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MEMORANDUMVia E-Mail

DATE: June 11, 2009

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Exempts Silver Ions in Food Contact Surface Sanitizers from the Requirement of a Tolerance

On June 10, 2009, the U.S. Environmental Protection Agency (EPA) issued a final rule exempting silver ions stabilized in citric acid and used to sanitize food contact surfaces at silver concentrations not exceeding 50 ppm from the necessity of a tolerance.¹ The petition that resulted in issuance of this rule was filed by ETO H₂O, Inc. and materials pertaining to the petition and final rule are available in Docket No. EPA-HQ-OPP-2007-0395, which may be accessed at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2007-0395>. Under Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408(g), any person may file objections or a request for a hearing concerning this final rule, and any such objections or request must be submitted no later than **August 10, 2009**.

EPA has strictly limited this tolerance exemption to silver ions generated by electrolysis and stabilized in citric acid as silver dihydrogen citrate. EPA explains that it has explicitly *excluded* metallic silver as follows:

This revised tolerance expression excludes any other silver-containing compounds whether they are other silver salts, complexes with inorganic polymers such as zeolites, or metallic silver in any form or dimension including nanoscale.²

¹ 74 Fed. Reg. 27447 (June 10, 2009).

² 74 Fed. Reg. at 27448.



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BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
June 11, 2009
Page 2

This is an important qualification because colloidal suspensions of metallic silver also have antimicrobial properties, and metallic silver particles can now be machined to nanoscale dimensions to increase their surface area and activity. Although the use of silver ions for antimicrobial purposes has sometimes been referred to as “nanotechnology,” this characterization is potentially misleading. Individual silver ions are indeed very small, but their production does not involve use of any novel technology. In contrast to nanoscale particles of metallic silver, silver ions have been used for antimicrobial applications for over a century and their human toxicology is well characterized. EPA has recently considered the antimicrobial use of silver ions in another context, where it determined that silver ions generated to sanitize clothing in a washing machine made by Samsung are a pesticide.³

Metallic silver is currently registered for antimicrobial use in water filters, where the filter media is impregnated with silver particles to retard bacterial growth. Colloidal suspensions of metallic silver can also be used for antimicrobial purposes in other products, and it has been suggested that in some instances these particles have been machined to nanoscale to increase their antimicrobial activity. A petition requesting that EPA regulate “nanosilver” as a separate pesticidal active ingredient is currently pending before EPA.⁴

The analysis upon which EPA has based its tolerance exemption for silver ions used to sanitize food contact equipment is based primarily on human epidemiological data resulting from administration of silver compounds for medicinal purposes. EPA has relied principally on this human data because humans and laboratory animals do not handle elevated doses of silver compounds in the same manner. The critical effect identified by EPA is argyria, a bluish discoloration of the skin. This effect is cosmetic but also permanent, and is not accompanied by other adverse effects. Argyria results when silver that has not been eliminated by the liver combines with proteins and is deposited in skin and membranes.

EPA has determined based on the human data that the Lowest Observed Effect Level (LOEL) for argyria is equivalent to an oral dose of 0.014 mg/kg/day. EPA notes that the same human data were previously used by the EPA Office of Water to establish a Secondary Maximum Contamination Level (SMCL) and in the derivation of an oral Reference Dose (RfD)

³ 72 Fed. Reg. 54039 (Sept. 21, 2007).

⁴ International Center for Technology Assessment, “Citizen Petition for Rulemaking to the United States Environmental Protection Agency -- Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides”, *available at* http://www.icta.org/nanoaction/doc/CTA_nano-silver%20petition_final_5_1_08.pdf.



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BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends
June 11, 2009
Page 3

under EPA's Integrated Risk Information System (IRIS). By regulating to prevent argyria, EPA believes it will protect the public from any more toxic properties of silver ions that may occur at higher doses.

EPA has based its exposure assessment on use of silver ions stabilized in citric acid to sanitize food contact surfaces by spraying, wiping, or full immersion. Treated surfaces will include countertops, equipment, and appliances in food service areas, cafeterias, and kitchens, and food processing and storage equipment at agricultural premises and dairy facilities. The maximum permitted rate is 50 ppm for the silver active ingredient. EPA will require a label restriction that prohibits any use of the product on utensils, dishes, and glassware, unless a new residue transfer study is conducted and found acceptable by EPA.

Section 408(b)(2)(C) of the FFDCA, as amended by the Food Quality Protection Act (FQPA), requires EPA to apply an extra ten-fold (10X) safety factor when evaluating threshold effects for infants and children, unless EPA determines based on reliable data that a different factor is appropriate. In this instance, EPA has not applied any inter-species uncertainty factor because the EPA analysis is based on human data, and has not applied any intra-species uncertainty factor because the range of human sensitivity to argyria has been adequately characterized. For oral risks, EPA has retained the ten-fold default uncertainty factor for infants and children established by the FQPA. EPA believes that this approach will be very protective, because argyria is not actually a toxic effect, there is no evidence that infants or children are more sensitive, and EPA has used a very conservative methodology to estimate exposure.

We note that this tolerance rulemaking does not address any environmental effects that may result from release of these silver ions. Concerns were raised in the case of the Samsung washing machine about the impact of the discharge of silver ions on the effectiveness of sewage treatment systems. This issue may also be raised with respect to use of these antimicrobial products.

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We hope this information is helpful. As always, please call if you have any questions.