



CTL® GMBH
Chemical Technological Laboratory

CTL Bielefeld GmbH

Dr. rer. nat. Gerald Prior

March 2017
ECTP Regensburg

European Commission Summary of
Analytical Methods,
Report EUR 27394 EN.

Death or Glory for ResAP(2008) I?

Dr. rer. nat. Gerald Prior

This speech is not about
chemistry so lean back, listen
carefully and just get your
logic caps on

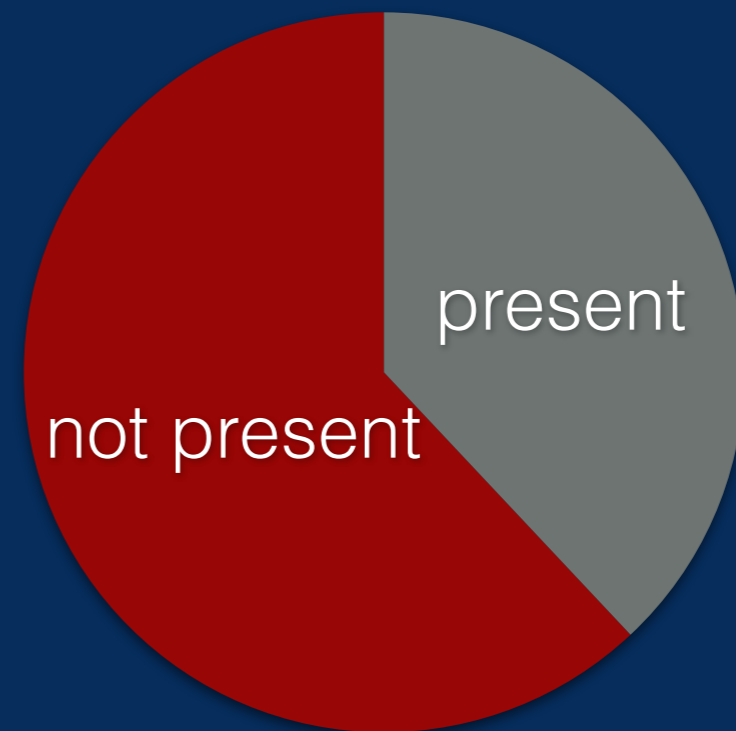
What is the position of ResAP(2008) I at present?

ResAP(2008) I is widely accepted by tattoo and PMU ink manufacturers as a minimum requirement. It is further the basis for several national laws

To get something like ResAP(2008) I accepted by the industry should not be taken for granted and this should, therefore, be respected by all involved

At a meeting of EU Member States and representatives from the Council of Europe in November 2014 one goal was to collect details of analytical methods being used by authorities in the EU for Tattoo and PMU inks and another was to publish the results as a book

But: less than 40% of EU Member States were present at the meeting



Recap:

There are 4 analytical parts in ResAP(2008) I:

1. Amines
2. Various Colourants/Dyes
3. Metals as Impurities
4. Polycyclic aromatic hydrocarbons (PAHs)

Outcome of the Meeting:

46 different methods were documented for the analysis of the chemicals in the 4 analytical parts of ResAP(2008) I

25 different methods are in use for the analysis of metals

The 25 methods range from extraction with gastric fluid to digestion with strong acids under high pressure or in a microwave system

Variation in results for Nickel due to different work-up:

Microwave digestion

Gastric Fluid



positive

negative



positive

positive



positive

negative

Variation in results for Nickel due to different work-up:

Iron Oxide based
Tattoo/PMU Ink



Microwave digestion

positive

Gastric Fluid

mainly
negative

only positive if
nickel is soluble

These are just a few variations possible due to different work-up methods showing different results

The broad range in work-up methods ultimately leads to a broad variation in the achieved results in different EU countries

Consequences:

Manufacturers and importers are having different legal problems with one and the same ink in different EU countries

Another Problem: Rapex Notifications

RAPEX is the EU rapid alert system for dangerous products:

For the majority of products being notified in the RAPEX System, e.g. toys, textiles, **EU harmonised** analytical methods are being used.

In practice this means all EU Member States achieve the same results if they test the same product

But there are no harmonised methods for Tattoo/PMU Inks in the EU

As EU Member States use different methods they
would achieve different results.

Are Rapex notifications valid for all EU Member
States?

Is it correct and legal to want to withdraw products
from other EU countries due to the analysis
conducted in one EU country?

Should you be allowed to use the Rapex System
if you are using local analytical methods?

Just one more thing:

Not mentioned in the report published by the EU are the different limits set in different EU countries.

Example:

Content of Nickel in an ink when using work-up method microwave digestion

≈ 6 mg/kg

Germany

forbidden

The Netherlands

permitted

The European Commission Summary of Analytical Methods, Report EUR 27394 EN is not only a summary of the different methods being used in various EU Member States

It is also a documentation of the catastrophic and unclear situation within the EU

It is hard to believe that the EU can justly be called a „common market“ in this field if there is no common denominator

Free trade, one of the basic rights in the EU is not possible

There are clearly **trade borders** within the EU

Back to the initial question - Is this death or glory for ResAP(2008)1?

Extremely positive:

This resolution has been accepted by the industry as a minimum requirement - there was never any real acceptance of ResAP(2003)2 due to several reasons. Ink manufacturers have been improving their products for over 20 years

It is seldom that such documents find great acceptance in industry

Customer protection, the ultimate goal, is well reflected in this document

It makes sense to those working in the tattoo/PMU industry

The industry was thankful for this document

This could have been the glory for the resolution - but it is not

What is the present situation?

- Disbelief that there will ever be harmonised analytical methods in the EU
- A lack of respect for the local authorities and the EU
- A feeling of not being involved or having any say in the matter
- A feeling of unconsciousness

The abundance of testing methods, each leading to different results, really makes it impossible for any manufacturer to fulfil the requirements in all EU Member States - this is leading to resignation

The increasing number of legal procedures are making business unnecessarily tedious and complicated.

They could have been avoided.

Some of the reports from local authorities are not even up to GLP standard and a disgrace for those working in analytical labs - but they still have to be tackled on a legal basis costing time and money.

The authorities and the EU are slowly losing contact with the industry as these are losing interest and disbelief in a real solution for them is increasing. Once you get the feeling nobody is listening you stop talking - this is a dangerous situation.

The Resolution is not dead yet

It just has a terminal disease

Time is running short before total resignation in the industry sets in

There are always 2 sides to a story - besides what has been mentioned there are also the Tattoo/PMU Ink manufacturers and the tattoo artists

The statistics on tattooing should be interpreted in a different manner:

View 1. From the perspective of the tattoo industry:

12% of people in the EU have at least one tattoo

This means **61 million** people in the EU have at least one tattoo - **sounds good** for the tattoo industry

As a comparison:

Italy has almost 60 million inhabitants

There are 46 million cars in Germany

View 2 - A look at these numbers from a different perspective:

88% of people in the EU do NOT have a tattoo

451 million people neither have a tattoo nor know anything about the industry

This is approx. 9 out of 10 people who are:

- not involved in the topic
- the industry is not talking to
- have never seen a tattoo studio from the inside
- have no idea of what is going on
- some in this group of 9 out of 10 still think people with a tattoo are not normal or rogues or rascals

It is high time the Tattoo/PMU Industry and the
representing associations start talking to the
the 9 out of 10 people without a tattoo or
PMU

These people are important and making
decisions which will shape the future of the
industry

And never forget:

People fear things they know nothing about

Timescale and history for AZO colorants in Textiles:

1895: First mention of Bladder Cancer due to AZO Dyes(1)

1994: Ban of certain AZO Dyes in textiles in Germany (2)

1995: Method for the analysis of AZO Dyes in Textiles (CTL), (3)

1996: Publication in the media of underwear containing Benzidine based dyes (4) - Breast Cancer from Bras?

1998: Official Method for testing of AZO-Dyes in Germany (5)
- a method which does not show the most dangerous benzidine amines! Reason: Moaning from the industry?

2002: EU Ban on certain AZO Dyes (6)

2003: (December), EU Method Part I for detection of certain AZO colorants (7)

ONLY 10 years to get everything sorted out

Timescale for Tattoo Inks and PMU

1998: Extensive Media Coverage of problematic ingredients in Tattoo Inks - Öko-Test, K-Tipp, Television ... Testing Lab CTL

2003: ResAP(2003)2 - with a request to be harmonised at European level

2008: ResAP(2008)1 - Recommends Laws and Regulations in the EU Member States

2009: German „Tätowiermittelverordnung“ - Basically ResAP(2008)1 with small amendments

2013: Inauguration ESTP Copenhagen

2015: 2nd meeting ESTP, Bruges

2017: 3rd meeting of ESTP, Regensburg

Since ResAP(2003)2 14 years have passed.

Since the first large scale media coverage 19 years have passed. Progression?

My appeal to the Tattoo/PMU Industry:

It is high time the tattoo and PMU industry get themselves organized

Millions of people are working in the industry and it is a billion dollar business.

Both industries do not have a competent person representing them at EU level for this topic - (lobby)

The organizations representing the tattoo industry and tattoo studios and artists must do more for their members

Many things have improved in the past 20 years, even before any legislation - make this public

Do something positive

If you just lean back and wait for doomsday then doomsday will come

My appeal to all:

- Get together, throw all aversions overboard.
- Go back to the initial goal: **the safety of the consumer**
- Stop fighting each other, whether competitor or not.
- Local authorities all across the EU should get together and try to harmonise analytical methods.
- If this is not done then the chance of the authorities losing their grasp on the industry will fade. Ink samples will have to be purchased via eBay - they are all fakes anyway.
- If the speed of progression of this topic does not increase the number of inks bought on the internet will increase - there is no chance of checking these for dangerous substances. **The loser will be the consumer.**

A summary of what it should be

**a man's gotta do
what a man's gotta do**

A summary of the actual situation

**a man's gotta do
what a man's gotta do**

**... his wife will tell him
what that is**

The tattoo/PMU industry should become more aware of their future

- it is no longer only about making lovely portraits on the skin, making ladies look better or giving them an improved complexion
- it is not only about improved hygiene in the studios
- **it is about the use and misuse of chemicals.**
- is the industry prepared for this challenge?

Please start thinking how you want to
shape your future

Thank You For Your Attention

Lit.:

- (1) Rehn, L., Blasengeschwülste bei Fuchsin-Arbeitern, Arch. Klein. Chir., 50, 588-600 (1895)
- (2) Zweite Verordnung zur Änderung der Bedarfsgegenständeverordnung, BGB (I), 1994
- (3) K. Friedrichs, H.-D. Winkler, G. Prior, GIT Fachs. Lab., 10, 901 (1995)
- (4) Öko-Test, 2/1996
- (5) Official German Method for the Analysis of AZO-Dyes, § 35 LMBG 82.02-2 (1998)
- (6) EU AZO Colorants Directive 2002/61/EC
- (7) EU Method for the determination of certain aromatic amines derived from azo colorants, EN 14362-1, 12(2003)