Report to the QLD Health Department into the Developement of a Ink Standard for the State of QLD

RESEARCH AND INFORMATION COMPILED BY THE AUSTRALIAN TATTOOISTS GUILD (ATG)

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The Australian Tattooists Guild (ATG) have compiled the following report for use in the ongoing discussions with the QLD Heath Department's working group and other stakeholders regarding the potential development of an ink standard for use within the State of QLD.

The ATG and other industry stakeholder groups have met with the department's working group on numerous occasions since 2019. During these meetings and in subsequent email correspondence and phone discussions many issues have been discussed regarding the feasibility of developing an ink standard. It has been clearly stated by the department during round table discussions that their intent is to regulate tattoo ink in QLD based on the current EU ResAP 2020 and/or EU ResAP 2008 Regulations.

The ATG's position is that this adoption/emulation is premature given that there are massive unresolved issues facing the European tattoo industry and ink manufacturers worldwide brought about directly as a result of said EU legislation.

Due to the Australian Tattoo industry's total reliance on overseas tattoo ink manufacturers, any ink regulation must be formulated in consultation with a range of overseas companies already supplying the Australian market. If overseas manufacturers cannot or will not comply with the regulations of a tiny Australian market, Australian tattoo artists will have no supply of legal compliant ink.

For the industry to continue under the proposed ink standard, we require manufacturers who can simultaneously

a) produce a product range that complies with the standard's lists of banned substances and concentration limits
b) work with a compliance model imposed by QLD Health that demands its own labelling, testing, and certification regimes
c) produce a product range with a complete colour palette that is fit for purpose

From our extensive consultation with the QLD Health working group and various US and EU manufacturers we have no assurance that all of these outcomes are currently achievable from any manufacturer.

The findings of this research has left our commitee concerned that the current model, proposed by the department, which is a hybrid of the EU ResAP 2020 and 2008 EU regulations, endangers the future of Australia's small but thriving tattoo industry, and does not ensure the safety of the public as intended.

It is the opinion of our Committee that the focus of all stakeholders should be towards the development of real data when formulating a risk assessment for pigments that are currently in use. In light of there being no evidence to support a major public health issue, it is reasonable to assert that there should be time given to formulate data-driven regulation rather than a preemptive over-reaching model based on incomplete data that is considered by many experts to be of little relevance. If there is to be an emulation of overseas regulatory frameworks, there needs to be adequate time given to assess the workability of said frameworks, as well as a mechanism by which new data can affect changes to the regulatory approach in Australia.

Adoption of EU regulation at this time is premature given that stakeholders at all levels of the European tattoo industry (manufacturers, suppliers, artists/end users) are up in arms about the 2020 regulatory amendments.

Summary

- Current bans and limits as are outlined within the EU regulations are not supported by data
- No data exists to indicate that current industry-preferred pigments are a risk to public health and safety. Anecdotal examples of negative outcomes are proportionally minuscule compared to overall number of clients tattooed.
- There is no popular public sentiment demanding action be taken on this matter
- No data or risk assessment exists to indicate that the new pigment formulations which are now entering the market are fit for purpose
- In the event of data becoming available the EU Legislation may be overturned, and will likely impact any regulation in Australia
- There is currently extremely limited access to compliant inks within the EU coupled with low market confidence. Usage of non-compliant ink continues.
- Adoption of an as yet unworkable overseas regulatory framework within Australia is premature

Overview of EU regulations and perceived issues

The current EU tattoo regulation, Commission Regulation (EU) 2008/2020, uses the Precautionary Approach to limit the ingredients found in tattoo inks. This approach is not based on concrete evidence, but rather on theoretical worst-case toxicity scenarios and on general hazard classifications of chemicals. In fact, much of the available studies in humans show no correlation between tattoos and incidence of disease, including no risk of cancer or reproductive toxicity.

According to ECHA, “It is difficult to estimate the true overall incidence and prevalence of complications [caused by tattooing] because no registry and epidemiological studies are available. Furthermore, direct association with the effects and specific substances is extremely challenging due to variability of the components of inks, pigments, and contaminants that can be injected into the dermis. Also, few patients consult their physician regarding minor cases, opting instead to return to the tattoo parlour.” – Annex XV Substances in tattoo inks and permanent make up.

This does however not mean that there is no research available. In fact, the survey studies that have investigated possible links between tattooed individuals and incidence of disease have overwhelmingly showed a lack of correlation between diseases such as cancer and reproductive and developmental effects. - Kluger & Koljonen, 2012; Islam, et al., 2016; Kluger, 2015.

The reason these studies cannot be used by the regulatory agencies as evidence for safety of tattoos is because these studies lack a complete analysis of tattoo ink ingredients and purity of chemicals used to manufacture the inks. Therefore, the studies don’t allow for clinical assertions to be made about direct safety or hazard correlations between the ingredients commonly found in tattoo inks and the observed results.

Dossiers complied by the European Chemicals agency (ECHA), the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) which were compiled for the European Council to assess the risks of tattoo and PMU inks during the development of the EU ResAP Regulations, clearly outline that the proposed reasonable limits for harmful ingredients, additives and preservatives are based on risk reduction which has been determined in the absence of any substantive data.

ECHA asserts that certain pigments (Blue 15, Green 7, and others) should be excluded from the ban until safer alternatives are found, because the perceived safety concerns around the identified pigments and any potential alternatives are not based on research and data.

The European Commission has left the regulation open for future revisions, thus the potential for further unfounded bans is a dangerous possibility for the industry.

Within the current EU legislation there are no viable pathways to remove ingredients from the banned list without rewriting the entire regulation. In the corresponding Food and Cosmetic Regulations, there are pathways for the industry to submit data and have an ingredient removed from the banned list once sufficient proof of safety is provided. We feel this mechanism for appeal must be a part of any ink regulation proposed by QLD Health.

Findings from consultations

The ATG, the PTAA, and the Department's working Group collectively identified that input from overseas manufacturers was crucial to building workable legislation. The Working Group and the ATG separately undertook their own consultations with a number of overseas manufacturers. Concerningly, our consultation led us to a far more skeptical position than the departments working group on the feasibility of the proposed standard. We also have concerns that some major overseas manufacturers in the Australian market were not consulted.

Most manufacturers state that compliance with ResAP 2020 is simply unachievable due to the extensive list of banned substances, while others state that the costs of compliance is prohibitive to viable business. After a two year lead time on the implementation of Resap 2020, there are only two manufacturers currently with a compliant product range on the European market, one of which offers an incomplete colour palette. Both hold grave concerns for how the regulations can evolve, and do not see their current product offering as a final solution to the problems at hand.

It is highly noteworthy that in our consultations with the single manufacturer with a complete product range of EU-compliant inks the manufacturer was highly critical of the regulations, despite the potential for a market monopoly in Europe, and was critical of some of their own compliant products as compared to their original formulations when discussing fitness for purpose. This manufacturer has a thorough understanding of the EU regulations, and is a strong supporter of data-driven risk assessment. Furthermore, all manufacturers we consulted with were skeptical of how an Australia-specific compliance model could be workable, and noted that this was NOT discussed in any detail in their consultations with the QLD Health working group.

The supply crisis created by the EU bans has created renewed awareness among many industry stakeholders of the need to move forward in addressing the issues around the lack of toxicological data. Chemists and toxicologists attached to ink manufacturers consistently raised issues around the lack of standardisation in laboratory testing regimes across different jurisdictions carrying the potential for variations in findings from one laboratory to another.

Concerns regarding the lack of data around new alternative ingredients which are now being brought to market was also a consistent theme with all industry participants. Resap2020 is directly responsible for a number of currently industry-favoured pigments, with insufficient yet promising clinical safety data, to be banned in favour of alternatives that have no data, and no history of usage in tattooing.

Impact of current bans on end users (tattoo artists and tattoo clients)

Even after a two year lead time on implementation of ResAP 2020, tattoo artists in the EU currently have very limited or no access to compliant inks. They are also concerned that if adequate supply of compliant ink is established, they may not be fit for purpose or safe. Despite the lack of clinical data for reputable tattoo inks in use for the last 20 years, there is the lived experience of a huge mass of clients that does not support claims there is a risk to public health.

Due to a lack of communication with the tattoo industry by regulators in the EU, tattoo artists have also been left in constant uncertainty with regards to their obligations under the new legislation in their country of origin.

Tattoo artists will continue to be economically impacted by having to bear a sizeable amount of the increased costs of ink manufacturing. But more alarmingly, if manufacturers cannot reasonably comply with regulations, it is the regulatory model that is effectively banning the use of tattoo ink.

The main purpose of the EU regulations was to provide a harmonised level of protection for human health within the European Union. However, by only providing a negative list of tattoo ingredients to be ruled out for use in tattooing, there is no guarantee that the alternative tattoo ingredients will be safer for the end users. In fact, there is great and valid concern that the new regulations will lead the tattoo industry to trial the use of potentially less well known pigments and additives with less predictable outcome. This has huge potential to lead the public to a loss of confidence in the professional tattoo industry where before it was high due to no or extremely low incidence of negative outcomes relating to ink.

We can all be certain that due to the continued high demand for tattoo work, there will be clients who voluntarily and knowingly getting tattooed by non-compliant ink in Europe.

Moving forward

Work has already begun globally linking ink manufacturers, tattoo artists, and academia to facilitate conferences that identify and discuss many of the issues outlined in this report. Some manufacturers are now undertaking an analysis of how to obtain the data that will inform a more reasonable risk assessment of tattoo ink ingredients.

In their contributions to EU Legislation, both the EC Risk Assessment Committee (RAC) and Scientific Committee for Consumer Products (SEAC) opinion documents discuss the specific kinds of experiments that are needed to approve Blue .15 and Green .7 for use in tattoo and PMU inks. From these dossiers we can establish that, with the exception of skin irritation and allergic reactions, there is no documented evidence to support the idea that tattooing leads to incidence of major disease. Still, when it comes to placing a commercial product on the market, it is understood that regulators place the burden of proof for safe use upon the industry.

Achieving this is complicated by the fact that there is no established risk assessment models or guidelines to specifically assess the risk of systemic exposure to potentially toxic chemical as a result of tattooing.

It is understood that without these established risk assessment guidelines, regulatory bodies are free to apply their own risk assessment guidelines, leading to the most stringent and over-reaching restrictions on the industry.

Many industry stakeholders agree that they now need to discuss the funding of reliable and validated research projects that would accomplish two main goals:

1. fill in the incomplete data sets for chemicals used in tattoo inks
2. develop industry standards for risk assessment of chemicals used for tattooing

Certain pigments and chemicals are banned from being used in tattooing not because they have been proven to be toxic in tattooing, but simply because their hazard analysis studies are incomplete. This is the case for pigments Blue 15 and Green 7 where the only studies referenced relate to the pigments' uses in hair dying and the vastly higher concentrations required for that usage.

The ATG are aware that preliminary data obtained by one major manufacturer on mutagenicity, carcinogenicity, and reproductive toxicity show low or no hazard for these pigments. Only a few simple model systems were used for these studies and long term studies are needed. The evidence from these initial studies should however be seriously considered by regulators as early indicators around the safety of tattoo inks.

The development of standards from within industry for risk assessment may take some time and requires additional funding. Many stakeholders see this as the way forward. However, because there is no standard established for the risk assessment of chemicals for tattooing, the consensus within the European regulatory community is that all chemicals should be treated based on their overall hazard classification as established by published data.

The regulatory community assumes that any chemical which shows toxicity during other established exposure pathways (oral, dermal, inhalation) is expected to exhibit equal or worse toxicity when injected in the skin during the tattoo process.

This approach fails to take into account that the toxicity and hazard of a substance is largely dictated by the exposure route, mechanism of action, and quantity. Tattooing offers a unique exposure route for chemicals into the human body. As such, chemical safety in tattooing needs to be investigated using model systems that more accurately reflect this exposure route and relevant chemical concentrations.

Models systems will need to be developed to assess chemical safety with respect to the following hazard categories:

- Dermal irritation, sensitization, and corrosion
- Genotoxicity
- Carcinogenicity
- Reproductive Toxicity

Once the data has been compiled the following options for addressing the current bans and the pending Blue .15 and Green .7 ban exist:

- Submit data to the European Commission directly (standard method). Submit an Annexx XV dossier. This would need to be reviewed by Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC).
- Submit data to the Scientific Committee for Consumer Products (SSCP).

  note - the SSCP originally banned Blue .15 and Green .7 for use in hair dyes. The ban came because no one in the hair and beauty industry wanted to test these pigments for links to cancer.

The types of studies needed according to ECHA and SSCP (Highlighted in orange are the studies already done for Blue 15 which showed no toxicity).

Genotoxicity/Mutagenicity

Standard battery of *in vitro* assays suggested:

- Ames test (or Bacterial Reverse Mutation Assay, OECD 471)
- *In vitro* mammalian cell gene mutation test (Mouse lymphoma assay, OECD 490, is preferred to CHO HGPRT test according to SSCP).
- *In vitro* test structural chromosome damage (Mammalian Chromosome Aberration Test)
- Test for aneuploidy (*In vitro* micronucleus test, OECD 8)
- SSCP also suggests an additional test category (DNA Damanage and Repair, OECD 482).

The need for *in vivo* tests will depend on the results of the *in vitro* tests. These are the preferred tests:

- Mammalian Erythroccyte Micronuleus Test (OECD 474)
- Mammalian Bone Marrow Chromosome Abberation Test (OECD 475)
- Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells *in vivo* (OECD 486)

In vitro and *in vivo* Single Cell Gel/Comet Assay Carcinogenicity

- There is only one published study on the carcinogenicity of Pigment Blue 15. 20 mice were injected subcutaneously with 0.5 mg pigment once a week for 34 weeks. However, the study design does not meet the CLP guidelines.
- There are some substitution tests to not have to do animal studies
- *In vitro* Syrian Hamster Embryo (SHE) Cell Transformation Assay (OECD TG494)

Reproductive Toxicology

- There is only one published study for Blue 15 (Reproduction/Developmental Toxicity Screening Test, OECD 421). However, according to ECHA, oral and dermal studies are not ideal.
- Subcutaneous reproductive toxicity is needed.

Conclusion

Governments globally are progressively moving to protect both citizens and the environment from the effects of harmful chemicals and to ensure health and safety. The move by the QLD Health Department to develop a standard for the use of inks within the tattoo and PMU industry in Australia is understood in this context.

Whilst the concern for the safety and wellbeing of people who choose to get tattooed is of the upmost importance to tattoo artists and manufacturers globally, it is also our perspective that any move by Government and its departments to standardise and regulate the industry and its working practices and technologies must be based only on reliable and verified evidence.

As this evidence does not exist it is the opinion of our organisation that the department's funds would be better utilised by assisting the industry in developing the models and/or research that is now needed to obtain the data that will factually inform any potential future standard. Given the lack of evidence of any large public health issue, it is reasonable that time be allowed for the gathering of data, rather than hastily implementing legislation that shows clear signs of being unworkable for industry.

The Australian tattoo industry is only a very small market for the overseas ink manufacturers upon whom we are dependant. Legalisation that is difficult or unworkable for these companies will result in them withdrawing from our market. There currently exists in Europe, a situation where ink that is compliant with the latest regulations is scarce or unavailable. This is the case despite over two years of lead time for manufacturers to produce new ranges of compliant products, thus proving how unworkable these measures currently are, even in such a massive and profitable market. The EU REACH regulation was not developed with any serious consultation with the industry. There are clear failings within the regulation as far as workability for industry, and the Resap2020 is now solely and directly causing the ink supply issues in the EU at this time.

If there is to be regulation of tattoo ink in Australia, the ATG recognises the need to align regulations of our small Australian market with those of much larger functioning markets. The model the Department is trying to emulate cannot be described as "functional" at this stage. Furthermore, the compliance model by which any ink regulation is to be policed in Australia must be developed in consultation with manufacturers. It must be workable and streamlined for them to work with because in itself it can be a prohibitive deterrent to operating in our small Australian market, independent of any issues around producing ink that would meet an ink standard. A realistic and achievable compliance model is crucial to the workability of the overall regulation. However, it is evident from the ATG's own consultation with ink manufacturers that compliance was not adequately covered in their discussions with the Department's working group.

It is the lived experience of tattoo artists in QLD that State Government departments have previously implement regulatory requirements without evidence for their need, producing negative impacts for the sustainability and future of our art form, while not necessarily producing the intended improvements in public health and safety.

The ATG remain committed to working with Governments to ensure that any existing or future regulation has the best interests of both the industry and the broader community in mind.

Based on the information supplied within this report our organisation does not support the further development of an ink standard based on the EU Regulations and bans at this time.

solidarity, unity, to respect and protect

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