

**TAB 4 Excerpt of Comments from the SDA/CTFA Industry
Coalition Regarding the Impact of the 1994 TFM on Public
Health and Industry (75N-183H; C12, volume 1)**

1. THE IMPACT OF FDA'S PROPOSED TFM

FDA's proposed elimination of the antimicrobial (hand and body) soap category for use by the general public will have deleterious effects on an approximately \$1.0 billion industry and consumers who regularly use such products. A variety of upstream and downstream industries ranging from the suppliers of antimicrobial active ingredients and raw materials to the manufacturers of end-use products also will be negatively impacted by this rulemaking. A discussion of the areas negatively impacted by this rulemaking are presented below.

2. PUBLIC HEALTH IMPACT

FDA's elimination of the antimicrobial soap category as stated in the current TFM will result in stress at both the micro (i.e., individual) and macro (societal) levels. The elimination of the antimicrobial soap category will create uncertainty as to whether current infection and disease levels will remain stable or escalate due to the elimination of these products for consumer uses. The preventive nature of these products, as presented in the Healthcare Continuum, suggests that it may be reasonable to predict that the health risks of disease and infections within various population groups (e.g., consumers, casual occupational, and food handlers) will increase as antimicrobial hand and body washes are eliminated from the market. In order to understand the magnitude of effects potentially impacted by this rulemaking, a snapshot of various infection and disease statistics for the United States follows.

Recent data from the Center for Infectious Diseases and the Center for Prevention Services, Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics indicate that more than 742 million infections occur annually in the United States, resulting in approximately 195,000 deaths (Bennett et al., 1987). Such infections result in more than \$17 billion annually in direct costs, not including cost of deaths, lost wages and productivity, reactions to treatment, and other indirect costs. Days lost (i.e., disability days) from work, school, preschool, or housekeeping from such infections total over 1.9 billion for all cases. Hospital days resulting from such infections have been estimated at over 42 million.

Some of the major contributors to these negative impacts, as assessed from the CDC survey data (by infection group), are presented in Table 1.

Table 1. Annual Impacts of Certain Major Infections by Category, U.S. CDC Survey Data (1987)

INFECTION GROUP	DEATHS	INCIDENCE
Bacterial	68,200	36,026,000
Cutaneous	11,800	53,534,000
Day care-related	2,600	3,713,000
Enteric	10,800	25,227,000
Foodborne	9,100	6,496,000
Fungi	1,200	18,027,000
Nosocomial	51,100	4,100,000

The annual monetary costs of infectious diseases derive largely from the cost of hospital care. Nosocomial infections themselves account for the greatest direct costs; they complicate the course of recovery among hospitalized patients, increase the severity of illness, increase mortality, or prolong hospital stay, thus adding substantially to the consumption of expensive hospital services. Indeed, Haley (1985) estimated that the incidence of nosocomial infections in the U.S. was nearly 2 million cases, at a cost of almost \$4.5 billion (1992 dollars).

Other data from a recent CDC review of several national surveillance systems (Federal Register, 1995) indicate that 7 to 33 million cases of foodborne illnesses occur each year in the United States. 7,000 to 10,000 deaths result from these illnesses annually. Seventeen percent of these deaths involve meat and poultry products contaminated by pathogenic organisms. Some of these deaths are preventable with the appropriate precautions including handwashing with an efficacious product. These numbers are suspected to be inaccurately low due to the voluntary nature of the programs and the innumerable cases that go undiagnosed and unreported.

The 1995 CDC report also states that the medical costs associated with all foodborne illnesses in the U.S. in 1993 were between \$5.6 and \$9.4 billion. Of this estimate, meat and poultry products contributed approximately \$4.5 to \$7.5 billion dollars (i.e., 80 percent). Medical costs have been defined by

the USDA (FCN, 1995) as expenses associated with the treatment of the illness such as physician and hospital services, supplies, medication, long-term care or rehabilitation, and special procedures required for specific foodborne illnesses.

As presented in Table 1 and in the Healthcare Continuum, skin infections due to Gram positive organisms are also a common and significant public health problem in the United States. Data from the National Disease and Therapeutic Index (NDTI) indicate that on average from 1992 to 1994 there were approximately two million diagnostic visits per year to dermatologists, pediatricians, and general or family practitioners for impetigo, pyoderma, and carbuncles/furuncles. Data from another study indicate that approximately 5.5 million office visits per year are due to skin infections (Schachner et al., 1983).

The results of a recent survey conducted with the dermatological community at the American Academy of Dermatologist 1995 Annual Meeting (Dial, 1995) demonstrate that a majority of dermatologists surveyed consider recommending OTC soap products to their patients. Over 90% of the dermatologists surveyed consider OTC antibacterial cleansing products to be an important aid in the management of their patients medical conditions. These conditions include: (1) acne; (2) atopic dermatitis; (3) eczema; (4) folliculitis; and (5) impetigo. Over 80% of the physicians surveyed stated that their ability to manage the care of their patients would be adversely impacted if OTC antimicrobial cleansing products were no longer available. Table 2 provides a summary of the results of this survey.

It should be evident that the prevention of infection translates readily into economic savings and an improved standard of living. It should also be clear that FDA's proposal to eliminate antibacterial soap products for general and foodhandler uses is contrary to the principles critical to the prevention of disability, disease, and spread of infections within the United States.

Table 2. Dermatologist Survey Results (1995)

QUESTION	RESPONSE (n=204)												
1. Do you recommend any particular brands of soap or cleansing products (either antibacterial or not) to your patients?	90.2% YES												
2. Do you use antibacterial products in the management of some of your patients' medical conditions?	93.1% YES												
3. Are these antibacterial products Prescription or OTC or both?	35.0% OTC only 4.0% Prescription only 61.0% OTC & Prescription												
4. Do the OTC antibacterial products include bar or liquid soaps?	97.4% YES												
5. Are OTC antibacterial cleansing products an important aid in the management of your patients' medical conditions?	90.5% YES												
6. Would your ability to help manage your patients' medical conditions be adversely impacted if OTC antibacterial cleansing products were not available?	82.3% YES												
7. For which of the following conditions have you/would you recommend OTC antibacterial bar or liquid soaps?	<table border="0"> <tr> <td>Acne</td> <td>75.5%</td> </tr> <tr> <td>Atopic Dermatitis</td> <td>51.5%</td> </tr> <tr> <td>Eczema</td> <td>42.2%</td> </tr> <tr> <td>Folliculitis</td> <td>78.9%</td> </tr> <tr> <td>Impetigo</td> <td>72.6%</td> </tr> <tr> <td>Other</td> <td>9.8%</td> </tr> </table>	Acne	75.5%	Atopic Dermatitis	51.5%	Eczema	42.2%	Folliculitis	78.9%	Impetigo	72.6%	Other	9.8%
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Other	9.8%												

3. INDUSTRY IMPACT

Industry impact has been estimated for three broad categories encompassing proposed testing, antimicrobial market, and terminology-related impacts.

3.1 Proposed Testing Impacts

FDA's proposed elimination of the antimicrobial soap category by placing it in the same category as professional health care personnel handwashes will create overly stringent and unreasonable testing requirements, which have been estimated to be \$1.3 to \$6.5 million per product (excluding resistance testing, market searches, safety data, etc.). Table 3 provides a summary of the estimated costs for the proposed testing. These data were obtained from four independent testing laboratories which were contacted in April, 1995.

Clearly, these tests are financially burdensome for any firm - even large ones - and absolutely prohibitive for a small one. It is also expected the exorbitant costs associated with the tests being required under the proposed TFM will virtually eliminate all small innovative product companies from the market.

Table 3. Summary of Test Costs Proposed by TFM for Vehicle, Active, and Test Formulations (US\$)

Method	1994 TFM	Lab. A	Lab. B	Lab. C	Lab. D
MIC	333.470 (a)(1)(i)&(ii) (1300 isolates)	\$1,080,000	\$828,000	\$720,000- 2,700,000	\$360,000- 720,000
Time Kill	333.470 (a)(1)(iv) (25 isolates; 8 time points)	\$3,564,000	\$828,000	\$2,700,000- 3,600,000	n/a
HCPHW	333.470 (b)(2) (54 subjects testing three formulas ¹)	\$170,000- 190,000	\$91,500	\$129,600- 162,000	\$90,000- 120,000
Surgical Scrub	333.470 (b)(1) (90 subjects testing three formulas ¹)	\$225,000- 255,000	\$322,500	\$288,000- 345,600	\$150,000- 180,000
Pre-op Prep.	333.470 (b)(3) (96 subjects testing three formulas ¹)	\$480,000- 500,000	\$322,500	\$288,000- 345,600	\$150,000- 180,000

¹ Predicate, vehicle, and test formula

3.2 Antimicrobial Market Impacts

As currently written, FDA's proposed rulemaking will result in serious market and economic repercussions amongst the suppliers of antimicrobial ingredients and the manufacturers of antimicrobial end-use products. The TFM essentially removes current antimicrobial products from the marketplace as the result of the elimination of many of the active ingredients currently utilized. The current rulemaking proposes active ingredients (i.e., alcohol and povidone/iodine) which yield end-use products that are inappropriate for consumer uses due to their undesirable product performance characteristics.

It is estimated that the total size of the current U.S. Handwash and Bodywash market is approximately \$3.0 billion. Consumer Antimicrobial Handwash and Bodywash products comprise approximately \$1 billion or 35 percent of this market, while Foodhandler Handwash products account for about \$50 million or 5% of the antimicrobial market. The stringent testing criteria for the professional healthcare products would also place these categories in jeopardy. Many of the products currently used and recognized by the profession to be efficacious would be eliminated or would require significant reformulation which may result in undesirable product characteristics. This may lead to a situation where products are available, but they are unacceptable to end users.

The consumer antimicrobial market has undergone a significant transformation since the last TFM was issued in 1978. In 1978 non-antimicrobial bar soaps dominated the market, however, in 1995 liquid Antimicrobial Hand soaps make up a significant and growing portion of the market. It is estimated that the antimicrobial segment of the wash market has attained an average annual growth rate of approximately 8 percent in the last five years. The movement towards antimicrobial products by the general population represents a shift in consumer attitudes regarding the value of these products in their everyday lives.

Based on consumer use patterns, it has been conservatively estimated that a loss of the antimicrobial wash category would result in a 10 to 15 percent decline in total sale and consumption of soap products that would not be redistributed among non-antimicrobial soaps. This represents a permanent \$300 to \$450 million annual loss in sales to the manufacturers and formulators of antimicrobial end-use product and does not include the economic losses expected among antimicrobial active ingredient suppliers or other affiliated industries. This may translate into a 10 to 15 percent loss of industry jobs among product manufacturers. This analysis does not include other segments, such as Foodhandler products. The Foodhandler Handwash category (i.e., hand sanitizers and hand dip products) is a relatively mature market with a dollar value of approximately \$50 million.

3.3 "Antiseptic" versus "Antibacterial" Terminology Impacts

Preliminary consumer research has been conducted to evaluate the FDA proposed use of "antiseptic" versus "antibacterial" for product description. Eight hundred consumers were asked via a telephone survey to define the terms "antibacterial" and "antiseptic" (Dial, 1995b). The results of this survey indicate that: (1) the term "ANTIBACTERIAL" was significantly more likely to be defined as "kills bacteria" and "fights/removes germs/bacteria;" and (2) the term "ANTISEPTIC" was described significantly more often as "kill germs", "medicinal" (particularly "fights infections/sterilizes"), and "sanitized/sterilized".

As indicated in this study, the consumer's perception that "antiseptic" products are associated with medicinal, sterilized, and infection fighting, is inconsistent with the current marketing practices for consumer use antimicrobial products. However, the term "antiseptic" is widely used and understood among health care professionals. Therefore, we would like to reserve the use of "antiseptic" for the professional healthcare and Foodhandler categories of the Healthcare Continuum. The terms "antimicrobial" and "antibacterial" more precisely convey to consumers the key characteristics of the bodywash and handwash categories. We strongly believe (and market data supports) that if "antimicrobial" or "antibacterial" cannot be used on the label, consumers will not have an a proper understanding of the product category, and make uninformed purchase decisions. For instance, consumers are not going to buy a "deodorant" hand soap.

4. SUMMARY

In summary, it should be emphasized that:

- FDA's elimination of the antimicrobial soap category from the currently proposed rulemaking will have the result of removing these products (as well as active ingredients) from the market;
- There are no alternatives for existing consumer antimicrobial products;
- The elimination of the antimicrobial soap category will create uncertainty as to whether current infection levels will remain stable or escalate due to the elimination of these products for consumer uses;
- The unreasonable testing requirements proposed for consumer products proposed in the TFM will have the net effect of increasing the costs of manufacturing such products which will have to be passed on to the consumer;
- FDA's proposal to require "antiseptic" labeling will create confusion and possible misuse of these products by consumers due to their perception of the medicinal connotations of this term; and
- A variety of industries, jobs (especially jobs at small companies), and the health of the general population will be negatively impacted by this proposed rulemaking.

- The unreasonable testing requirements proposed for healthcare professional products will eliminate many formulations currently recognized to be efficacious, and OTC monograph products to replace them are unlikely to have the user properties that promote optimum compliance.

References

See Reference List in Tab 2 of the Background Package.