

Getting Started on Your EPA Registration: What You Need to Know

The Copper Development Association Inc. (CDA) has registered 355 copper alloys with the U.S. Environmental Protection Agency (EPA) as antimicrobial products with public health claims. This unprecedented registration has paved the way for fabricators of copper and copper alloy products to legally market the health benefits of their copper products and sell into new markets.

Piggybacking on the CDA registration, members and other interested manufacturers can now file for their own “me-too” registration. Registrations must be secured before products can be sold. Additionally, registrations must also be secured in each state in which fabricators intend to sell antimicrobial copper products, including states in which their customers will sell products.

CDA has taken several steps to make the registration process as easy as possible for its membership. To that end, CDA has retained Technology Sciences Group Inc. to complete each interested company's applications and submit them to the EPA and the states. This service is available at no cost (members are responsible for EPA and state registration fees, as well as copying and mailing charges). A Registration Tool Box Web site has also been developed to provide assistance to do-it-yourself registrants.

NOW is the time to bring your antimicrobial copper alloy products to market!

Register and profit from this new opportunity

By now, we hope you are aware of copper's intrinsic antimicrobial property as well as the substantial efforts behind the EPA registrations.

The EPA registrations were the result of a complicated and lengthy initiative designed to legally permit copper alloy fabricators, component makers, and others, including component distributors and service centers, to market the benefits of their products with public health claims.

Background: EPA FIFRA registration process

- The federal government considers bacteria to be pests, thus products that kill bacteria on inanimate surfaces are regulated as pesticides. Because of copper's antimicrobial property, EPA considers solid copper to be a pesticide and its use as a pesticide must be regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
- FIFRA mandates that human health claims regarding specific substances and products cannot be made until EPA grants an approved registration based on an extensive body of efficacy data. Products registered with human health claims have been proven to kill microorganisms infectious to humans on any inanimate surface.
- On February 29, 2008, EPA granted registrations to CDA for 275 copper alloys. 55 additional alloys have since been registered.
- NOW is the time for CDA members to take advantage of this incomparable market opportunity!
- Registration requirements and assistance regarding federal and state registrations are described below.

Public health claims permitted by EPA

The following public health claims were granted to CDA by EPA for registered copper alloys. CDA's membership (and non-members who agree to pay a fee to the CDA) can file for “Me-Too” registrations and market their products with public health claims. The claims were derived from an evaluation of an extensive body of antimicrobial test data conducted on five different bacteria: *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli* O157:H7, Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant *Enterococcus faecalis* (VRE), and *Pseudomonas aeruginosa*. They are:

Laboratory testing has shown that when cleaned regularly, antimicrobial copper alloy surfaces:

- Continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure.
- Kill greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.
- Deliver continuous and ongoing antibacterial* action, remaining effective in killing 99.9% of bacteria* within two hours.
- Kill greater than 99.9% of bacteria* within two hours, and continue to kill 99% of bacteria* even after repeated contamination.
- Help inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.

*Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, *Enterobacter aerogenes*, Vancomycin-resistant *Enterococcus faecalis* (VRE), and Methicillin-resistant *Staphylococcus aureus* (MRSA).

What CDA members must do to get registered

Although CDA completed the lion's share of the regulatory work on behalf of its members, those that wish to manufacture, produce, package, label, or sell products with associated health claims must do the following:

- File their own federal registrations with EPA, *and*
- File state registrations for every state in which they or their customers intend to sell and promote antimicrobial copper products.

"Me-Too" Federal Registrations

There are different classes of federal EPA FIFRA registrations. What CDA members will be preparing are called "Me-Too" registrations. These registrations are appropriate for products that are substantially similar in composition and use to the alloys registered by CDA.

Upon receipt of your application, EPA will compare the compositions (specific alloys) and uses of your products with those cited in the CDA registration to determine whether your registration is acceptable on a "Me-Too" basis. Your application will be approved if antimicrobial claims on your proposed labels are the same as CDA's approved label and if the alloys used are within the specifications of those approved by EPA.

Related information:

Fees: EPA charges \$1,050 for each federal registration product application. The 282 registered alloys are categorized in six alloy groups based on copper content; each group is considered a separate product. You may need to remit payment for up to six federal registration applications.

Company Number: To get started, you will first need to obtain an EPA Firm Number for your company. This entails the submission of a simple form to the EPA. The EPA will assign a company number and inform you in writing within about 2-3 weeks.

Review Period: EPA takes up to three months to review your "Me-Too" application. Once accepted, you will be provided an EPA Notice of Pesticide Registration.

Deadline: There is no deadline to register. You can apply at any time. However, the sooner you secure your registration, the sooner you can market your products with public health claims!

Maintenance Charges: The EPA charges an annual maintenance fee to "renew" registration(s). This fee, which was \$3000 per application in 2009, is due on January 15th.

CDA's Efficacy Data: CDA maintains exclusive ownership of the antimicrobial efficacy data needed for registration. However, CDA will provide its members with a letter to the EPA granting permission to use its database on behalf of member registrations. Members who apply for registrations do not submit copies of CDA's data. Data rights granted to any registrant cannot be reassigned to any other company.

Fees for Non Members: CDA will charge non-members a fee to use its antimicrobial efficacy data for the purpose of securing registrations. This fee will help defray the cost for producing and submitting the data required by EPA.

State Registrations

Each state and U.S. territory has its own laws and regulations governing the sale and use of pesticide products. Before any pesticide product can be offered for sale in any state, it must first be registered with the state's pesticide regulator. If your company or your customers plan to sell antimicrobial products nationally, or plan to distribute them through a chain or big box store, you must first register your products in every state, plus the District of Columbia. Federal registrations must be obtained first. Applicants then use their federal EPA registration numbers to complete state registration applications.

Related information:

Approval process: In some states, the approval process may take a few days or weeks; others may take up to four months or longer to process documents.

Brand names: EPA-registered products may be marketed and sold under more than one brand name. Nearly all states register products based on brand names, so each brand name requires a separate registration and fee (each group of Antimicrobial Copper Alloys must have a different brand name). A brand name may be specific to a particular end-use (e.g. Antimicrobial Doorknob) or may be broader in scope representing any end-use that could be made from the product (e.g. Antimicrobial Surface). The Copper Development Association Inc. specifically developed the EPA-approved federal label language so that it would encompass state registrations that allow different end-use products to be made from the registered alloys.

State registration fees: As of July 2009, registration fees for various states ranged from \$75 to \$750 per brand name. Approximate costs for registering one brand in all 50 states plus the District of Columbia are \$11,500.

Registration renewals: State registrations are valid from 1 to 5 years depending on the state and must be renewed. Forty states require that product registrations be renewed annually. Only a few states issue registrations that are valid for two to five years.

- **Forms, fees, labels and supporting documents:** Each state plus the District of Columbia has its own documents and regulations. CDA and Technology Sciences Group Inc. are available to assist you with your state registrations.

Label violations: As is the case with unregistered products at the federal level, if an unregistered product is identified by state inspection officials, a Cease and Desist Order will be issued. It is likely that fines would be levied to offenders. If member companies believe another company is making claims in violation of the terms dictated by EPA in the CDA registration, or if they believe a company is offering to sell an alloy that is not registered for use as an antimicrobial alloy, please contact CDA. CDA can investigate and, if necessary, alert EPA and/or state enforcement offices regarding the violations.

Member Insights: PMX prepares “Microguard™” for antimicrobial market

“Just when we thought we knew all of the positive attributes of copper, the metal’s antimicrobial properties are opening up an entirely new market for us,” says Richard Pratt, Director of Marketing and R&D with PMX Industries Inc., a copper and brass fabricator based in Cedar Rapids, Iowa. “This is a very exciting time.”

PMX is preparing to take advantage of the emerging antimicrobial market for its Microguard™ copper and brass products. “We registered our brand at the federal level with the EPA and we already received approved registrations from thirty-seven states,” says Pratt. The company seeks registrations in all fifty-one state jurisdictions, which includes the District of Columbia.

PMX praises CDA for its foresight and diligence in seeking EPA registrations for copper alloys and expanding market opportunities for the industry. “I can’t say enough about what CDA accomplished,” says Pratt. “This is a textbook example of what a trade association is supposed to do for its membership.”

Federal registration process was “easy”: PMX found that the federal registration process was fairly simple and straightforward. It took about two days to download the forms, read the instructions, understand what needed to be done, and complete the registration materials. “CDA’s instructions were self-explanatory,” says Pratt. “We made just one phone call to CDA for assistance.”

Pratt believes firms that apply for registrations should appoint a senior manager to complete the registration forms. “These forms require the same level of responsibility as is necessary to complete other tasks with potential regulatory and liability impacts, such as risk management, insurance, or tax initiatives,” says Pratt.

Pratt found that information companies put on the federal applications can be modified at any time. New applications can also be filed, as necessary. “The applications are not cast in stone,” says Pratt. For example, brand names can be changed if warranted. “This is a living/breathing document, not like a social security number.”

State registrations can be more complicated: More challenges are presented with state registrations since each state has its own pesticide regulations and requirements. “Many state registrations were fairly easy,” says Pratt. “But, several states presented complex issues that needed to be understood and sorted out.” Issues with several states are being worked out at this time.

To ensure success, PMX is pursuing multiple approaches at the state level to obtaining and utilizing their registrations properly and safely. “Anytime there is a new technology, it is necessary to evaluate associated risks,” says Pratt. “This emerging antimicrobial market is no exception.”

PMX found that states generally did not think of the registration in terms of 275 different alloys. Rather, they thought in terms of five separate products...the same five alloy categories from the federal registration. "We found that all of the alloys within a particular federal registration group were thought of as a single product by the states," says Pratt. "This will help us to implement marketing strategies and refine our message."

Editor's note: Since this article was written, PMX has obtained registration in 49 states and the District of Columbia. Registration in the state of California is currently pending approval.

Assisting CDA members with registrations

CDA has made several resources available to its members to assist with the federal and state registration process.

Assistance with registrations: CDA has retained Technology Sciences Group Inc. (TSG) to help members with all of their registration needs. **TSG can provide guidance or complete all forms required for your federal and state registrations.** TSG will also submit all forms to EPA on your behalf. There is no charge for this service to CDA members. For assistance with your federal registration, contact Heather Bjornson at 202.828.8945. For assistance with state registrations, contact Oleta Melnicoe at 530.757.1243. Let them know that you are a member of CDA.

Do-It-Yourself Registrants: CDA has assembled an online FIFRA Registration Tool Box that contains a full set of step-by-step instructions for registrants, as well as registration forms, Q&As, and a discussion of labeling responsibilities. The tool box is available at www.register-safe-alloys.info. A password and username is required to access this site.

To take advantage of the registration tool box:

- Contact CDA to obtain a username and password.
- Go to www.register-safe-alloys.info and log in.
- Review the step-by-step instructions for registrants

For federal registrations, download and complete federal registration forms for each of the six groups of alloys in which your firm will do business, obtain an EPA number for your company, remit the federal application to EPA by mail or at www.pay.gov, and complete the Stewardship Plan Commitment Letter.

For state registrations, download and complete state registration forms for each state in which you or your customers plan to sell products and submit these to the states after obtaining your federal EPA registrations. Also, download and complete the Revised Pesticide Producing Establishment Form (revised on 1/12/09) for each facility that manufactures, fabricates, packages, or labels copper alloys. This form is submitted to each EPA regional office that oversees the state in which the facility is located.

For further assistance, please contact Harold Michels, Senior Vice President of Technology and Technical Services, at 212.251.7224 or via email at hmichels@cda.copper.org.

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