Insightful Food Safety Technology and Regulatory Advisory Services

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On-site Pesticidal Devices

by Thomas Johnson, President of JDP, Inc.

A review of regulatory compliance criteria relating to electro-chemical activation systems (ECA or ECAS) in the U.S.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is an Act of Congress that authorizes U.S. EPA to interpret and enforce all antimicrobial marketing claims made by manufacturers and distributors of such products: http://www.epa.gov/agriculture/lfra.html

Section one FIFRA (page 3) provides its scoping statement:

"To regulate the marketing of economic poisons and devices, and for other purposes"

Is it not revealing that the U.S. Congress refers to all of the packaged chemical concentrates that make antimicrobial claims as *"**economic** poisons"*? A search-engine search for *"economic poisons"* reveals the truth. It is an irrefutable fact that there are long-term adverse health consequences to people and animals associated with persistent exposures to the antimicrobials we rely upon. Equally interesting is that a goal of FIFRA is to regulate "**MARKETING"**, a reference to the CLAIMS antimicrobial manufacturers and distributers make regarding their effectiveness (efficacy) and their safety (toxicity).

The Executive branch of the U.S. Governments includes each of the federal agencies including, FDA, USDA, HHS and EPA. Each has the authority to adjudicate, legislate, and enforce laws within their specific areas of delegated power and as promulgated in their codes through the Code of Federal Regulation's (CFR's). EPA is delegated the power to interpret and enforce FIFRA. When other agencies codes overlap and couch within them criteria relating to antimicrobial claims, those codes must make separate reference to the predominant code (FIFRA) using the appropriate CFR reference. Note that title 40 in the Code of Federal Regulations pertains to rules promulgated by EPA, whereas title 21 pertains to FDA promulgated rules.

FDA Food Code 7-204.11

Section 7-204.11 of the **2001** FDA Food Code refers to 21CFR 178.1010 as the relevant code for requirements relating to Food Contact Surface Sanitizers. 21 CFR 178.1010 does not list Hypochlorus acid (HOCl) HOCl as approved food contact surface sanitizer. HOCl is the most powerful antimicrobial species of chlorine, yet it is non-toxic at its ready to use concentrations. ECA machines using dilute brine electrolysis produce HOCl in their anode chambers. The failure to recognized HOCl in FDA's Foods Code editions in 2001 and earlier comprised a restraint to the commercialization of ECA in the U.S food and beverage industries and in licensed foodservice and retail operations.

Fortunately, CFR title 40 in section 180.940 does list HOCl and it states a maximum tolerance concentration at 200PPM free available chlorine (FAC). The concentration of chlorine in HOCl is measured just as it is with any other chlorine-based system using chlorine test strips, or titration using potassium iodide reagents and sodium thiosulfate neutralizers.

Due to this inappropriate reference in FDA Food CDode editions 2001 and earlier JDP, Inc. (with the assistance of the Director of the Pesticide Division of EPA) submitted an issue to the CFP requesting that the reference in FDA Food Code section 7-204.11 be changed to 40 CFR 180.940. This was done over the objection of the lobby from chemical companies (CHEMCOs). Our strategy was to cause the reformation of the CFP's standing sanitizer committee as EPA had agreed to push this issue through. By the next biennial CFP conference the mission was accomplished. A letter from the CFP was sent to FDA recommending that section 7-204.11 be revised to instead refer to 40CFR 180.940. This change is reflected in all subsequent editions of the FDA Food Code. Because of this, HOCl as generated by on-site ECA generators is now recognized as an approved food contact surface sanitizer.

Then, in 2010 on behalf of another client, JDP, Inc. petitioned the National Conference for Interstate Milk Shippers (NCIMS) to revise the Grade A Pasteurized Milk Ordinance (Grade A PMO). Like the FDA Food Code, the PMO had been referring to 21CFR178.1010 for approved food contact surface sanitizers. The only detractors at the NCIMS to our submittal to revise were once again, the CHEMCO's. Once again, EPA supported JDP's submittal request and again an federal administrative rule was successfully revised opening the regulatory door for the commercialization of ECA systems, this time in the U.S. Dairy Industry.

40 CFR 180.940 Tolerance Exemptions … *(for Food Contact Surface Sanitizers)*

The above regulation in CFR title 40 lists hypochlorus (HOCl) as an approved food contact surface sanitizer and it sets an upper limit of concentration at 200PPM FAC.

40 CFR 152.500 Requirements for Devices

FIFRA categorizes ECA systems as on-site pesticidal ***"devices".*** If solutions produced in an on-site device are used on-site then those solutions are exempt from the label registration requirement for antimicrobials as found in section 3 of FIFRA. This section details other requirements specific for devices. For example, manufacturers of devices are required to obtain an EPA Establishment number form EPA. They are also required to submit to EPA an annual report as to how many units it shipped into or in the U.S. and they must be current with their annual filing fee requirements. Devices must be labeled with their EPA establishment numbers. HOCl generated on-site can be used for whatever antimicrobial applications desired providing it is supported by 3rd party validation data. The FDA Food

Code provides a further requirement for Food Contact Surface beyond FIFRA requirements stating that food contact surface sanitizers efficacy data must be acquired by a 3rd party lab under "good laboratory practices" (GLP's).

40 CFR 156.10 Labeling requirements
The reservoir or containers of on-site generated ECA antimicrobials must be labeled as to the active and inert ingredients in the reservoirs along with any appropriate safety data sheet notices. So too must the name and EPA Establishment number associated with the device/generator be listed on this label. Each application needs appropriate use instructions too with pertinent labels provided at each different applications point of dispensing or point of use. Labels should not state that containers contents are non-toxic.

Other compliance criteria for on-site devices

ANSI UL 979 is the required electrical shock-safety certification needed for on-site devices that are electrically powered. This certification is required for any electrically powered commercial product in order to obtain product liability insurance. In addition to UL, CSA, ETL and TuV are ANSI certifying bodies for ANSI UL 979.

Equipment installed within the licensed foodservice or retail food operation space is required to comply with the requirements of Chapters 4-1 and 4-2 of the FDA Food Code. If such located equipment is labeled by an ANSI sanitation certifying body, that equipment is deemed to comply with the code. Unlisted equipment may also comply. There are no special sanitation criteria requirements for ECA equipment installed outside of this space (eg., janitors closets or chemical lockers).

For further information, contact me.

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