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Office of Hazard Identification and Reduction  
U.S. Consumer Product Safety Commission  
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April 20, 2021

Dear Dr. Woodcock, Mr. Regan and Dr. Thomas,

Re: Engineered nanomaterials in masks claimed as protection against COVID-19

We write to urge you to use your authorities and competencies to ban the import and sale of medical masks and civilian equivalents in the United States and its territories that incorporate certain nanoscale materials. Furthermore, you should recall any such masks presently in the United States and its territories and strongly advise against the continued use of such masks because wholesale and retail recalls will not prevent the use of these masks by individuals unaware that regular use of the masks, e.g., by teachers and school children, will result in inhaling these nanomaterials at occupational exposure levels.

Jim Thomas, of the ETC Group in Canada, has aggregated Department of Commerce Harmonized System data on U.S. imports of Shengquan Group masks. Shengquan is a prominent global manufacturer of medical and civilian use masks incorporating biomass derived nanographene. Mr. Thomas estimates that companies including Shengquan USA, SQ Medical, Shengquan Canada, Aussino, Dolbec International, BP Exploration and others have imported into the U.S. over 600 million masks from Shengquan New Materials company since the beginning of the pandemic.<sup>1</sup> We attach an Excel spreadsheet with Mr. Thomas's Harmonized System data and his aggregation calculations. (Attachment 1) Shengquan masks incorporating nanographene "heal fiber" are not always advertised as such, so it is impossible to determine what percentage of the masks incorporate nanographene. The certificate of registration by one importer of the Shengquan masks explicitly notes that the certificate does not constitute Food and Drug Administration approval of the mask.<sup>2</sup> However, Shengquan states in its marketing materials that its nanographene masks provides "equivalent protection" to that of National Institute for Occupational Safety and Health (NIOSH) certified masks and implies its imported masks are FDA approved.

We make this request in the full recognition that mask wearing continues to be a public health measure of critical importance as we enter the fourth wave of COVID-19. However, recent events concerning masks that incorporate antimicrobial nanomaterials provide evidence of the urgent need for you to take precautionary actions for imported masks that have not undergone pre-market safety reviews and post-market surveillance.

On April 2, Health Canada issued an advisory, "Face masks that contained graphene may pose health risks" due to the inhalation of nano-scale graphene particles.<sup>3</sup> Canadian TV disclosed that the masks entered Canada through a misstep on the supply chain, along with an emergency order to facilitate COVID-19-related supplies, so the masks were subject to very little oversight. The FDA spokesperson Audra Harrison contradicted the company claim that its masks had "passed the United States FDA certification." The FDA told CTV that there's no such thing as an FDA certification. In fact, they had to send letters to several mask manufacturers telling them to stop making such claims. The FDA hasn't authorized any graphene-coated masks and "is unaware of any face masks with graphene being legally marketed or distributed in the U.S. at this time. In the U.S., any devices that include drugs, biologics [biological materials] or additives such as graphene... require FDA's specific review and marketing authorization," she said.<sup>4</sup>

On April 6, five weeks after Belgian authorities recalled masks containing nano-scale titanium dioxide and silver particles, four European and Canadian non-governmental organizations wrote to the President of the European Union Commission, the European Parliament, the Executive Director of European Chemical Safety, and the Commissioner of the Directorate General of Health and Food Safety to urge them to ban the import and sale (physical or

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<sup>1</sup> [https://www.amazon.com/SHENGQUAN-2021-Disposable-Face-](https://www.amazon.com/SHENGQUAN-2021-Disposable-Face-Masks/dp/B08WZ99VWY/ref=sr_1_7?dchild=1&keywords=SHENGQUAN&qid=1617997825&sr=8-7)

[Masks/dp/B08WZ99VWY/ref=sr\\_1\\_7?dchild=1&keywords=SHENGQUAN&qid=1617997825&sr=8-7](https://www.amazon.com/SHENGQUAN-2021-Disposable-Face-Masks/dp/B08WZ99VWY/ref=sr_1_7?dchild=1&keywords=SHENGQUAN&qid=1617997825&sr=8-7)

<sup>2</sup> [https://cdn.shopify.com/s/files/1/0286/5171/6682/files/SQMS\\_-\\_Certificate\\_of\\_FDA\\_Registration\\_a71022ff-0a60-46d0-9b95-c74242fe4cd2.pdf?v=1112431288921580820](https://cdn.shopify.com/s/files/1/0286/5171/6682/files/SQMS_-_Certificate_of_FDA_Registration_a71022ff-0a60-46d0-9b95-c74242fe4cd2.pdf?v=1112431288921580820)

<sup>3</sup> <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75309a-eng.php>

<sup>4</sup> <https://montreal.ctvnews.ca/recalled-masks-were-worn-by-thousands-of-quebec-kids-feds-say-import-rule-wasn-t-followed-1.5388068>

electronically mediated) of the masks labeled as containing nanographene or biomass graphene.<sup>5</sup> On February 20, the Shengquan Group boasted that EU President Ursula von der Leyen was shown in a photo wearing one of their biomass graphene masks (FFP2).<sup>6</sup> According to the company, its FFP2 masks have a “protective effect [is] equivalent to N95 mask which certified by National institute of Occupational Health and Safety.”<sup>7</sup>(sic)

On April 13, the city of Nancy and Nancy urban district in France recalled millions of products containing nanographene, following Canadian authorities’ decision.<sup>8</sup>

On April 15, the Spanish Agency for Medicines and Health Products issued a report calling for the cessation of marketing and use of graphene IIR surgical masks manufactured by Shandong Shenquan New Materials Co. Ltd, China.<sup>9</sup> The Spanish Agency is conducting research on the safety of the nanographene masks and recommends cessation of the use of surgical masks containing graphene.

The Shengquan Group claims to be able to produce 3 million masks per day from biomass graphene.<sup>10</sup> The company has exported at least 74 shipments of its nanographene masks, with the brand name “heal fiber” to the U.S., mostly through its own U.S. subsidiary but also through global medical supply sourcing companies, such as Microbridges, based in Virginia. In February, the Shengquan Group announced it had developed a material, trade marked as “Nano VTS” that claims to kill 100% of three coronaviruses, including COVID-19.<sup>11</sup>

Although EPA has conditionally registered one nanosilver product, HeiQ AGS-20, the conditional use permit was for a textile preservative against mildew and mold<sup>12</sup> and it has registered another nanosilver product NSPW Nanosilver, also as a textile preservative.<sup>13</sup> The HeiQ respirator that had been approved by the FDA is no longer approved.<sup>14</sup> To our knowledge, with the exception of the revoked HeiQ authorization, none of your agencies has issued a conditional use permit or conducted a voluntary consultation with manufacturers of nanotechnology enabled textiles for use in masks, whether for medical personnel or for

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<sup>5</sup> <https://www.ciel.org/wp-content/uploads/2021/04/Final-nanographene-sign-on-letter.pdf>

<sup>6</sup> <http://e.shengquan.com/index.php?m=content&c=index&a=show&catid=19&id=240>

<sup>7</sup> Ibid.

<sup>8</sup> <https://infodujour.fr/societe/48267-nancy-precautions-a-propos-des-masques-contenant-du-graphene>

<sup>9</sup> La AEMPS informa sobre el cese de comercialización y utilización de las mascarillas quirúrgicas tipo IIR con grafeno fabricadas por Shandong Shenquan New Materials Co. Ltd, China

<https://www.aemps.gob.es/informa/notasinformativas/productossanitarios/seguridad-3/2021/la-aemps-informa-sobre-el-cese-de-comercializacion-y-utilizacion-de-las-mascarillas-quirurgicas-tipo-iir-con-grafeno-fabricadas-por-shandong-shenquan-new-materials-co-ltd-china/>

<sup>10</sup>[https://nm.manufacturer.globalsources.com/si/6008852295560/CompanyProfile.htm?state\\_filt=CN\\_CNFUJ?source=GSOLHP\\_Top20\\_Trending\\_2](https://nm.manufacturer.globalsources.com/si/6008852295560/CompanyProfile.htm?state_filt=CN_CNFUJ?source=GSOLHP_Top20_Trending_2)

<sup>11</sup> <https://www.prnewswire.com/news-releases/newly-released-antiviral-fabric-from-sq-group-kills-covid-19-virus-301225627.html>

<sup>12</sup> <https://www.federalregister.gov/documents/2012/02/22/2012-3928/pesticide-product-registrations-conditional-approval>

<sup>13</sup> <https://www.epa.gov/pesticides/epa-registers-new-nanosilver-active-ingredient-materials-preservative>

<sup>14</sup> <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixa> Date authorization revoked:

10/15/2020 HeiQ Materials AG Respirator number HVB-FFP2-01

civilians. Nonetheless, a large portion of masks sold have been identified as using nano materials, which are apparently not approved for use in masks.<sup>15</sup> However, the Wall Street Journal did report that in addition to the HeiQ respirator, a large number of N95 masks were rejected by the FDA for not meeting standards, reducing the number of mask importers from 80 companies to only 14, and some of these rejected mask companies contain nano in their names.<sup>16</sup> More than 1,300 Chinese medical-device companies that registered to sell protective gear and other equipment in the U.S. during the coronavirus pandemic listed as their American representative a purported Delaware entity CCTC that uses a false address and nonworking phone number, according to a Wall Street Journal analysis.<sup>17</sup> The Shengquan Group is one of those companies that used CCTC.

We believe that the scientists in your agencies are fully aware of the potential toxicity of nano silver, nanocopper and nanographene as used in masks. Still, we would point you to a 2018 review of studies on the toxicity of nanographene in ACS Nano. The authors conclude that “based on the scarce available evidence, it cannot be excluded that some forms of graphene will be as potent a toxicant as carbon nanotubes”.<sup>18</sup>

We strongly support the wearing of masks to protect against COVID-19, but the masks must all use properly registered ingredients and not be toxic to the masks’ users.

We urge you to withdraw these potentially toxic nanographene, nano silver and nano copper masks from the U.S. market.

Sincerely,

Jaydee Hanson, Policy Director, International Center for Technology Assessment & Center for Food Safety, [jhanson@centerforfoodsafety.org](mailto:jhanson@centerforfoodsafety.org)

Steven Suppan, Senior Policy Analyst, Institute on Agriculture and Trade Policy, [ssuppan@iatp.org](mailto:ssuppan@iatp.org)

Jim Thomas, Research Director, ETC Group, [jim@etcgroup.org](mailto:jim@etcgroup.org)

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<sup>15</sup> See list of nano masks identified by Center for Food Safety in summer of 2020. These masks were previously reported to CPSC and EPA. <https://www.centerforfoodsafety.org/blog/6201/know-the-health-risks-before-investing-in-an-antimicrobial-nano-silver-mask-and-what-to-buy-instead>

<sup>16</sup> [https://www.wsj.com/articles/fda-pulls-approval-for-dozens-of-mask-makers-in-china-11588873151?mod=article\\_inline](https://www.wsj.com/articles/fda-pulls-approval-for-dozens-of-mask-makers-in-china-11588873151?mod=article_inline)

<sup>17</sup> <https://www.wsj.com/articles/over-1-300-chinese-medical-suppliers-to-u-s-including-mask-providers-use-bogus-registration-data-11591991270>

<sup>18</sup> Bengt Fadeel, et al. Safety Assessment of Graphene-Based Materials: Focus on Human Health and the Environment ACS Nano 2018, 12, 11, 10582–10620 Publication Date: November 2, 2018 <https://doi.org/10.1021/acsnano.8b04758> See also:

Ou, L., Song, B., Liang, H. et al. Toxicity of graphene-family nanoparticles: a general review of the origins and mechanisms. Part Fibre Toxicol 13, 57 (2016). <https://doi.org/10.1186/s12989-016-0168-y>

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