May 21, 2024

Rosemarie Gnam
Head, Division of Scientific Authority
U.S. Fish and Wildlife Service
5275 Leesburg Pike, Falls Church, VA 22041–3803.

Re: [Docket No. FWS–HQ–IA–2024–0033; FXIA16710900000–245–FF09A10000] Convention on International Trade in Endangered Species of Wild Fauna and Flora, Conference of the Parties, Twentieth Regular Meeting; Request for Information and Recommendations on Species Proposals, Resolutions, Decisions, and Agenda Items for Consideration

Dear Ms. Gnam,

For over 100 years, AAEI has served as a prominent national voice for the United States' international trade community. AAEI proudly represents various industry sectors within the global trade landscape, comprising manufacturers, importers, exporters, wholesalers, retailers, and various service providers such as customs brokers, freight forwarders, trade advisors, insurers, security providers, transportation interests, and ports. Many of its members are small businesses seeking opportunities to export to foreign markets, while the larger entities help to fuel the economy through their supply chains. As the premier U.S. international trade organization, AAEI is recognized for its expertise in the day-to-day facilitation of trade, including the administration and compliance with import and export laws of the United States, making it an indispensable resource for those directly involved in and impacted by developments in international trade.

We respectfully present these remarks on behalf of our members within the biopharmaceutical industry and related sectors. The objective of our comments is to advocate for the complete removal of African Monkey Kidney Cells (Chlorocebus aethiops, aka Chlorocebus sabaeus & Cercopithecus aethiops), commonly referred to as vero cells, from CITES appendices. Currently categorized under list II, we seek their exclusion altogether.

The widely utilized cells in question are Vero cells, originating from those isolated and cultured in 1962 at Chiba University, Japan. These cells, derived from African Monkey Kidney Cells (Chlorocebus aethiops), hold no conservation value warranting CITES regulation.

Recognized by esteemed bodies such as the World Health Organization (WHO) and Chinese Pharmacopoeia for vaccine production, Vero cells are commonly procured by the biopharmaceutical industry from reputable sources like the American Type Culture Collection (ATCC). ATCC, a nonprofit organization, specializes in the collection, storage, and distribution of standard reference microorganisms. The chain of custody is maintained very strictly as a matter of standard regulatory practice in the biopharmaceutical industry. The ATCC vero seed stock (ATCC reference CCL 81) is present at passage number (PN) 121. ATCC CCL 81 was passaged to PN 134 and characterized by the World Health Organization (WHO) for use in vaccine manufacture. This seed stock was designated as vero (WHO) 10-87 and deposited at the European Collection of Cell Cultures (ECACC) and the ATCC. The vero (WHO) 10-87 cell line deposited at the ATCC is under the custodianship of the US FDA/CBER Office of Vaccines Research and Review Division of Viral Products.

The passage number of the cells that are commonly used in industry is over 100 times. In cell culture, the "passage number" refers to the number of times a cell line has been sub cultured or passaged since its original isolation or acquisition. Each time cells are sub cultured, they are typically detached from the culture vessel, diluted, and replated into a new vessel to continue growing. For example, Passage number 134 would indicate that the cells have undergone this process 134 times since their original isolation or acquisition. Therefore, the amount of original primate material is greatly reduced from the original cells.

The Relationship between Vero Cells and Viral Vaccines as explanation; Viral vaccines have been widely used in preventing many diseases, including rabies, influenza, and smallpox. However, vaccines are still not widely affordable for vulnerable populations in endemic areas, the cost of the vaccine and the tremendous need worldwide are the main hurdles for equitable and global use of human viral vaccines.

The Vero cells can be applied to vaccine production ranges from live rotavirus vaccines to live attenuated influenza vaccines to the development of inactivated whole virus vaccines. Vero cells cannot express antiviral protein interferon due to their inherent genetic defects. Therefore, the broad susceptibility of Vero cells has promoted the development of vaccine production using Vero cells as a substrate.

It is critical that industry have access to these cells as there are new vaccines and production of vaccines that require them. However, their inclusion on the CITES list significantly amplifies the challenges associated with importing and exporting. Obtaining CITES approval in the United States alone can often exceed six months and sometimes stretches to a year or longer. Such delays have dire consequences for both patients and businesses. Reiterating our earlier point that the use of these cells does not serve any conservation purpose for the originating animal species, we strongly appeal for their removal.

Your consideration and approval of this request would benefit industry and does not harm the conservation effort of the animal they came from over 50 years ago.

If you have any questions or require any clarification of our responses, please contact my staff lead Mitchell Hart at MHart@aaei-hq.org.

Sincerely,

Eugene C. Laney
President & CEO

+1 202-857-8009 1300 Pennsylvania Avenue NW Suite 450 Washington D.C. 20004 www.aaei.org