How effective are current alcohol based gels, wipes and swabs.

Antiseptics made with alcohol, iodine, CHG or cholorhexidine gluconate, and ammonia have been contaminated with a range of bacteria – including Bacillus cereus -- and implicated in problems ranging from injection site infections to death.

When the regulations were written in the 1970s, experts thought the antiseptic solutions were strong enough to kill any bugs. But recent reports of contamination in widely used antiseptics have raised new worries, said Dr. Christina Y. Chang and Dr. Lesley-Anne Furlong of the FDA.

Dec. 1, 2010 death of Harrison Kothari, a Houston 2-year-old who developed lethal bacterial meningitis after surgery. His parents, Shanoop and Sandra Kothari, sued the Triad Group and H&P Industries of Hartland, Wis., claiming that the alcohol wipes used on the boy transmitted the Bacillus cereus bacterium that caused his infection. The Triad case was only one among dozens of outbreaks involving infections tied to tainted swabs, pads or solutions dating back decades.

Existing reports probably vastly underestimate the scope of the problem, the experts say. “Reports of these infections are rare, but we don’t know how common the infections may be,” said Chang and Furlong, who addressed the question in this week’s New England Journal of Medicine. That’s because consumers and even clinicians may assume, wrongly, that the antiseptic products can’t be contaminated because they kill all bacteria. “They don’t always think to test these products when someone develops an infection days after surgery or injection,” the experts said.

While regulators sort out the issue, the FDA experts are urging health care workers and consumers to consider antiseptic pads and solutions as possible sources of unusual infections.

Intrinsic contamination occurs when microorganisms gain entry to the product during the manufacturing process and remain viable. Bacterial contaminants have been isolated from pharmaceutical water supplies and non-sterile antiseptic manufacturing environments. By contrast, extrinsic contamination occurs when microorganisms are introduced into a finished product by the end user. Extrinsic contamination can arise from a variety of causes, including dilution of the product with contaminated water, failure to use appropriate aseptic techniques during handling, and repeated use of non-sterile containers for product storage.