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BIOLOGICS RESEARCHERS AND SUPPLIERS BEWARE: INTERNATIONAL EXCHANGE OF NON-PATHOGENIC RESEARCH MATERIALS INCLUDING COMMON VSV-G PACKAGING PLASMIDS MAY TRIGGER EXPORT PENALTIES

WHAT HAPPENED?

On February 1, the Department of Commerce, Bureau of Industry and Security (BIS) announced a settlement with Princeton University, which BIS alleged exported animal pathogens and genetic elements of animal pathogens without required export licenses to researchers in the U.K., Canada, Australia, Europe, South Korea, India, Singapore, and China.

Although Princeton voluntarily disclosed the violations, BIS imposed a penalty of \$54,000, mandated two audits of Princeton's export compliance program (with findings reported to BIS), one of which must cover a twelve month period pre-dating the settlement and be conducted by an external third party (at Princeton's expense), and further mandated submission to BIS of two reports detailing enhancements to Princeton's export control processes.

In the words of the responsible Special Agent in Charge, "[t]his action demonstrates that the Office of Export Enforcement will continue to leverage our unique authorities as enforcers and regulators of our nation's export control laws to

investigate possible violations by research institutions and hold them accountable when appropriate."

The full order, charging letter, and settlement agreement may be accessed at this [link](#).

WHY DOES IT MATTER?

BIS' enforcement action against Princeton is an important reminder to biologics researchers and suppliers about a too-often overlooked portion of U.S. export regulations that imposes significant restrictions on certain human, animal, and plant pathogens, as well as genetically-modified organisms and genetic elements that contain or code for genes of such pathogens.

The scope of the pathogen-related export controls is significantly broader than many researchers assume, diverging from common intuitions in several ways. First, the controls apply to shipments to all countries, including "friendly" countries, and for all purposes, including purely academic collaboration and medical treatment development. Second, the

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export controls at issue apply to more pathogens than the domestic rules regarding "Select Agents" (pathogens determined by the Centers for Disease Control and Prevention (CDC) and/or the US Department of Agriculture to pose a severe threat to health). Third, the controls in some cases apply to materials that are attenuated or otherwise not themselves pathogenic, and that researchers therefore do not think of as sensitive or dangerous. Fourth, the controls apply even when the materials at issue are widely available and in use internationally. In short "it isn't dangerous," "it isn't on the Select Agents List," "it's only Australia," and "you can get it anywhere," are not reliable guideposts, and biologics researchers and suppliers assume significant risk if they proceed without understanding the precise scope of the regulations.

BIS' imposition of significant mandatory audit requirements as part of the settlement with Princeton also underscores the need for research institutions to go beyond adopting an export compliance policy to implement an effective export compliance program that tracks the requirements identified in BIS' **compliance program guidelines**, including control mechanisms that are regularly audited and calibrated. While the penalty imposed on Princeton was relatively modest, it was still twice the estimated value of the materials shipped, and researchers should be aware that civil penalties can reach \$305,292 or twice the value of the transaction, whichever is greater, while criminal penalties (which apply to willful violations) can reach \$1,000,000 with the potential for jail time of up to 20 years.

WHICH RESEARCH MATERIALS ARE AFFECTED?

The controls at issue impose a requirement to obtain export authorization for shipment to any international destination (including Canada) of certain controlled human, animal, and plant bacteria, viruses, fungi, and toxins. In addition, they restrict the export of genetically modified organisms (GMOs) or genetic elements that contain or code for the genes of controlled pathogens or subunits of controlled toxins, including in some cases where the GMOs or genetic elements are not themselves pathogenic.

The pathogens and toxins that are controlled for export purposes are listed under Export Control Classification Numbers (ECCN) 1C351 and 1C354 of the Commerce Control List. Examples include: Chikungunya virus; Cholera toxin; Coxiella burnetii; Ebola virus; Enterohaemorrhagic E. coli (EHEC); Pseudorabies virus; Salmonella typhi; Saxitoxin; Tetrodotoxin; Vesicular stomatitis virus; and Vibrio cholerae. As noted above, the export-related list is broader than the domestic Select Agents List. The current version of the full lists (updated through January 14, 2021) may be found on pages 65-73 of the PDF document [at this link](#) (from the BIS website).

Importantly, the controls apply not only to the complete, wild-type organisms listed in the above-referenced ECCNs, but also to any GMO that contains, or any genetic element that codes for, genes of the listed organisms or subunits of the listed toxins. "Genetic elements" is broadly

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defined to include (without limitation) chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part. These derivative controls are described under ECCN 1C353 (on pages 70-71 of the above-referenced PDF).

Notably, while a GMO that contains, or genetic element that codes for, genes of controlled bacteria and fungi is subject to control if it “[i]n itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health” or “[c]ould endow or enhance pathogenicity,” GMOs that contain, or genetic elements that code for, genes of controlled viruses, or subunits of controlled toxins, are controlled for export even if they are not themselves harmful. The strict treatment of GMOs and genetic elements related to controlled viruses has significant practical consequences. To take just one example, commonly-used expression/packaging plasmids containing the VSV-G gene require export authorization for all destinations, irrespective of non-pathogenicity and their widespread domestic and international availability. As a result, researchers and suppliers must have export authorization to send such plasmids to colleagues overseas, even if the plasmid involves no other elements of

any pathogen and is not itself dangerous to health.

There is some good news: there are special rules that lower the controls applicable to certain vaccines, immunotoxins, medical products, and diagnostic and food testing kits containing controlled genetic elements or GMOs. A complete discussion of these special rules is beyond the scope of this alert, but an important example is that vaccines that contain ECCN 1C353 items are controlled under ECCN 1C991, resulting in a requirement for export authorization only to countries designated as State Sponsors of Terrorism (Cuba, Iran, North Korea, Syria), or recipients designated by the U.S. government as prohibited or restricted parties, or prohibited end uses (e.g., development of biological weapons). However, an important limitation applies: a vaccine is eligible for the lower level of control only if it is in a pharmaceutical formulation approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture.

Have a question or need help addressing non-compliant exports or creating compliance processes to prevent future violations?

Contact Wiggin and Dana’s practical and experienced team of international trade compliance attorneys through the co-chair of our practice group, **Tahlia Townsend**.