

FDA's Tattoo Ink Survey, Inspection and Sampling 2012 to Present

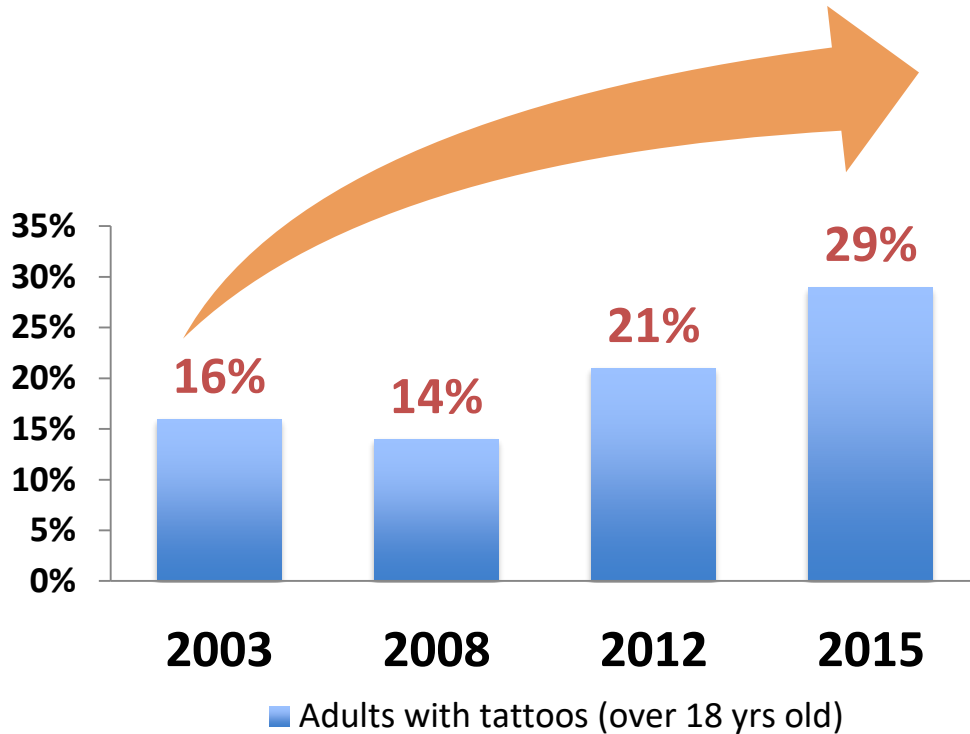
Kathleen Lewis, J.D., Senior Advisor
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition
US FDA, College Park, MD

Outline



- **FDA's Regulatory Authority over Tattoo Inks**
- **Risks, Outbreaks, Adverse Events, and Recalls**
- **FDA's Tattoo Ink Research Projects and Results**
- **Regulatory Actions and Public Health Impacts**
- **Conclusions and Future Direction**

Tattooing in the U.S. rising!



- 2015 Harris Poll showed that about 29% of Americans have at least one tattoo.
- Tattoos are more prevalent among younger Americans, with nearly 50% of millennials.

Tattoos & Permanent Makeup Jurisdiction

Cosmetics

- Any product intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. (FD&C Act, sec. 201(i))

Tattoo Inks

- **“Tattoo inks”** sold and used in the US are considered as **“Cosmetics”**. As such they fall under **FDA jurisdiction**.

Practice of Tattooing

- The practice of tattooing is regulated by **State and Local jurisdictions**, which focus on the safe practices at the tattoo parlors.



Types of Risks Related to Tattoos



- Infections and inflammatory reactions
- Swelling, cracking, peeling, blistering, scarring
- Granulomas, keloids, and systemic sarcoidosis
- Allergic reactions (acute/delayed)
- Pruritis, local or generalized, acute or chronic
- Photosensitivity in tattooed areas
- Disfigurement
- Others



Case Report: Tattoo-Associated Nontuberculous Mycobacterial Skin Infections – Multiple States, 2011-2012

FDA



FDA

- **Oct 2011** - A person (Rochester, New York), presented with a persistent papular rash beginning 1 week after being tattooed
- **Jan 2012** - The Monroe County Dept. of Public Health (NY) investigated an outbreak:
 - *M. chelonae* was isolated from a skin biopsy
 - 14 confirmed with *M. chelonae* out of a total of 19 infections
 - Company A prediluted gray ink was used
 - *M. chelonae* was isolated from tissue specimens, one opened and one unopened bottle of company A prediluted gray ink (indistinguishable).
 - Water and environmental samples: negative for *M. chelonae*.
- **Feb 2012** - CDC disseminated an **Epi-X public health alert**:
 - Identified additional tattoo-associated NTM skin infections from three states (**Washington, Iowa, and Colorado**).

Nontuberculous Mycobacterium (NTM)

NTM species (e.g., *M. abscessus* and *M. chelonae*):

- Environmental mycobacteria (found in water)
- NTM contamination can occur:
 - During the ink manufacturing process as a result of using contaminated raw materials
 - As a result of dilution of inks with nonsterile water by the tattoo artist before use.



Tattoo-associated NTM infections:

- Range from mild inflammation to severe abscesses requiring extensive and multiple surgical debridement
- Difficult to treat and can require a minimum of 4 months of treatment with a combination of two or more antibiotics



Tattoo and Permanent Makeup (PMU) Ink Recalls ,2003 – 2015 (2017 -19 recalls discussed later)

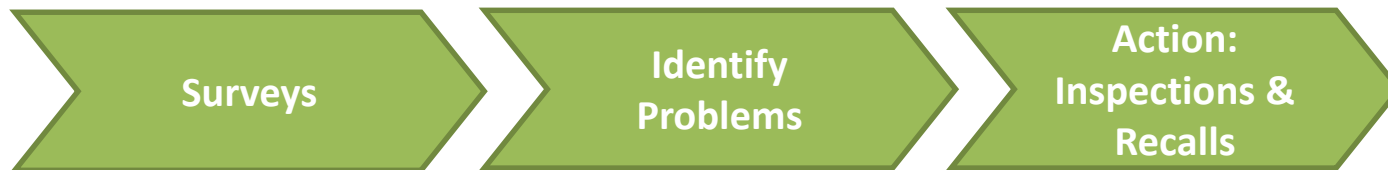


Brand	Color	Ink Type	Year of Recall	Issues	Source of Issues
1	All colors	PMU	2003, 2004	Allergic	Benzimidazolone was suspected as a cause of allergic reaction but not confirmed
2	Black	Tattoo	2004	Micro	<i>Pseudomonas aeruginosa</i> Mold: <i>Acremonium</i> spp.
3	Black	Tattoo	2011	Micro	NTM: <i>Mycobacterium abcessus</i> , <i>M. chelonae</i>
4	Grey washes	Tattoo	2012	Micro	NTM: <i>Mycobacterium chelonae</i>
5	Black	Tattoo	2014	Micro	<i>Nocardia. farcinica</i> and <i>Nocardia</i> spp.
6	All colors	Tattoo	2014	Micro	Multiple Microbes: <i>Sphingomonas paucimobilis</i> , <i>Bacillus</i> spp.
7	Grey washes	Tattoo	2015	Micro	NTM: <i>M. chelonae</i> , Mold: <i>Penicillium</i> spp., and <i>Cryptococcus albidus</i>

*NTM: nontuberculous mycobacterium

FDA's Tattoo & PMU Ink Research

- 1) Conduct multiple surveys of tattoo & PMU inks on the US market, for the prevalence of microbial contamination
- 2) Developing effective detection methodologies for microbial contamination of tattoo & PMU inks



Tattoo Ink Survey Results

Years / Lab	Number of Samples	Number Positive	BAM 23* Non-Compliant
2013-2015, private	75	32 (43%)	12 (16%)
2015-2017, FDA	85	42 (49%)	16 (18%)
2017-2018, FDA	41	18 (44%)	10 (24%)
Total	201	92 (46%)	38 (19%)

*Samples were evaluated following Bacteria Analytical Manual, Chapter 23

What we learned from the surveys

- ❑ A large portion of tattoo and PMU inks available on the US market that were assessed were found to be contaminated with microorganisms
- ❑ Some of the inks contained high levels of microorganisms, more than 1000 CFU/mL (e. g., 16 out of 42 contaminated tattoo inks)
- ❑ Some of microorganisms isolated from the inks are opportunistic human pathogens

Ongoing Tattoo Ink Project

- A collaborative project with NCTR to assess microbial burden in tattoo ink
- Expand to include ink intended for permanent makeup and microblading procedures
- Products intended for use in the eye area

Agency and Public Health Impacts

- Tattoo ink surveys are used to help assess prevalence of the contaminated inks on the US market
- The survey results provide scientific evidence to develop policies
- Helps FDA undertake appropriate enforcement activities in order to remove unsafe products from the market
- Recent tattoo ink recalls protect consumers from potentially serious adverse events caused by contaminated inks
- FDA's tattoo ink surveys and regulatory actions increase awareness in the tattoo industry and consumers for microbiological safety

Tattoo Ink Recalls – FDA Initiated (2017-2019)



Brands	Location	Recall Initiation Date	Colors	Issues	Source of Issues
1	TX	11/14/2017	Blue, Green, Orange, Purple	Micro	Multiple Microorganisms
2	CA	12/12/2017	Lining Black	Micro	<i>Bacillus altitudinis</i> , <i>Paenibacillus</i> spp.
3	FL	5/15/2018	Orange	Micro	<i>Bacillus pumilus</i> and <i>Bacillus licheniformis</i>
4	NJ	6/26/2018	Red, Blue	Micro	<i>Bacillus halosaccharovorans</i> , <i>Brachybacterium conglomeratum</i> , <i>Pseudomonas andersonii</i> , <i>P. balearica</i> .
5	MI	9/25/2018	Red, Blue	Micro	<i>Bacillus cohnii</i> , <i>Pseudomonas andersonii</i> , <i>Lysinibacillus fusiformis</i>
6	NY	2/22/2019	Black	Micro	<i>Pseudomonas aeruginosa</i> , <i>Brevibacillus choshinensis</i> , <i>Clostridium butyricum/clostridioforme</i> , others
7	FL	3/12/2019	Black	Micro	<i>Bacillus cereus</i>
8	FL	3/20/2019	Red	Micro	<i>Clostridium clostridioforme</i> , <i>C. ramosum</i> & <i>Clostridium</i> spp., others.



Regulatory Action: Tattoo Inspection and Sampling

- Focus on firms identified during recall investigations
- 12 firms inspected
- 61 samples tested
- 31 samples positive (51%)
- 7 of 31 samples recalled (23%)

“Sterile” Tattoo Ink

- 31 samples were labelled “sterile”
- 15 tattoo inks labelled as “sterile” were found to contain microorganisms (48%)
- Manufacturers not following a validated procedure

Inspection Conclusions

- Industry not addressing contamination issues
- “Sterilization” not validated or controlled
- Gamma levels used only lethal to vegetative bacteria, not spores.
- A standard for tattoo ink sterilization is needed.

Current Situation

- Contamination is found in all colors, not just black and graywash
- High Plate counts or presence of known pathogens is “adulteration”
- Sterility labeling and sterilization methods are a concern
- If labelled “Sterile” it must be free of microorganisms
- Inks that contain microorganisms, but are below BAM 23 limits are misbranded.

Future Direction

Safety

- Additional , focused assignments
- Monitoring Adverse Events
- Determine health effects of endotoxin

Methods

- NTM method (Multi-lab validation)
- Endotoxin Assay
- Sterility testing

Guidelines/Policies

- Guidance for Industry
- Policy Development

Collaboration

- Working with Local/State Jurisdiction
- Develop sterilization protocol for tattoo ink with industry/AFDO

Education

- Education for tattoo artists, public, and health professionals

Questions?



U.S. FOOD & DRUG
ADMINISTRATION

Thank you!