

April 25, 2023

## Bureau of Industry and Security Imposes Export Restrictions on BGI Group, the World's Largest Genomics Company

Restrictions apply to all items subject to the EAR, including items located in the United States and U.S.-origin items

On March 2, 2023, the Bureau of Industry and Security (“BIS”) within the U.S. Department of Commerce added three affiliates of BGI Group (“BGI”) to the Entity List:

- BGI Research;
- BGI Tech Solutions (Hongkong) Co., Ltd.; and
- Forensic Genomics International.<sup>1</sup>

**Attorneys**  
[Ama Adams](#)  
[Mark Barnes](#)  
[Brendan C. Hanifin](#)  
[Emerson Siegle](#)  
[Kurt Fowler](#)  
[Minal Caron](#)  
[Sarah Dohan](#)

The Entity List is a set of specific foreign parties that are subject to license requirements for the export, reexport, and/or transfer (in-country) of items subject to the U.S. Export Administration Regulations (“EAR”). Generally, and in the case of BGI, **all items subject to the EAR—including, *inter alia*, items located in the United States and U.S.-origin items (regardless of physical location)—have now become subject to restriction.**

As a result of the March 2 designation, U.S. and non-U.S. parties alike must seek advance authorization from BIS prior to exporting, transferring, or disclosing any item subject to the EAR to these BGI entities. This has potentially very significant consequences for the many universities, companies, and other entities that transact and collaborate with BGI. In universities and academic medical centers, for example, faculty may have collaborative, subaward, or vendor agreements with BGI entities. It is also possible that faculty members are participants in international collaborative research projects or academic discussion groups that include employees of or consultants to BGI entities, but institutional compliance and screening processes may not detect those sorts of collaborations, in that they would not involve contracts or subawards that would be routinely screened.

### BGI

BGI Group, a Chinese entity, is the world's largest genomics company. On March 2, BIS designated three BGI affiliates—BGI Research, BGI Tech Solutions (Hongkong) Co., Ltd., and Forensic Genomics International—to the Entity List based on information indicating that the entities' collection and analysis of genetic data “poses [*sic*] a significant risk of contributing to monitoring and surveillance by the government of China, which has been utilized in the repression of ethnic minorities in China” and “present a significant risk of diversion to China's military programs.”<sup>2</sup>

Previously, in July 2020, two other BGI affiliates—Xinjiang Silk Road BGI and Beijing Liuhe BGI—were designated to the Entity List for their alleged support of human rights abuses in the Xinjiang region of China.

### Export Administration Regulations (EAR)

The EAR, administered by BIS, regulate the export of dual-use commodities, software, and technology. Among other things, the EAR regulate the physical movement of U.S.-origin items across borders, as well as the disclosure of U.S.-origin technology to foreign nationals (whether in the United States or abroad).

All commodities (e.g., physical end products, parts, hardware, equipment), software, and technology (collectively, “items”) are “subject to the EAR” if they are:

- Physically located in the United States;
- U.S.-origin, wherever located;
- Foreign-made commodities that incorporate controlled U.S.-origin commodities; or
- Certain foreign-made direct products of controlled U.S.-origin technology or software.<sup>3</sup>

A subset of items subject to the EAR are “controlled,” meaning a license may be required to export, transfer, or disclose such items to foreign countries or foreign nationals. However, as discussed below, **an Entity List designation significantly expands the scope of applicable licensing requirements.**

Pertinent to many higher education and research institutions, “technology” is synonymous with “know-how” in the context of the EAR. Specifically, technology is subject to the EAR if it is necessary for the “development,” “production,” or “use” (which includes operation, installation, maintenance, repair, overhaul, or refurbishing) of an item subject to the EAR, *regardless of* the item’s sensitivity or technical characteristics. Technology can be contained and communicated in virtually any medium, including written or oral communications, blueprints, drawings, photographs, plans, diagrams, models, formulae, tables, engineering designs and specifications, computer-aided design files, manuals or documentation, electronic media, or information revealed through visual inspection.

### BGI Entity List Designations

As a result of the March 2 designation, any export, transfer, or disclosure to the designated BGI entities—including via email, videoconference, electronic download, or other means—of any item (including technology) subject to the EAR would require advance BIS authorization. **This restriction applies to any item subject to the EAR (i.e., any item that is in the United States or U.S. origin), without regard to whether the item is controlled under the EAR.**

Higher education and research institutions must take care to ensure that interactions with BGI affiliates and their employees and representatives, including those pursuant to formal research agreements or informal collaborations, do not involve the export, transfer, or disclosure to designated BGI entities of any item (including technology) subject to the EAR. Because the EAR impose strict liability for civil violations, even inadvertent violations could subject researchers or their employers (regardless of nationality) to potential liability.

Importantly, to date, only a handful of BGI entities have been designated to the Entity List. In contrast to certain U.S. sanctions programs, the restrictions attendant to Entity List designations are not imputed automatically to non-designated, legally distinct BGI affiliates. **However, BIS guidance emphasizes that persons who plan to export, transfer, or disclose items subject to the EAR to non-designated affiliates of a party on the Entity List are encouraged to proceed with caution.** To comport with regulator expectations, parties intending to provide non-designated BGI affiliates any goods or technology subject to the EAR should therefore conduct enhanced due diligence to satisfy themselves that the (1) items are not ultimately destined for a designated BGI affiliate; and (2) recipient is a separate, legally distinct entity (as opposed to a branch or operating division of a designated BGI affiliate).<sup>4</sup>

### Conclusion

The March 2 designation does not impose an across-the-board prohibition on all dealings with BGI. However, U.S. and non-U.S. higher education and research institutions alike that interact with BGI affiliates, and their personnel and representatives, would be well served to take note of the designation, identify the specific BGI affiliates with which there

are established contractual or collaborative relationships, and undertake appropriate steps to ensure ongoing compliance with the EAR.

- 
1. The Entity List identifies multiple aliases for each newly designated BGI entity. For BGI Research, these include BGI Genomics Institute; Shenzhen BGI Life Science Research Institute; Shenzhen Huada Gene Research Inst.; and Shenzhen Huada Gene Research Institute. For BGI Tech Solutions (Hongkong) Co. Ltd., these include Hong Kong Huada Gene Technology Service Co., Ltd. and Hong Kong Huada Laboratory Co., Ltd. For Forensic Genomics International, these include BGI Forensic Technology (Shenzhen) Co., Ltd; BGI Judicial; FGI; Huada Judicial; and Shenzhen Huada Forensic Technology Co., Ltd.
  2. Additions and Revisions of Entities to the Entity List, 88 Fed. Reg. 13,673, 13,674 (Mar. 6, 2023).
  3. Although the EAR incorporate certain exclusions for research-related activities, such exclusions are subject to various limitations and restrictions.
  4. Bureau of Indus. & Sec., Policy Guidance FAQs, [https://www.bis.doc.gov/index.php/policy-guidance/faqs#faq\\_134](https://www.bis.doc.gov/index.php/policy-guidance/faqs#faq_134) (last visited Apr. 24, 2023).