THE US-CHINA BUSINESS COUNCIL
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USCBC Comment on Controls on Certain Laboratory Equipment and Related Technology to Address Dual Use Concerns About Biotechnology

Bureau of Industry and Security, Department of Commerce

Docket Number: 250108-0012

RIN 0694-AJ95

The US-China Business Council (USCBC) welcomes the opportunity to submit comments to the Bureau of Industry and Security (BIS) on the Controls on Certain Laboratory Equipment and Related Technology to Address Dual Use Concerns About Biotechnology. USCBC solely comprises more than 270 US companies that do business in China. Many of our members depend on their market share in China to enhance and undergird their global competitiveness. As such, their businesses in China make America stronger and more secure by providing revenue sources that fuel investments and drive employment back at home.

USCBC appreciates the crucial role export controls play in preventing the proliferation of technologies with national security implications and dual-use applications. However, we believe that export controls can only be effective national security tools when they control technologies for which there is no foreign availability. In instances where China possesses the ability to domestically manufacture controlled products and when other countries do not adopt equivalent export control measures, US export controls simply disadvantage American companies without inhibiting access to controlled products. Removing American companies from the market will, contrary to US national security objectives, reduce competition in China and artificially create market space for Chinese and international firms to fill.

Further, onerous license requirement will provide China with an impetus to accelerate domestic substitution initiatives. USCBC data indicates this is already occurring. According to our member survey, 43 percent of companies have been affected by US export controls. Of that group, 48 percent say export controls cause them to lose sales to Chinese competitors and 30 percent lost sales to international competitors.

It is therefore crucial that such measures be structured so that they only impact items for which the US is the sole source and are clearly linked to national security end uses. To that end, robust, transparent mechanisms should be instituted to assess foreign availability in the long term and adjust the parameters of ECCNs accordingly. Further, given the overwhelmingly civilian end uses of technologies controlled in the IFR, a robust exemption process should be instituted for items that are destined for hospitals and other research institutions for medical end uses.

State of foreign availability in China and international competition

At the policy level, the Chinese government supports the indigenous capabilities of advanced research equipment. China's 14th Five-Year Plan and the Long-Range Objectives Through 2035 sub initiative explicitly underscore the need to strengthen manufacturing for high-end scientific instruments. A 2023 Politburo study session highlighted the importance of localizing scientific instruments.

At the product level, ECCN 3A069 is defined as "a. Flow cytometers and cell sorters that are 'specially designed' for spectral analysis or contain 26 or greater detectors or channels." One Chinese firm has published a spectral product offering 64 channels and a second firm has published a spectral cytometer offering 38 channels. By removing US established companies from the equation, Chinese domestic manufacturers are already targeting US companies' customers through increased offerings and investments.

Given this reality, USCBC urges BIS to recalibrate the parameters of ECCN 3A069 and corresponding ECCN 3E069 so that they do not capture products for which there is domestic availability. We do not wish to see export controls inadvertently strengthen China's industrial policies.

In the mass spectrometry market, US companies face stiff competition from foreign competitors that manufacture in Singapore, the UK, and the EU. As such, they are not subject to licensing requirements in the IFR and will gain a competitive advantage over American companies. As with our recommendations on flow cytometry, USCBC recommends BIS adjust 3A069 so that it only controls items for which there is no foreign availability.

Implementation should be suspended until changes can be made

The IFR was issued on January 16, 2025 — four days before the change in administration — and the rule went into effect immediately. USCBC understands that there was neither consultation with industry prior to the issuance of the IFR, nor was there an opportunity to provide public comments before the rule became effective. Given deficiencies in the IFR, most critically, its catalyzing role in the indigenous development of controlled technologies in China, USCBC recommends that BIS indefinitely suspend the implementation of this rule until necessary adjustments are made.

Absent indefinite suspension, BIS should pause implementation for 60 days while it reviews comments collected pursuant to RIN 0694-AJ95. Doing so will enable BIS to conduct an appropriate review of the regulations and halt adverse impacts to US market share and adverse impacts to competitiveness.

License exceptions should be added for hospitals

Given that flow cytometers and liquid chromatography mass spectrometers serve overwhelmingly civilian end uses — such as cancer research, new drug development, and single cell analysis — BIS must exercise caution to ensure the smooth flow of critical equipment to the healthcare sector. USCBC suggests that BIS create a license exemption MED for exports to hospitals or entities involved in drug development, medical research, and medicine. Absent this change, BIS should maintain a case-by-case licensing policy or licensing policy with a presumption of approval for these ECCNs.

Review licenses on a case-by-case basis

To the extent any export licensing is required pursuant to this IFR, we request that licenses be reviewed on a case-by-case basis and not under a presumption of denial, as the higher presumption of denial license review policy would unduly restrict commercial transactions that do not present significant national security or foreign policy risks.

Clarify that 3E069 does not cover after-sales service

BIS should clarify that ECCN 3E069, which controls technology for the development and production of 3A069 flow cytometers and mass spectrometry equipment, does not apply to after-sales servicing and product upgrades. Controls on services and upgrading will damage the brand reputation of American enterprises and cause global customers to question the reliability of their American business partners. Absent clarification, we request that the License Exemption Technology and Software Under Restriction be added for China.

Maximize American competitiveness

Given the market dynamics for high-parameter flow cytometry and the need for BIS to properly review the efficacy of the IFR and its adverse impact on US industry, we respectfully request that BIS suspend or pause the export control rule for at least 60 days. If that is not possible, we request that BIS implement a temporary general license to allow transactions to proceed while the IFR is reviewed.

We hope this feedback helps BIS to reconsider the IFR to ensure that US export control policy remains focused on enhancing, rather than impeding, US technological leadership and national security.