is bilingual country.

One economic operator stopped selling the non-compliant inks and rest of the economic operators added the missing labelling to the inks.

4. Results and conclusion

4.1 Control objects and inks

In this project, a total of 211 tattoo inks sourced from 64 different economic operators were examined. The inspections covered various business ventures, including stores, tattoo shops, web pages, web page marketplaces, and private importers. Among the inspected enterprises, 35 were users of tattoo inks, 29 were suppliers, and two operated as both user and supplier.

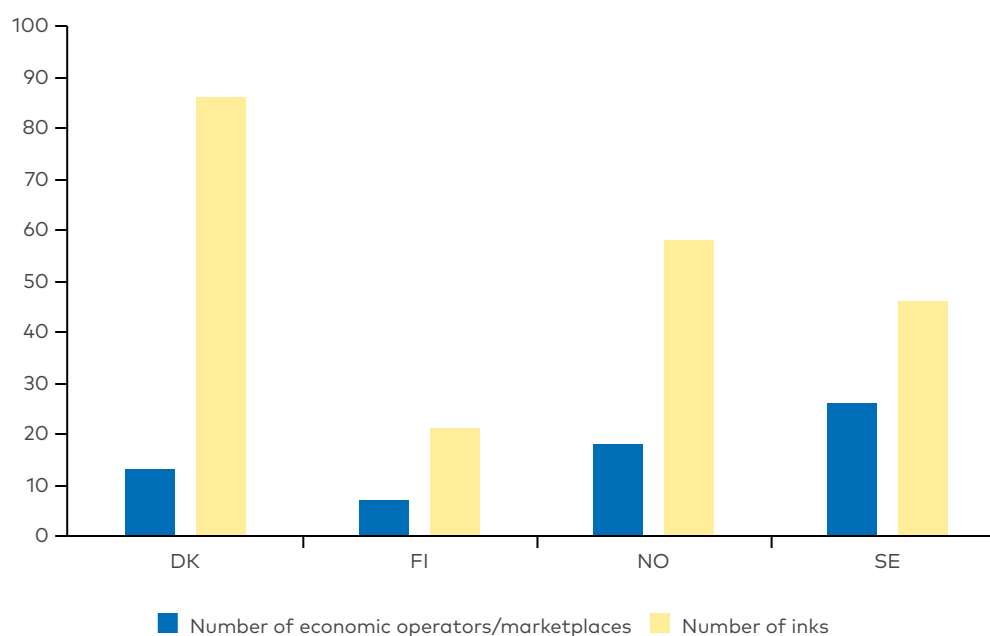


Figure 1 Number of controlled economic operators/marketplaces and inks per country

Origin of inks

More than half of the controlled inks originated from the US. Approximately a quarter were manufactured within the EU, while the rest have origins in China, UK, other non-EU countries. Two inks had unknown origin.

Ink brands

A total of 48 different brands were controlled, 12 of the brands were found in several countries.

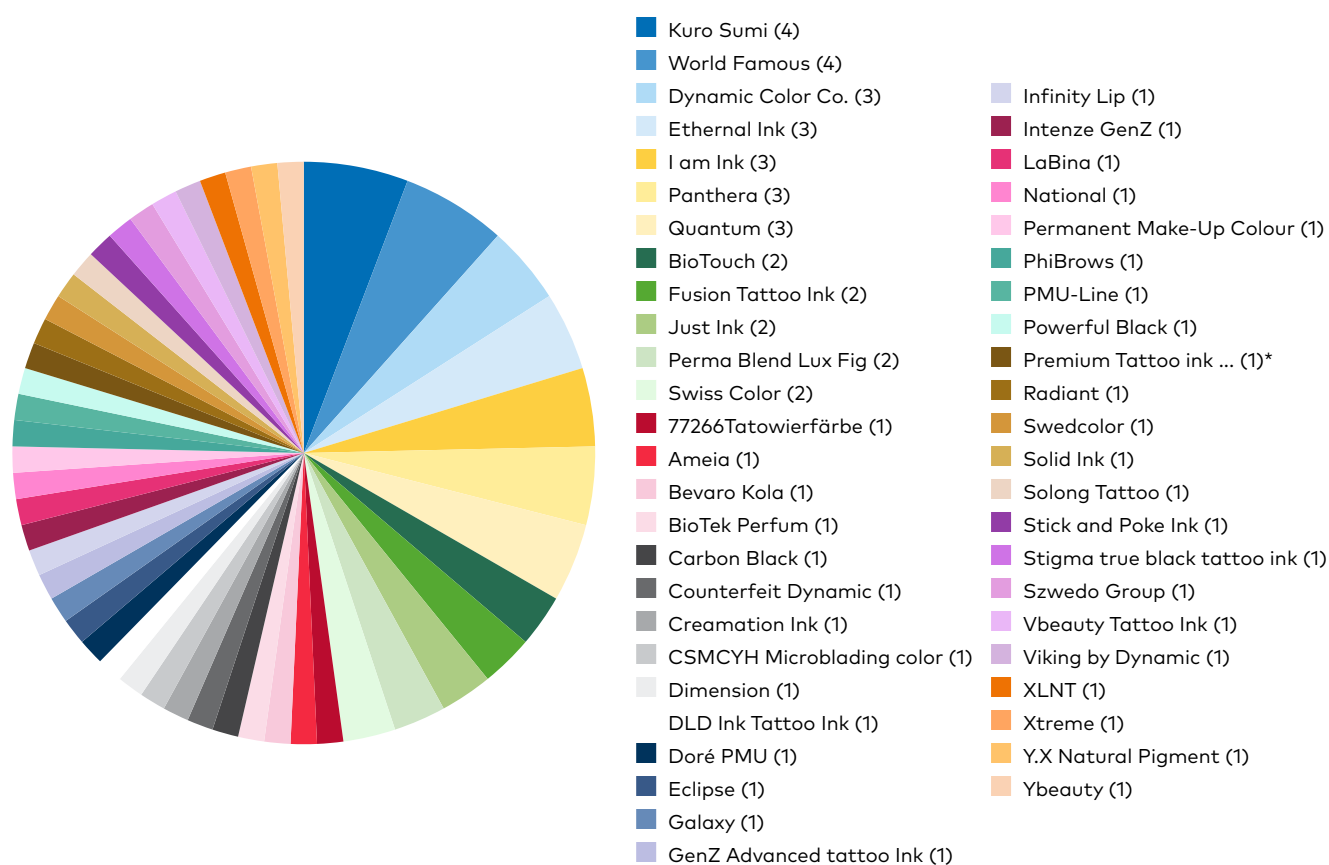


Figure 2 Brands and number of countries they were controlled in. The number of countries the tattoo ink was controlled in is stated behind the brand name.

* Premium Tattoo ink Tattoo Tomato is red black

4.2 Compliance for content and labelling

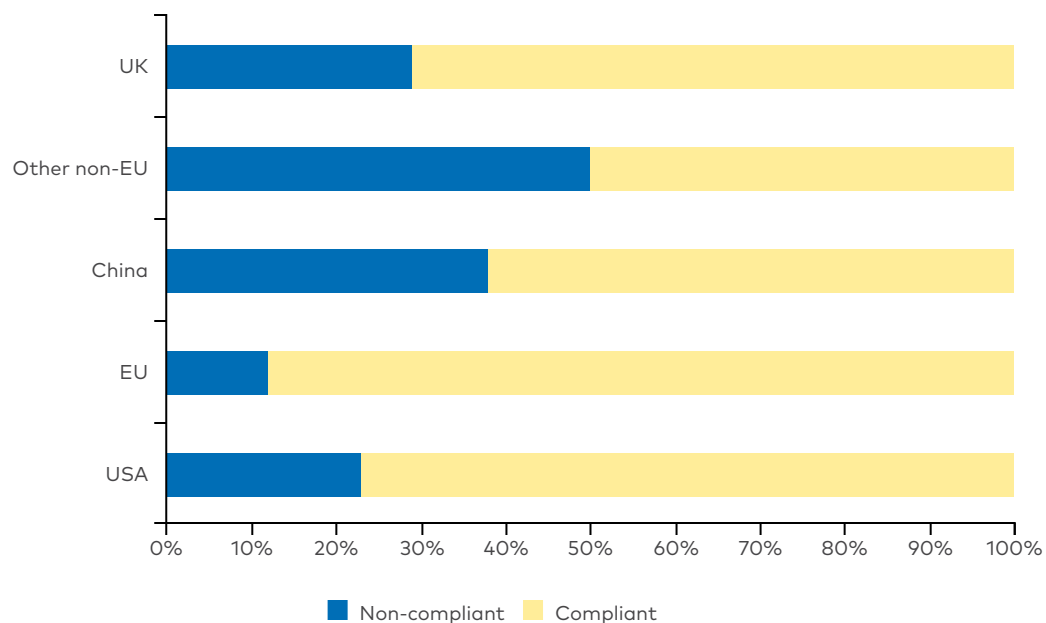
4.2.1 Restricted substances or substances above limit value

All inks were checked for content of restricted substances. Forty-six of the controlled inks (22%) contained one restricted substance, and 6 inks (3%) contained two restricted substances:

- 10 inks (5%) contained carcinogenic substances
- 1 ink (0.5%) contained a skin corrosive/irritating substance
- 4 inks (2%) contained substances prohibited by Cosmetic Regulation (Annex II to EC 1223/2009)
- 37 inks (18%) contained restricted substances listed in appendix 13 to REACH Annex XVII

Thirty of the restricted substances were detected via analysis, while the rest (22 substances) were detected by checking the list of ingredients on the tattoo ink label. 23 out of 67 analysed inks (34%) contained one or more substance above the permitted concentration limits.

The largest percentage of inks containing restricted substances originated from other non-EU countries, China, and the UK:



Figur 3 Percentage distribution of inks containing restricted substances, and origin

4.2.2 Labelling

Of the 211 controlled inks, 194 (92%) were missing mandatory labelling items.

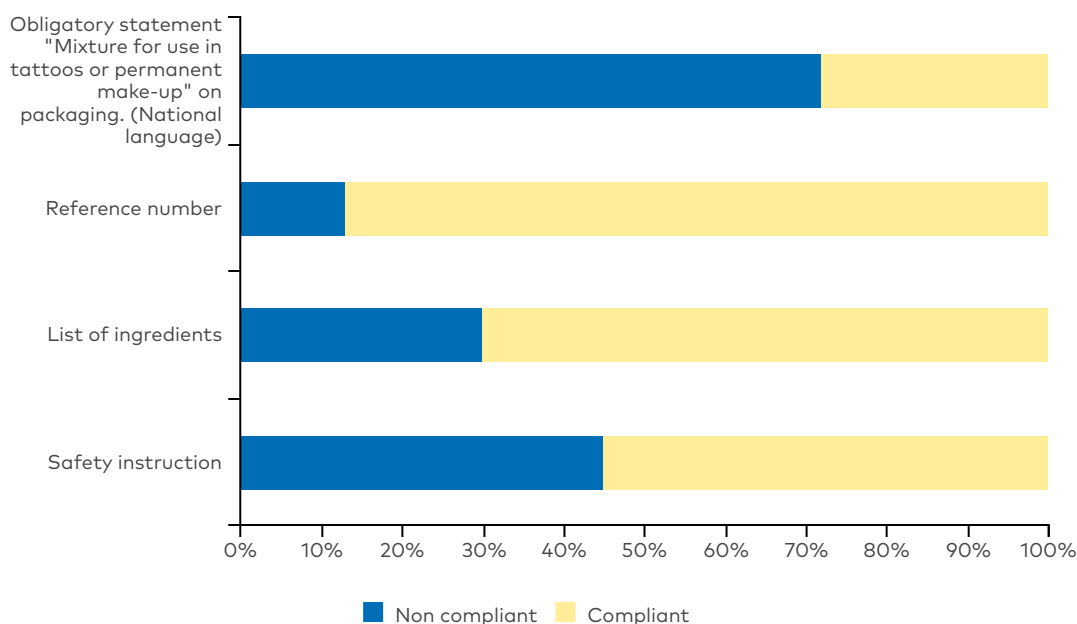


Figure 4 Compliance for labelling items in percent

All tattoo inks controlled in this project were checked for labelling of reference number, list of ingredients and safety instruction. More than half of the inks featured this labelling on their packaging. Notably, the highest compliance rate was observed for reference numbers, approaching 90%.

Two hundred and nine inks were checked for labelling of the obligatory statement "Mixture for use in tattoos or permanent make-up". Approximately a quarter of the controlled inks included this obligatory statement on their packaging. However, nearly three quarters of the inks lacked this labelling. Specifically, 102 inks (49%) were completely missing the statement, and 44 inks (21%) had the correct statement but not in the required national language. This shows that the most common non-compliance in labelling was a lack of the obligatory statement "Mixture for use in tattoos or permanent make-up".

None of the inks imported from China and the UK had the correct labelling.

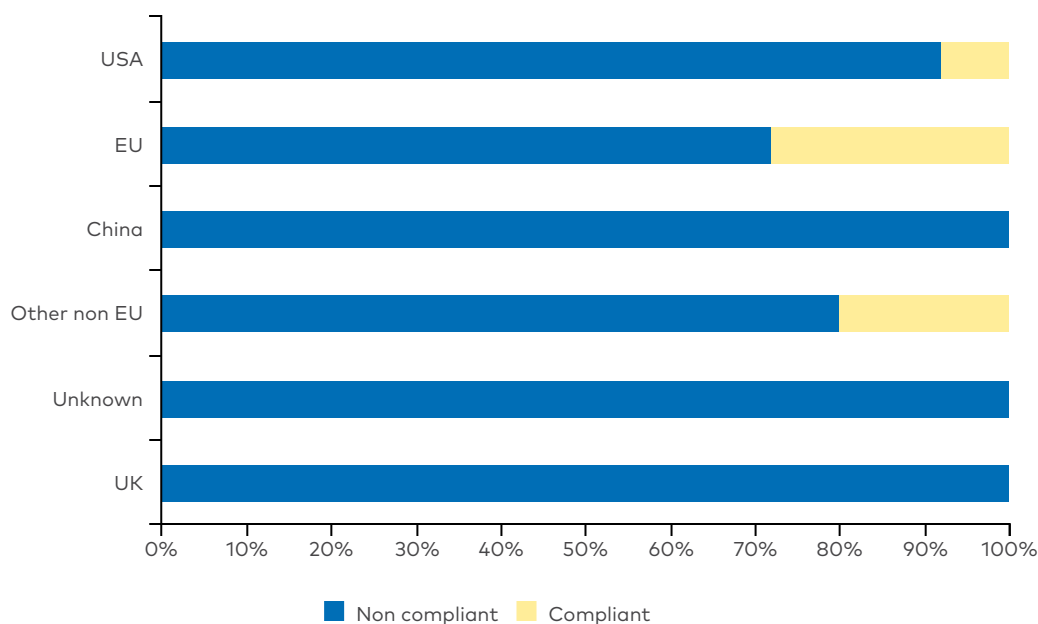


Figure 5 Overview of origin of inks and compliance for labelling, in percent

4.3 Results Norway

A total of 18 controls were conducted across tattoo shops and stores. 16 were users of tattoo inks and 2 were suppliers.

Inks and origins:

- 58 inks from 16 different brands were subject to control.
- Origin of the inks:
 - 23 originated from the EU, 1 was from the UK and 34 were from the USA.

Content:

- Restricted substances or substances exceeding limit values:
 - 4 inks (7%) contained substances listed Reach annex XVII item 75 number 1, e) annex II in EU 1223/20009 (cosmetic regulation)

Labelling:

- 30 inks (52%) featured the mandatory statement "Mixture for use in tattoos or permanent make-up". 26 inks lacked this required statement: 6 were completely missing it, 2 lacked information on the packaging and 18 inks had the statement but not in Norwegian.

- All inks had a reference number on their packaging.
- 39 inks (67%) provided a list of ingredients.
- Correct labelling of safety instructions was present on the packaging of 18 inks (31%). Another 36 of the inks had the labelling, but not in the correct language. 4 inks were missing safety instructions entirely.

Compliance summary:

- Overall, only 3 inks (5%) were compliant.

Comments

The Norwegian Environment Agency also investigated whether tattoo artists conveyed packaging information to their clients. Out of 16 tattoo artists, only three informed customers about the ink's labelling details.

Regarding specific pigments, Pigment Blue 15:3 and Pigment Green 7 did not need to comply with entry 75 before January 5th, 2023. Therefore Norway has opted for guidance rather than enforcement in this project.

Finally, several tattoo artists reported discontinuing the use of coloured inks following the implementation of the new regulations.

4.4 Results Sweden

46 inks from 22 economic operators and 4 online marketplaces were controlled by analyses and control of the labelling. 13 were suppliers placing on the market (note that some could have dual roles, also being users), 9 were only users and 4 were online marketplaces.

Inks and origins:

- 46 inks from 32 different brands were subject to control.
- Origin of the inks:
 - 2 had unknown origins, 6 came from China, 13 originated from the EU, 7 were from other non-EU countries, 3 were from the UK and 15 were from the USA.

Content:

- Substances exceeding allowed limit values:
 - 20 out of 46 tattoo inks (43%) that were analysed contained one or more substances above the permitted concentration limits. One tattoo ink exceeded the maximum permitted level of isopropyl alcohol, as indicated in the list of ingredients.
 - 7 inks (15%) contained carcinogenic or mutagenic substances, 1 ink (2%) contained a corrosive/irritant substance and 19 inks (41%) contained substances listed in appendix 13 to REACH annex XVII

Summary from the analyses

Of the tattoo inks purchased from marketplaces, 11 out of 15 (73%) contained one or more substances above the legal limit. Of the 31 tattoo inks that had a designated EU/EEA economic operator, 9 of these (29%) contained one or more substances above the legal limit.

7 out of 46 tattoo inks (15%) contained one or more polycyclic aromatic hydrocarbons (PAHs) above the permitted levels, with 6 of these containing a total of approximately 3–60 mg/kg PAHs.

18 out of 46 tattoo inks (39%) contained heavy metals above the permitted levels (arsenic, antimony, cobalt, lead or nickel).

None of the tattoo inks contained any of the aromatic amines that were analysed.

Labelling:

- 27 inks (59%) did not meet the requirement for the mandatory statement "Mixture for use in tattoo or permanent makeup" or its Swedish equivalent. 10 of these 27 inks did not have this label at all and the rest had deficiencies in its wording or that it was stated in, for example, an instruction manual and not on the packaging (bottle and/or outer packaging).
- 8 inks (17%) did not have a reference number on their packaging (7 of them were from an online marketplace).
- 4 inks (9%) did not have an ingredient list and 20 inks (43%) had one or more ingredients that were not declared in accordance with the nomenclature to be used.
- 19 inks (41%) had labelling of safety instruction in English, but the safety instructions were not translated to the correct language (swedish) and 9 inks had a correct labelling of safety instructions. 18 inks had a correct labelling in regard to the economic operator's role and responsibility.

Compliance summary:

- Overall, only 4 inks (9%) were compliant.

Conclusions from the Swedish MPA's project

Compliance regarding chemical content has improved slightly compared with the Swedish MPA's inspection project in 2020, with regard to tattoo inks with a designated supplier with an address in the EU/EEA. Tattoo inks from the marketplaces CDON.se, Amazon.se, Fyndiq.se and Fruugo.com had more serious deficiencies in terms of content and labelling.

The proportion of inks with non-compliant labelling was high and each economic operator should engage with its supplier to increase compliance throughout the chain. Correct labeling is also important as the tattooist has an obligation to provide the person to be tattooed (the customer) with specific information contained on the packaging (the bottle and any outer packaging) and any attached leaflet. In order for the tattooist to fulfill these obligations the information on the tattoo ink must be correct.

4.5 Results Denmark

A total of 13 shipments were taken out for inspection in cooperation with The Danish Customs Controls. Two were suppliers and 12 were users.

Inks and origins:

- 86 inks from 11 different brands were subject to control.
- Origin of the inks:
 - 8 had unknown origins, 10 came from China, 1 originated from the EU, 3 were from the UK and 64 were from the USA.

Content:

- Restricted substances or substances exceeding limit values:
 - 18 ink contained a substance listed in appendix 13 to REACH annex XVII.

Labelling:

- 70 inks (81%) lacked the mandatory statement "Mixture for use in tattoos or permanent make-up". 16 inks had the statement but not in Danish.
- 64 inks (74%) had a reference number on their packaging.
- All the inks provided a list of ingredients.
- Correct labelling of safety instructions was present on 57 inks (66%). Seven of the inks (8%) was missing safety instructions entirely.

Compliance summary:

- None of the inks were compliant.

A fact sheet was prepared in advance to The Danish Customs Control to clarify the rules of restriction nr 75 (help to spot non-compliance products).

In addition The Danish Chemical Inspection Service performed 5 physical inspections. 2 inspections were carried out at tattoo shops (downstream users), 1 inspection at the manufacturer of PMU colors (permanent makeup) and 2 inspections were located at the largest distributors in Denmark. All the physical inspections had focus on guidance.

4.6 Results Finland

A total of 7 inspections were conducted across stores, web pages and web page-marketplaces. All of the inspected entities were suppliers of tattoo inks.

Inks and origins:

- 21 inks from 10 different brands were subject to control.
- Origin of the inks:
 - 13 originated from the EU, 3 were from other non-EU countries and 5 were from the USA.

Content:

- Restricted substances or substances exceeding limit values:
 - 3 inks contained carcinogenic substances.

Of these, two inks contained both carcinogenic substances and one ink contained heavy metals. One of these three also contained a significant amount of microbes.

Labelling:

- 9 of the inks (42%) featured the mandatory statement "Mixture for use in tattoos or permanent make-up". 2 inks lacked this required statement, 10 had the statement but not in Finnish and Swedish.
- 19 of 21 inks (90%) had a reference number on their packaging.
- 19 inks (90%) provided a list of ingredients.
- Correct labelling of safety instructions was present on the packaging of 12 inks (57%). Another 4 of the inks had the labelling, but not in the correct language. 2 inks were missing safety instructions entirely.

Compliance summary:

- Overall, 9 inks (42%) met all labelling requirements
- According to the performed chemical analyses, 3 out of 21 tattoo inks (14%) tested contained one or more substances above the permitted concentration limits. Two of the inks (10%) exceeded the concentration limits with PAH substances and one ink (5%) exceeded the concentration limits with heavy metals.

4.7 Compliance summary and conclusion

In total only 14 out of the 211 controlled inks (7%) were compliant regarding content and labelling. These 14 inks came from 9 different brands. Seven of the inks originated in the EU, 5 in the US, and 2 from other non-EU countries.

In summary, it can be said that a large number of non-compliances from the regulations were found among most actors, regardless of where the ink originated from. Some actors have updated themselves on the new regulations, but the introduction of new regulations requires that the entire supply chain follows the current regulatory requirements and stays updated on the rules that apply in the industry they operate in and for the products they use.

Therefore, there will be a need for further follow-up and supervision of this industry and the new Reach regulations. It will still be useful for the Nordic authorities to cooperate on this work and share experiences in the future.

4.8 Follow up on non-compliant tattoo inks

The participating countries in this project conducted their controls over varying time spans and scopes. Additionally, different types of enterprises were controlled, ranging from small operators on online marketplaces to large importers. Various enforcement methods and actions were used. Some countries analysed inks while others did not.

Where applicable, all enterprises have been informed about the results of the controls. Some surveillance authorities opted for guidance for compliant inks or those with minor non-compliances. For inks containing restricted substances, the results were presented to the supplier or user when possible. In some cases, inks with restricted substances were withdrawn from the market, and in other instances, they were seized and destroyed.

In this project, enforcement actions were not pre-determined by the project group. However, in retrospect, it is apparent that the follow-up actions were quite alike for similar findings.

4.9 Remarks

CLP and safety instruction

None of the inks controlled in this project were labelled according to the CLP-regulation (regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures). The requirement for tattoo inks (Reach Annex XVII entry 75, 7 (g) is that safety instructions should be marked on the label, insofar as they are not already required to be stated on the label by the CLP regulation).

The requirements for safety instructions appear somewhat unclear, as there is no specific description of the text that should be included on the label. Consequently, it is challenging to identify deviations in this area, especially since safety instructions are not mandatory for all inks. It is also not possible to determine if CLP-labeling is required solely based on the information provided on the label.

"Reach compliant"

Several inks were labelled with "Reach compliant", both compliant and non-compliant inks. This information can be misleading for users and should therefore be discontinued.

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Appendix I Definitions in this project

Term	Explanation
Tattoo ink/ink	Mixture for tattooing purposes, including inks used in traditional tattoos and permanent make-up
For tattooing purposes	Injection or introduction of mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, microblading and micro-pigmentation), with the aim of making a mark or design on his or her body
User	A downstream user who does not sell or supply inks further down the supply chain
Supplier	Any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture
Store	A physical location where one can buy inks
Shop	A tattoo studio, where tattooing is performed
Web page	Online store, traditional form of e-commerce
Online marketplace	Web based market which offers products from different operators
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
Cosmetic regulation	Regulation (EC) No 1223/2009 on cosmetic products
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
Compliant	No non compliances for the items checked at the time of the control

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by the Nordic Enforcement Group 2023–2024



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SWEDISH MEDICAL PRODUCTS AGENCY



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The Nordic Council of Ministers
Nordens Hus
Ved Stranden 18
DK-1061 Copenhagen
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