ALM
LAW JOURNAL NEWSLETTERS
The China Trade Law Report
ALM

December 2006

The EPA May Take a Close Look at Regulating Nano-Particles in Antimicrobial Articles and Devices

Chinese Manufacturers Take Note

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Nano-scale materials are said to have unique and potentially valuable properties in comparison to the same materials that exist naturally in larger than nano-scales, which can include greater tensile strength, enhanced electrical conductivity, and the ability to contribute to new chemical synthesis pathways. (**Note:** Nanotechnology is the science of manipulating materials at the atomic and molecular level to develop new or enhanced materials and products. A nanometer is one billionth of a meter in length and particles that have been specifically configured in the range of 100 nanometers or less in length for use in commercial applications often are described as being within the construct of "nano-scale" — although no uniform definition of "nano-scale" has been reached.) These unique properties may lead to advances in industrial chemistry, engineering, biological, agricultural and medical applications. The U.S. Government's spending alone on nanotechnology research is said to exceed $1 billion annually, and the Government of China has recently announced that nanotechnology is one of 16 key technologies for which it will increase research and development spending over the next 15 years. As Chinese companies increasingly design, develop, and manufacture products based on nanotechnology, and export these products to the United States, they will confront and need to understand the emerging perspectives and concerns of U.S. government regulators who are struggling to reckon with perhaps hundreds of products employing nanotechnology that reportedly are already on the market and perhaps thousands more products soon to come on the market. U.S. Federal agencies are working independently, and occasionally in concert, to try to identify appropriate policies and practices to monitor and respond to this apparently sweeping new market development. *See*, *e.g.*, National Science and Technology Council effort known as the National Nanotechnology Initiative. www.nano.gov/html/about/home_about.html.

The Environmental Protection Agency (EPA) offers a case study of a federal agency whose own position on nanotechnology (including the position of the Office of Pesticide Programs) is still very much "under construction". *See*, *e.g.*, EPA's "White Paper" examining regulatory issues and options appearing at www.epa.gov/OSA/nanotech.htm. The EPA's experience to date is of keen interest to Chinese companies and distributors of Chinese products, both because the EPA regulates some consumer and industrial products that Chinese companies market in the U.S. and because the EPA may offer a preliminary indication of the regulatory struggles and tradeoffs that agencies will encounter in various ways when considering how to regulate products that incorporate nanotechnology. Recent actions by the EPA may be changing the regulatory landscape for the makers and

marketers of products that contain or release antimicrobial ingredients, especially when the active ingredient involves chemistries involving nano-scale particles. These events could have profound implications not only for U.S. manufacturers, but also Chinese and other foreign makers and assemblers of commodities that: a) contain an antimicrobial active ingredient as a materials preservative; or b) make claims about the antimicrobial attributes of the product itself, if they intend to ship their products to the U.S.

Background — Regulating 'Antimicrobial' Claims and Treated Articles

Products that are intended to mitigate "pests" are considered to be "pesticides" under U.S. law and generally must be registered with the EPA before they can be imported into and marketed in the U.S. from China or other countries. *See generally*, the Federal Insecticide, Fungicide and Rodenticides Act (FIFRA), 7 U.S.C. §§136-136y. Any imported product that is regulated as a pesticide in the U.S. also must be preceded by a pesticide "Notice of Arrival" document meeting certain importation requirements. (Basic information on the requirements for importing pesticides can be located on EPA's Web page at www.epa.gov/compliance/monitoring/programs/fifra/importexport.html.) If a product claims to control microorganisms (such as bacteria, mold, mildew, fungi) other than on or in humans or animals, the product is considered to be an antimicrobial product, and such products also are regulated as pesticides. For years, EPA has exempted from the registration requirements for pesticides, certain manufactured items (so-called "articles") that are formulated with an antimicrobial additive, when the additive functions as a materials preservative (*i.e.*, the additive is intended to protect the article itself from deterioration caused by certain microbes). Thus, such an exempt product is known as a "treated article". However, to qualify for this exemption, the *additive* that is incorporated into the treated article must have been registered with EPA and labeled specifically for the purpose of being used as a materials preservative and the treated article must not be marketed with claims that the treated article or the additive within it have any antimicrobial effect on anything that is outside of the article itself. (The "treated articles" exemption has been codified within EPA's pesticide regulations at 40 CFR §152.25(a); it is one of a number of exemptions from the registration requirements that have been issued by EPA pursuant to its authority under §25(b) of FIFRA.) If the treated article conforms to the requirements of the regulation and is marketed solely within its limitations, the article is exempt "from all provisions of FIFRA". 40 CFR §152.25.

Treated articles that incorporate an active ingredient to preserve the product itself can be contrasted with pesticide "devices", which use only physical or mechanical means to trap, destroy or repel pests. Section 2(h) of FIFRA defines "device." Devices do not need to be registered with EPA, although they are subject to other provisions of FIFRA; specifically devices must: 1) meet certain labeling requirements, (including the prohibition against false or misleading claims); 2) be produced in an establishment (whether located in the U.S. or not) that has been registered with EPA; and 3) comply with certain import and export requirements (any imported device, like pesticide products generally, must be preceded by the Notice of Arrival document discussed above, which is submitted to EPA for review *prior* to the shipment's entry to the U.S.). *See,* 40 CFR §152.500 and a more robust discussion appearing in historical guidance appearing at 41 *Federal Register* 51065 (Nov. 19, 1976).

There is yet another category of related products that EPA considers to be "equipment". Equipment can be used in the application of a pesticide and over which EPA has, on a fact-specific basis, exercised jurisdiction. Although the Agency does not generally require pesticide application equipment to be or registered by EPA; the Agency will require review

of equipment when its use is explicitly one of the conditions of use of the registered pesticide product. EPA also will review and perhaps require the registration of a treated article or a device-like product which contains a pesticide chemical substance that must be ejected or exuded during use in order to have the desired effect upon a pest located outside of the product itself.

Use of Silver in Antimicrobial Applications

Silver active ingredients in several forms have been registered in the U.S. since 1954 for use in pesticide products in many antimicrobial applications, including for use in swimming pool and spa water treatment. EPA Reregistration Eligibility Determination document for Silver (EPA-789-F-93-005). In 1976, EPA issued guidance concerning the use of silver as a component incorporated into bacteriostatic home-use water treatment units intended for use with potable water and required that such products be registered. (*See*, 941 *Federal Register* 32778 (Aug. 5, 1976). The notice stated that such units required registration with EPA and expressly limited the kinds of claims that could be made for the capacity of the unit to have any bacteriostatic effect on water passing through the unit.) EPA performed a general reassessment of all then-currently-registered uses of silver in pesticides during 1993, and determined that all such uses did "not pose unreasonable risks or adverse effects to humans or the environment." Furthermore, in 1997, EPA corresponded with registrants of residential bacteriostatic water filter products and indicated that registration of such products no longer would be necessary provided the products (and marketing claims) conformed to the terms of the treated articles exemption. *See,* "Dear Registrant" letter dated Feb. 13, 1997 and signed by EPA's (antimicrobial program) Product Manager 31. We could not locate this document on public portions of EPA's Web site or in publications. Nevertheless, the Agency has begun to reconsider its conclusions, especially with regard to what data EPA might wish to receive as part of registration applications for uses of silver in new applications. This reconsideration is particularly significant for Chinese and other manufacturers of any of the several dozen products, including socks, shoes, and plastic storage containers, that incorporate nanosilver as part of efforts to prevent fungus and bacteria growth. *See,* Agence France Presse, Nanotech Needs Tighter Controls, Nov. 29, 2006, http://cooltech.iafrica.com/science/483348.htm (last viewed Dec. 19, 2006). It is worth noting that EPA has a history of taking enforcement actions against unregistered imported pesticide products, including certain articles and pesticide products arriving from China. *See,* www.epa.gov/pesticides/health/illegalproducts/index.htm#antibacterial.
Recently, a growing number of "treated-article" type products have been marketed with antimicrobial claims based upon the presence of silver-based antimicrobial ingredients within the product. However, EPA regulators historically have expressed concerns about the manner in which treated articles have been promoted, especially when printed product literature and electronic forms of marketing bear claims which might state or imply that: a) there could be some health benefit derived from the use of such product; or b) the article might have an antimicrobial effect on microorganisms that are beyond the scope of the pesticide-treated components that were built into the article itself. To that end, during 1998 EPA issued detailed regulatory guidance in the form of a draft, and subsequently during 2000 a final version of, Pesticide Registration Notice (PR) 2000-1 which specifically addressed the applicability of the treated articles exemption to certain antimicrobial products. PR 2000-1 describes the limitations of the regulation and EPA's policies for implementing it, and even includes a list of the kinds of claims for such treated article products that EPA considers to be permissible or which would require the product to be registered (typically, because the claim implies the product has an antimicrobial effect upon a microorganism which is present outside of the article itself). (PR Notices are

available on EPA's Web site at www.epa.gov/PR_Notices/.) When issuing PR Notice 2000-1, EPA stated that the policy was being articulated in a manner that was entirely consistent with positions that always had been taken by EPA when interpreting and recognizing the exemption, even before it was codified during the 1970s.

The treated articles exemption, like many pesticide program policies at EPA, has been subject to fact-specific interpretations issued by EPA staff and managers over the years in response to numerous individual and trade association inquires. EPA's declaration in 1997 that the terms of the treated articles exemption applied to silver-containing residential use water filtration units which employed active ingredient silver technologies that were already registered with the Agency is one such interpretation. The terms of the exemption and the 1997 letter are such that the marketers of such products are not permitted to make claims concerning the unit having any antimicrobial effect on the water which comes in contact with the unit — because such claims would imply an effectiveness upon pests which are within the water, not within (*i.e.*, part of the components of) the treated article. More recently, it has been suggested that similar correspondence might have been issued as little as one year ago to (or at least relied upon by) the manufacturer of a washing machine product which contained and generated (apparently through electrolytic reaction), microscopic silver particles, perhaps even on a "nano" scale.

Nano-Scale Silver and Recent Developments from EPA

EPA's 1997 interpretation as it applied to residential use silver-containing water filtration units preceded three important and recent trends that appear to be working coincidentally to force the Agency to reconsider this position and similar interpretations provided to other correspondents with EPA:

1. There has been a recent surge in marketing of "antimicrobial" products that contain forms of silver-based active ingredients (some perhaps bearing claims that exceed the scope of the treated articles exemption limitations, and some that even might contain silver from sources that have not been registered by EPA specifically for such use).
2. Marketers of certain products have an apparently unquenchable enthusiasm to claim their product incorporates "nanotechnology" (and, in some cases, "nano-scale" silver).
3. EPA is being forced to create its own internal policies concerning nanotechnology "on the fly" because it has not, in advance of either trend, arrived at a well-formed or articulated position in this regard.

While the Agency is struggling to formulate official policies concerning nanotechnology products, EPA's program offices are encountering products that incorporate nano-scale applications of chemistries and uses that fall within the offices' traditional jurisdiction spheres — and EPA staff are being forced to respond on a nearly "real-time" basis. Thus, EPA officials have been quoted in the press as having reconsidered some of the Agency's prior pronouncements concerning the use of silver in products that are used in certain components of consumer products, specifically, a washing machine product that was being marketed with claims that it helped sanitize wash water or the clothes therein. (*See*, *e.g.*, Rick Weiss, *Washington Post* Nov. 23, 2006, at A01. As of the date of this writing, there remained posted on the Web site of the washer manufacturer background information concerning the method by which the product functions to release silver. *See*, ww2.samsung.co.za/silvernano/silvernano/wash_faq_popup.html.) This position appears (from press-reports) to have been taken because the Agency has concluded (and apparently the washer manufacturer conceded) that the machine releases during use, small quantities of silver. Accordingly, it appears that EPA has taken the position that the

washing machine unit must be registered as part of a "pesticide-releasing-application-equipment."

Is this New or Old Policy?

More questions than answers abound as a result of the recent reports in the press concerning EPA's position vis-à-vis the silver-releasing washing machine. To some, the Agency's position seems to signal a sea change. Some have even speculated that the policy reflects a bias on the part of EPA as part of a larger "big industry" conspiracy against the use of silver in competitive antimicrobial applications. *See,* Report dated Dec. 4, 2006 posted on www.NewsTarget.com/z021231.html. An alternative view is that this determination is an update or adjustment being made to prior regulatory interpretations and not one that is particularly unique to silver-based technologies, or even nano-scale particles *per se*. Proponents of that view might conclude that, when one considers the claims being made and the fact that the machinery has been purported to emit a substance that is intended to kill a microbial pest, it is consistent with the Office's historical policies concerning treated articles, devices, and certain pesticide-releasing equipment to require a registration-like review of the entire product.

Greater clarity is expected to be obtained when EPA issues during 2007 a *Federal Register* notice to address the situation. In the meantime, the makers of any products that: 1) contain, or emit, an antimicrobial chemical substance (on a full-scale or nano-scale size); and 2) for which antimicrobial claims are or will be made, would be wise to review carefully the contents of their products, the manner in which they affect microbes, and the marketing claims being made about the products' effects on microbes outside of the products themselves ***before*** the product is launched in the market place. This approach is prudent for U.S. manufacturers and distributors, and particularly for manufacturers located in China and in other exporting countries, and for U.S. distributors of such imported products.

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