What about Germicides and Cleaning Technologies That Do Not Meet EPA FIFRA Criteria?

by Robert Powitz

Since 1972, when the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) underwent a major revision, and authority for its enforcement was given to the newly created Environmental Protection Agency (EPA), we have relied on EPA Registration Numbers as an assurance that germicidal label claims were verified and that recommended use-concentrations offered some degree of safety of chemicals that leave an active residual. We felt comfortable with this second- and third-party approach to validation, and the EPA Registration number became the norm for the janitor industry. So much so that we required all germicides used in health care, food-service and institutions to have a registration number on the label.

A dramatic change took place in the 1980s as a result of Earth Day awareness and other ecological events that touched our lives. We started seeing the development of new technologies that were both efficient and sustainable. They began carrying an “environmentally friendly” label as part of their new description and marketing strategy.

Because of this ecological paradigm shift, in 1992 President Clinton signed an executive order that defined “green cleaning” and mandated the use of green alternatives in lieu of traditional cleaning products ... including disinfectants and sanitizers. Green cleaning was simply defined as “cleaning to protect health without harming the environment.” This definition implied using cleaning tools, chemicals, equipment and other products that have little impact on the environment, the user and building occupants.

The marketplace responded by introducing custodial products that contained neither toxic compounds nor persistent chemicals, nor did they demonstrate any damaging effects to either the environment or to the user. For all good intent and purpose, these new technologies were indeed green in the truest sense of the meaning. Most were well outside the scope of FIFRA-defined pesticide products and thereby qualified for an exemption to an EPA registration number.

On the downside, these new technologies failed to make significant and immediate inroads into the janitor industry, partially due to their novelty, but more significantly, some of these new products could not be registered; they did not meet the criteria that required EPA approval. In short, these new products and technologies were not “pesticides” and did not require proof and oversight that they would not cause damage to the environment or were harmful to the user when used in accordance with label instructions.

Over the past several years, we have been experiencing yet another evolution of the green movement through the emergence of toxin-free cleaning, toxin- or chemical-free cleaning is the epitome of green. It basically relies on water and includes such technologies as plain water that is used heated and/or under pressure; dry and wet steam, electrolyzed/engineered water and its non-toxic hypochlorous acid chemical adjuncts; hydrogen peroxide and ozone. Other technologies that are equally friendly to the environment were also introduced into the janitor market. These include carbon dioxide, walnut shell, ultrasonic cleaning, enzymes, microfiber, ultraviolet light, and such novel advancements as self-cleaning surfaces, to name just a few of today’s unique offerings. Interestingly, none of the newest cleaning technologies or non-toxic janitorial products come under the rubric of FIFRA. There is no EPA registration number required for them. For definitive information on the details of these regulations, see the following references: Pesticide Registration Manual – Chapter 13 – Devices and 40 CFR 152.500 – Devices; both are available online.

Even though some of the new cleaning technologies may be ex-
empt, EPA is not totally out of the picture. Regardless of how benign a product or technology is, if a microbiological kill claim is made, that product or technology is required to have an EPA-assigned establishment number; as opposed to a registration number. The establishment number is required by any businesses that produce pesticides, active ingredients or devices, including companies or establishments that import into the United States. In the context of this article, “devices” is the operative word. The EPA further requires companies that manufacture and/or distribute these devices to file an initial and an annual production report. Although a registration is not required, devices are regulated in that “false or misleading claims” cannot be made about their effectiveness. If a manufacturer is making claims about a device, they are required to have scientific data to back up the claims. These data do not have to follow the methodology or format required under registration. Examples of devices that are regulated in this way include ultraviolet light units used for water purification; any water treatment device used to reduce or eliminate microorganisms from water, including electrolysis and ozone units; and air treatment units designed to reduce or eliminate microorganisms or allergens. To reemphasize, these EPA regulated devices do not include registration.

Even though we are given assurances that new technologies and solutions are exempt, there are still concerns that have to be addressed. Customers want to know if there is a reliable equivalency to EPA registration. And if so, how can these non-toxic product and device claims be validated and user safety assured? The answer has been around for 69 years.

Founded in 1944, NSF International is an independent, not-for-profit organization that is a leading ANSI-accredited developer of more than 50 American National Standards that protect public health and the environment. In addition to the standards development, NSF headquarters in Ann Arbor, Michigan offer a full array of laboratory capabilities for product certification against these and other industry standards, particularly with regard to toxicology. Their capabilities include verifying manufacturers’ claims and substantiate product performance. Products that meet these standards bear the NSF mark, which is respected by consumers, manufacturers, retailers and regulatory agencies at the local, state, federal and international levels.

As part of their standards activities, NSF also develops protocols for unique and new technologies including consumer products. Protocols are specifically designed to address consumers’ public health, safety, performance and efficacy concerns. The protocols are every bit as rigorous as their American National Standards counterparts, except that they are targeted to individual products or those products with a limited market, but that nonetheless requires a comprehensive description and sanitary requirements — a rigorous peer review and ultimate certification that include laboratory challenges.

An NSF protocol written for EPA-exempt products describes the requirements for the safety (continued on next page)
laws, codes, regulations and standards that are applicable to the device; it ensures conformance to these conventions. In summary, FIFRA-exempt "pesticide" devices that produce sanitizing solutions or deliver sanitizing methods can now be certified to NSF protocol criteria that are equal to, and in many cases more rigorous than, those specified by the EPA.

Earlier this year, NSF developed and published a protocol for a newly developed cleaning and sanitizing device. The completed protocol was vetted by industry, regulatory and user experts and critically reviewed by the NSF Council of Public Health Consultants. Known as NSF Protocol P423: Electrochemically Activated Water Cleaning and Sanitizing Devices in Commercial Food Operations, it specifies the materials in its construction to ensure that no toxic products are released; it provides the requirements for its design and construction to ensure general sanitation and electrical safety of the device; it details the labeling and product information requirements, including the necessary information that appears in the operation and instruction manual, and most importantly for the customer, the protocol details performance criteria. In this specific Protocol, the performance criteria are based on Section 4-501.114 of the 2009 FDA Food Code. It mandates that the device repeatedly demonstrates and meets specific characteristics of free available chlorine as specified in the code. Along with performance specifications, NSF developed a test procedure to evaluate sanitizer production and efficacy. Finally, the protocol lists the acceptance criteria that the device must undergo, including rigorous in-situ testing requirements, in order for the device to bear the NSF mark. It is quite obvious that
this program goes far beyond EPA requirements for regulated products.

Also in development is a protocol for portable steam cleaning equipment designed for use in food service; in this case, dry steam. It follows the same format as the one mentioned above. However, it will also include a surface microbiological reduction challenge test and criteria for the various steam and chemical dispensing accessories and appliances that come with the unit, as well as the performance criteria for a vacuum system that may be integral to the steam cleaning unit. As with all NSF protocols and standards, the focus is on public health and safety, with emphasis on performance and efficacy. For more information on protocol development, visit NSF Engineering and Research Services on the web at www.nsf.org.

The NSF protocol development and certification process, along with their product listing, provides continuity of validation for the manufacturer to the consumer. Their program fills in the gap where regulation leaves off, providing assurance to the consumer that a regulation-exempt product undergoes the same, if not greater, scrutiny as with a governmental agency. The rigors of the protocol development program set the criteria by which non-pesticide disinfectants and sanitizers, and non-toxic cleaners and methods can be validated. This program is designed to provide assurance to the consumer that the new green technologies and products are effective and safe to use, and that they meet all applicable public health and safety standards.*

Robert W. Pouwitz received his undergraduate education from the State University of New York and the University of Georgia. He holds M.P.H. and Ph.D. degrees in institutional environmental health from the University of Minnesota. Bob began his career as a state Sanitarian and Health Officer in New Jersey. He is currently a forensic sanitarian in private practice and serves as health director for three Connecticut towns. For more than 12 years, he was director of environmental health and safety at Wayne State University in Detroit, Michigan. He also served as Biological Safety Officer for the United States Department of Agriculture at the Plum Island Animal Disease Center. He serves on the Council of Public Health Consultants at NSF International and is currently writing articles and presenting seminars on chemical-free cleaning and objectively measuring cleanliness.