

VUMC Export Compliance Export-Controlled & Restricted <u>Genetic Elements</u>

Genetic elements and genetically modified organisms

- Any genetically modified organism that contains, or any genetic element that codes for, any of the following:
 - Any gene, genes, or translated product(s) specific to any virus on this list;
 - Any gene or genes specific to any bacterium on this list or any fungus on this list;
 - In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; or
 - Could endow or enhance pathogenicity; or
 - o Any toxins, or their subunits, on this list

NOTE: Genetic elements or Genetically Modified Organisms from any of the categories above are also controlled.

"Genetic Elements" include, inter alia, 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. Nucleic acids from an inactivated organism, virus, or sample are considered to be 'recoverable' if the inactivation and preparation of the material is intended or known to facilitate isolation, purification, amplification, detection, or identification of nucleic acids.

"Genetically Modified Organisms" include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation.

** Such materials are controlled regardless of quantity or attenuation. **

Of utmost concern are materials that could either represent a significant hazard to human, animal, or plant health or those materials that have been modified to endow or enhance the pathogenicity of the target. 'Endow or enhance pathogenicity' is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.