Insanitary Conditions and the Risk of Microbial Contamination in Tattoo Inks

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Nearly one-third of Americans have at least one tattoo,[1] but tattoos remain subject to a patchwork of local, state, and federal regulation that has historically failed to prevent consumer injuries from contaminated tattoo ink. After years of warning letters, safety alerts, and recalls citing microbial contamination in tattoo inks, in October 2024, FDA finalized its prior draft guidance titled *Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination* (the "**Guidance**"), to help tattoo ink manufacturers and distributors recognize and prevent insanitary conditions that may potentially render tattoo inks injurious to health.[2]

How does the FDA regulate tattoo inks?

FDA regulates tattoo inks, as cosmetics under the Food, Drug & Cosmetic Act (FDCA) because they are "intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance." However, FDA does not have the authority to regulate the practices of tattoo parlors or individual tattoo artists.

Why is the contamination of tattoo inks a concern for FDA?

After receiving multiple reports of adverse events caused by tattoo inks, FDA tested sealed tattoo inks in the United States and found many to be contaminated with microbes. As a result, in 2019, FDA alerted consumers, tattoo artists, and retailers to the potential for serious injury from contaminated tattoo ink and issued several related warning letters. There have also been 18 recalls of contaminated tattoo ink between 2003-2024.

Since tattoo inks are inserted below the epidermis, they bypass the body's primary physical barrier against pathogens, which makes their potential for harm higher than that of topical cosmetics. As a result, contamination introduced into tattoo inks from insanitary conditions can cause serious infections and potentially life-threatening complications, especially in individuals who are immunocompromised or have other underlying medical conditions. For this reason, FDA's aim in issuing the Guidance is to assist tattoo ink manufacturers and distributors in recognizing situations that may put their products at risk of adulteration that may be injurious to consumer health.

When are tattoo inks considered adulterated?

A cosmetic is adulterated under the FDCA if, in relevant part, it:

- Bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in its labeling;
- Consists in whole or in part of any filthy, putrid, or decomposed substance;
- Is prepared, packed, or held under insanitary conditions such that it may have become contaminated with filth or rendered injurious to health;
- Is placed in a container composed, in whole or in part, of any poisonous or deleterious substance which may render the cosmetic injurious to health; or
- Is manufactured or processed under conditions that do not meet good manufacturing requirements.[3]

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[1] According to Pew Research Center's July 2023 survey of 8,480 adults.

[2] *See Guidance for Industry: Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination*, FDA (Oct. 2024).

[3] 21 U.S.C. 361(a–d, f).

How can manufacturers and distributors of tattoo inks identify insanitary conditions?

Manufacturers and distributors should be on high alert during the manufacturing or preparation of tattoo inks for any circumstances or occurrences that could cause products to be contaminated with microorganisms. For example, the Guidance highlights the following as insanitary conditions of which tattoo-ink suppliers should be aware:

- Preparation or packing of tattoo inks in facilities not suitable for such activities (e.g., product preparation in carpeted areas that are difficult to clean);
- Ink, ink components, and primary packaging containers held uncovered (e.g., near air ducts), resulting in potential exposure to airborne microbial contaminants and filth;
- Ink and ink components held or mixed in uncovered containers or using containers or instruments that have not been properly cleaned and sanitized;
- Personnel lacking the appropriate attire (e.g., failure to use hairnets, lab coats, aprons, gowns, masks, or gloves);
- Lack of soap, water, and signage in employee restrooms directing employees to wash their hands;
- Disposal of used personal protective clothing (e.g., gloves, masks, gowns, etc.) in the production area; and
- Storage of packaged products in locations that expose them to contamination (e.g., near heavy buildup of dust and debris).

What does FDA recommend manufacturers do to prevent insanitary conditions?

FDA recommends that manufacturers establish good manufacturing practices (GMPs) and take the following measures to safeguard their tattoo ink products against microbial contamination:

- Test ink and ink components for microbial contamination or, alternatively, purchase materials from suppliers that test for microbial contamination;
- Discard any production materials that contain or may contain microorganisms of the types or at levels that may harm consumers if present in the finished product;
- Examine the manufacturing process, itself, to ensure it does not introduce microbial contamination (e.g., conduct adequate cleaning and sanitization of manufacturing equipment; provide personal protective equipment to employees; etc.);
- Ensure that the sterilization methods used are validated;
- Ensure that any cleaning or sterilization method used does not adulterate the finished product (e.g., confirm that irradiation does not cause the formation of poisonous or deleterious byproducts in the ink);
- Examine manufacturing and validation procedures to determine the cause of any contamination in the final product; and
- Take corrective actions to prevent the release of any final product for which microbiological testing indicates the presence of microorganisms of a type or at a level that may be harmful to consumers.

What else should manufacturers and distributors of tattoo inks know about the Guidance?

FDA's recently finalized Guidance embodies the Agency's current views on how regulated industry should work to achieve compliance. It is still, in its current form, largely a set of recommendations. However, tattoo ink manufacturers should take heed of FDA's recommendation to examine existing systems and processes to align with established cosmetics

production standards, such as International Organization for Standardization (ISO) 22716[4] (many of which were incorporated into FDA's June 2013 Draft Guidance outlining (voluntary) good manufacturing practices (GMPs) for cosmetics), as FDA will soon be issuing *mandatory* cosmetic GMPs under the increased authority granted to the Agency by the Modernization of Cosmetics Regulation Act (MoCRA). The Guidance can, thus, be viewed as an interim step that manufacturers and distributors should consider to assess whether any GMPs should be implemented and what, if any, immediate changes may be needed to (1) prevent microbial contamination and (2) prepare for increased FDA oversight of, and stricter standards for, the manufacturing of tattoo inks under MoCRA.

[4] *Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices.*