

BIS Licensing for Biological Commodities and Technologies



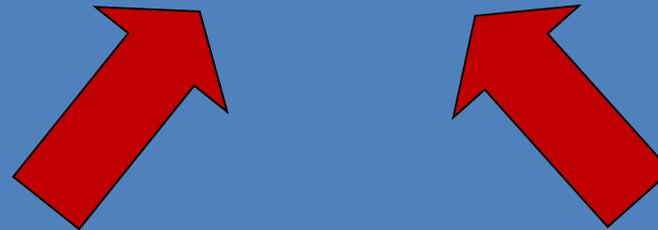
Wesley Johnson, PhD
Chemical and Biological Controls
Office of Nonproliferation and Treaty Compliance

U.S. Export Controls

- Department of Commerce: Dual-use and “600” series military items
- Department of State: Munitions
- Nuclear Regulatory Commission: Trigger list
- Department of Energy: Technology for special nuclear material
- Department of the Treasury: Financial transactions and special sanctions

U.S. Export Controls

Rationale



Internal Considerations

National Security Concerns
Foreign Policy Initiatives
Economic Concerns

External Considerations

Wassenaar Arrangement
Missile Technology Control Regime
Nuclear Suppliers Group
Australia Group

Commerce Export Controls

- Dual-use commodities and technologies
 - BIS jurisdiction
 - Predominantly commercial or academic application
 - Potential use in nuclear, biological, or chemical weapons (WMD).
- Codified in the Export Administration Regulations (EAR)
 - Listed-based controls - Commerce Control List (CCL)
 - Catch-all controls – End User/End Use based

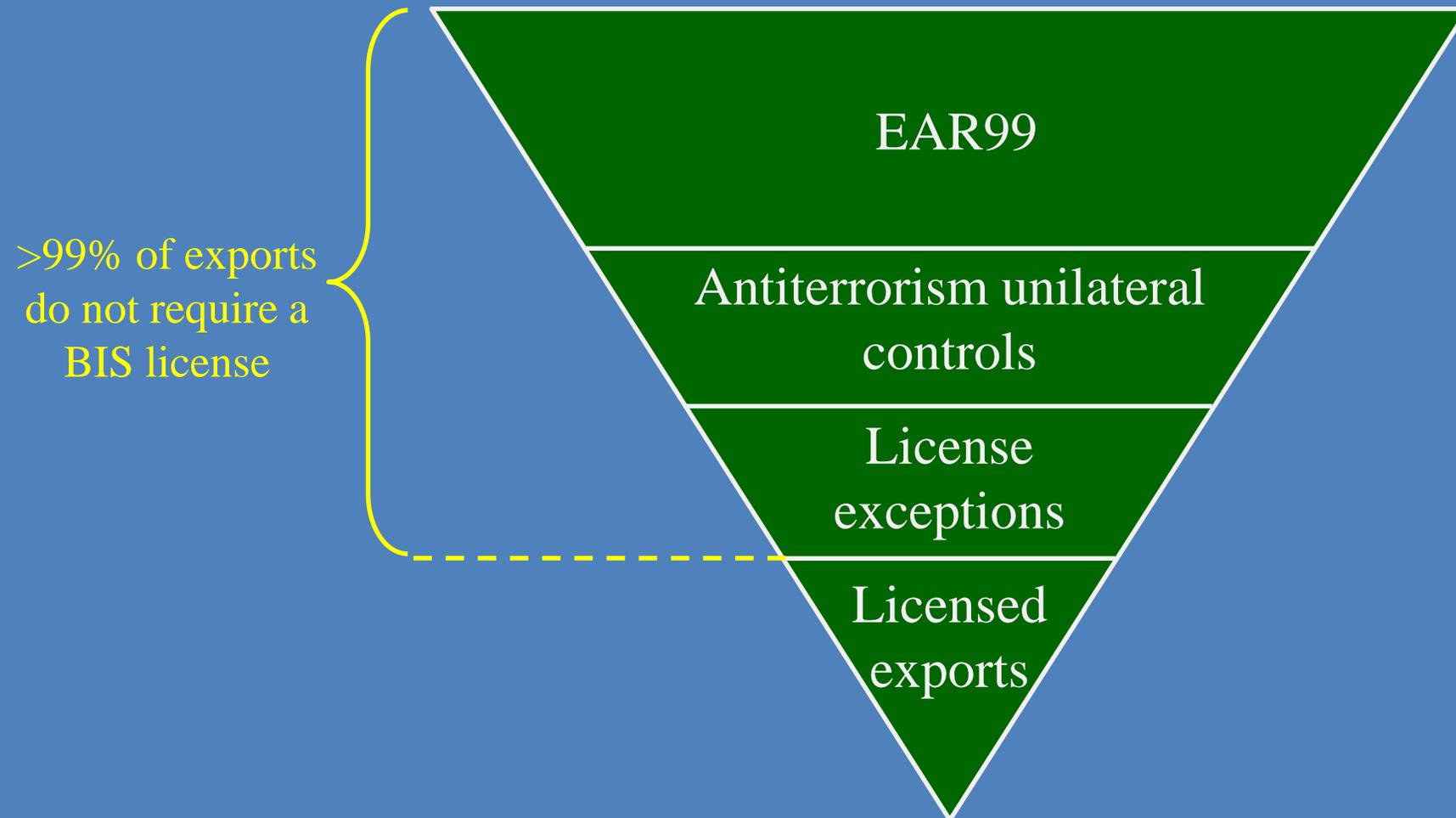
What is Subject to the EAR?

- Everything in the United States except...
- Commodities and technology under other agencies' jurisdiction
- “Publicly Available” technology and software
- Information already published or will be published (734.7)
- Technology that arises from fundamental research (734.8)
- Educational (734.9)
- Information included in patent applications (734.10)

The Commerce Control List

- Chemical and Biological Weapons
 - Australia Group
 - Chemical Weapons Convention
 - Biological Weapons Convention
- Missiles
 - Missile Technology Control Regime
 - Hague Code of Conduct
- Nuclear
 - Nuclear Suppliers Group
 - Zangger Committee
 - Nuclear Nonproliferation Treaty
- Conventional Arms
 - Wassenaar Arrangement

Licensing Pyramid



What Might Require an Export License?

- Biological agents and genetic elements
 - ECCNs 1C351, 1C353, and 1C354
 - CB1 (worldwide license requirement)
 - Some toxins STA eligible
- Vaccines, immunotoxins, medical products, diagnostic and food testing kits
 - ECCN 1C991
 - AT1 (limited countries)
- Biological processing equipment
 - ECCN 2B352
 - CB2 (all but AG members)

What Might Require an Export License?

- Technology associated with “development” or “production” of biological agents or genetic elements
 - ECCN 1E001
 - CB1 (worldwide license requirement)
- Technology associated with “development”, “production”, or “use” of biological equipment
 - ECCNs 2E001, 2E002, and 2E301
 - CB2 (all but AG members)
- Foreign nationals in US facility (deemed export)
- Re-exports (as well as deemed re-exports)
- Available license exceptions: GOV, STA, TSU, RPL

CCL is More than Select Agents

- Check Category 1 of the CCL
- Agents/Toxins with
 - History of attempted use in biowarfare
 - Serious economic/public health potential
 - Australia Group Member consensus
- Sample of AG controlled non-Select Agents
 - Yellow Fever virus
 - Chlamydomyxa psittaci
 - Lyssaviruses

Ebola and HPAI

- Ebolavirus
 - License required for all Ebolaviruses
 - License exception GOV may apply
 - Emergency licenses may be requested if needed
- HPAI
 - Has to be a highly pathogenic avian influenza virus as defined in ECCN 1C351

Genetic Elements and Genetically Modified Organisms

- Genetic elements or GMOs that contain
 - nucleic acid sequences “associated with pathogenicity” of controlled microorganisms
 - nucleic acid sequences coding for any controlled toxin or toxin subunit
 - for a virus, most sequences will be assumed “associated with pathogenicity”
- Controlled under 1C353 *if agent* on CCL

Genetically Modified Organisms



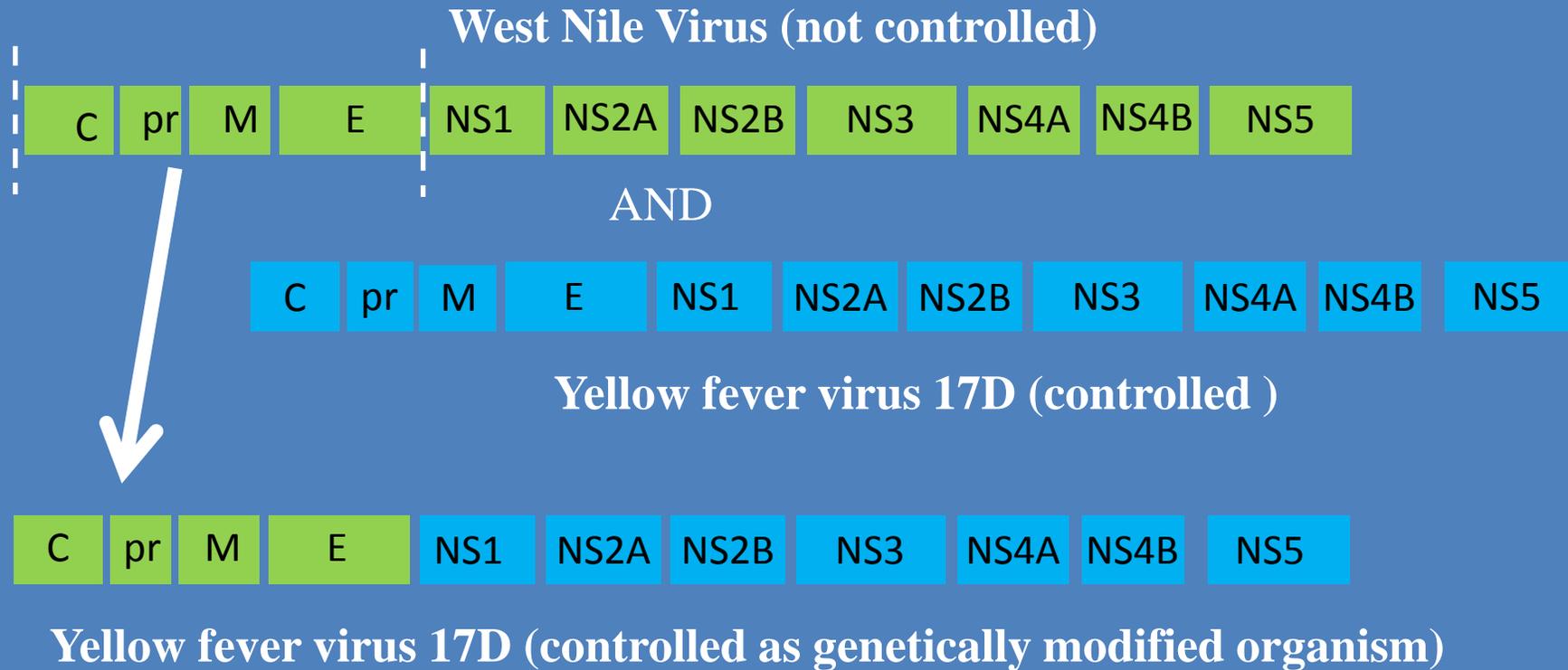
Chimeric viruses

Ebolavirus

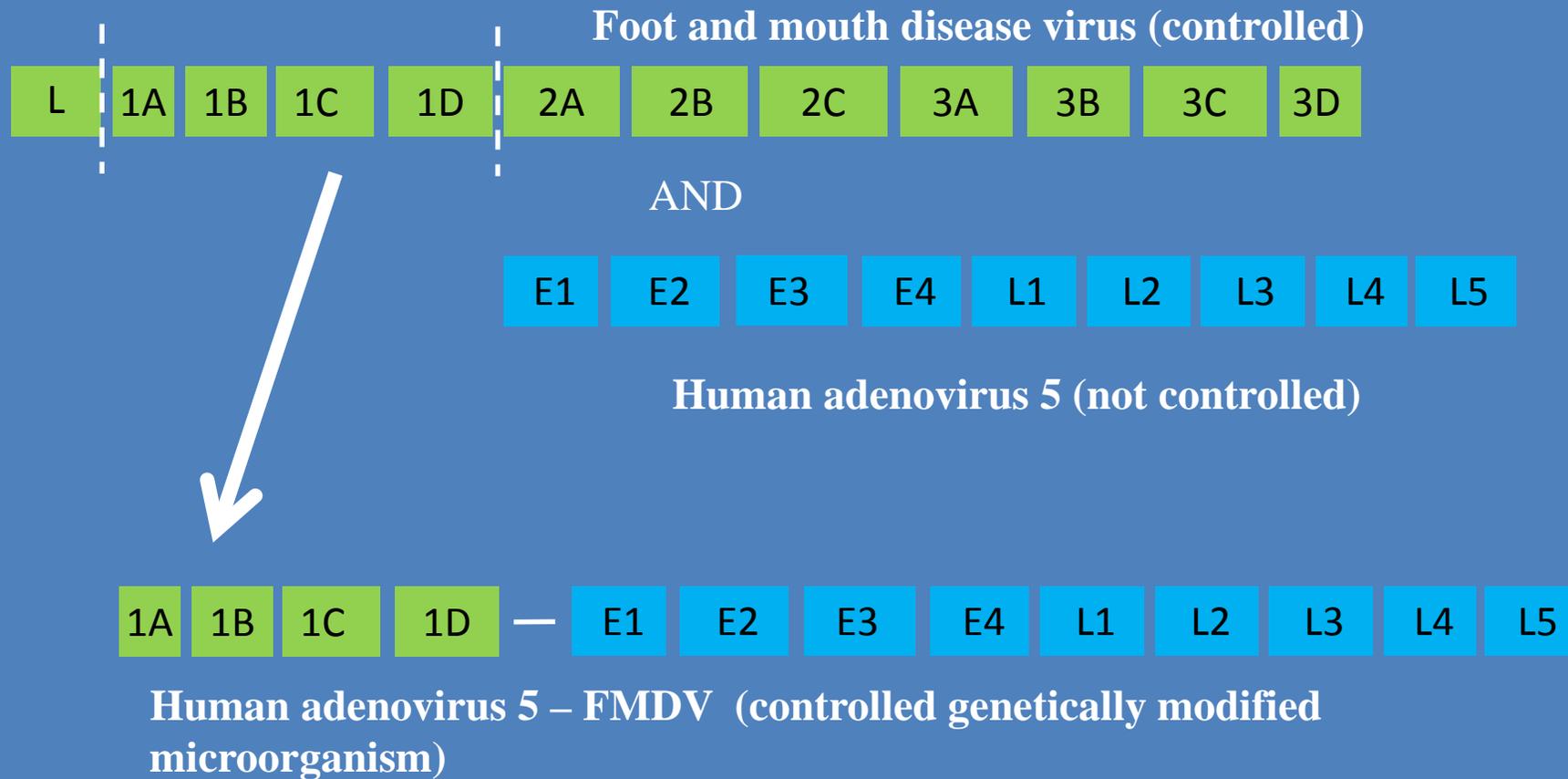


**Genetically modified Vesicular Stomatitis Virus
(controlled as genetically modified VSV)**

Genetically Modified Organisms

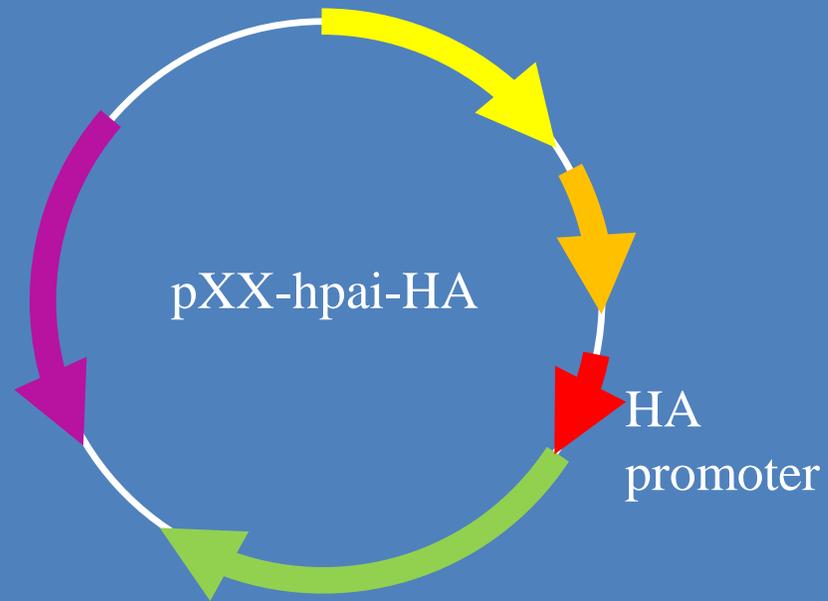


Genetically Modified Organisms



Genetic Elements

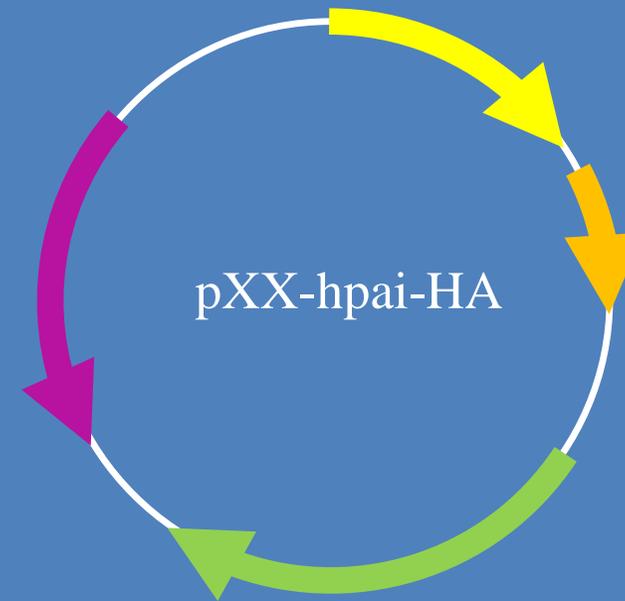
Expression plasmid +
promoter – Controlled



HA from High-path
Influenza

HA + promoter = complete gene (viral
particle_replication competent)

Expression plasmid – Not Controlled



HA from High-path
Influenza

Without the promoter, the element is
not replication competent

EAR Questions

Q. If an agent is on the Commerce Control List (CCL) and is on the Select Agent and Toxin Exclusion list, is a license for export required?

A. Yes – a license for export is required for any item on the CCL with ECCN 1C351, 1C353, or 1C354 to any destination.

EAR Questions

Q. What if we are sending a CCL listed toxin (ECCN 1C351.d) other than saxitoxin or ricin?

A. One may use license exception STA (see §740.20)

- No more than 6 shipments per toxin per year to same consignee
- No more than 100 mg per toxin per shipment
- 36 countries

EAR Questions

Q. What if we are sending a biological agent that produces a CCL listed toxin (ECCN 1C351.d ?

A. Unless the biological agent is on the CCL no license is required

- Staphylococcus aureus - no license required
- Clostridium botulinum - license required

EAR Questions

Q. What if I am sending a CCL listed agent, toxin, or biological equipment to another government?

A. One may possibly be able to use license exception GOV (see §740.11)

- Use by Government agencies of Cooperating Countries*
- Does not apply to Africa, most of Asia and South America
- Exports to a department or agency of the U.S. government (Includes contractors for support)
- Certain exports made for or on behalf of the USG
- Certain items exported at the direction of DOD

EAR Questions

Q. Do I need an export license if I have a foreign student working with a CCL pathogen?

A. Probably not unless being provided access to:

- Non public domain production techniques
- Proprietary production, development, or “use” technology of controlled biological equipment or pathogens
- Do monitor visa status

Contact Information and Guidance

- Wesley Johnson 202-482-0091
- Wesley.Johnson@bis.doc.gov
- www.bis.doc.gov
- www.bis.doc.gov/licensing/index.htm
- www.bis.doc.gov/deemedexports
- www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls