

# The Commerce Control Regulations and What Researchers Need to Know

# Training will focus on

- Introduction
- Dual Use Research of Concern
- EAR – Export Administration Regulation, Commerce Control List, Bureau of Industry and Security (BIS), U.S. Department of Commerce
- (Note – ITAR – International Traffic in Arms Regulations, U.S. State Department Does NOT apply to ARS)
- What is an Export? What is an Item?
- What is a Deemed Export?
- What is a Reexport?
- Why are MTAs critical?
- Denied Person List, Entity List, Debarred List

# Training will focus on

- Country Control List
- Group E Countries
- SNAP-R and the ARS Application Process
- Reporting a Mistake!
- Example
- Application Information Sheet
- Contact Information

# Introduction

As most of you know Technology Transfer professionals both at OTT and in the field handle matters related to intellectual property, patenting, licensing and collaborations. We support your research endeavors by marketing your research, finding you collaborators, and making sure that the right agreements are in place whether you want to collaborate with one or more outside parties, or you simply want to send or receive data or materials from them. When sending or receiving such material, there are export laws and regulations that you need to follow.

As part of an on-going effort to provide you with TT resources, we bring you this training along with ONP. As you can imagine, some scientific contexts may give rise to unique challenges. One such area is a research project that falls under Dual-Use research of Concern.

The goal of this training is to at once inform you of export control, deemed export and dual use research of concern.

# Dual Use Research of Concern (DURC)

# What is Dual Use Research of Concern or DURC?

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research. It is our goal today to talk to you about DURC, help you ask the right questions to determine whether recent developments in the research project or environment would preclude you from publishing results and require deemed export licenses when information is released to foreign nationals, and last but not least to offer you a resource to help with any and all concerns that you may have in the area of DURC.

# What is DURC at ARS?

The U.S. Department of Commerce Control list will be the main focus of this training however, before we start the Federal Government has a separate P&P for Dual Use Research of Concern that contains fifteen Agents and Toxins that federal agencies, including USDA/ARS, is required to report on. Any ARS scientist that works with any of these Agents or Toxins are required to report biennially their research project(s) to their National Program Leader. Your report(s) will be assessed by ONP for potential DURC research. ONP will report the results of their assessment biennially to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

# What Experiments Fall under DURC?

- Enhance the harmful consequences of the agent or toxin;
- Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
- Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- Increase the stability, transmissibility, or the ability to disseminate the agent or toxin;
- Alter the host range or tropism of the agent or toxin;
- Enhance the susceptibility of a host population to the agent or toxin; or
- Generate or reconstitute an eradicated or extinct agent or toxin listed above.

# 15 Agents Covered by USG Policy

The list of Agents and Toxins are from P&P Dual Use Research of Concern, No. 621.0:

- Avian influenza virus (highly pathogenic)
- Bacillus anthracis
- Botulinum neurotoxin
- Burkholderia mallei
- Burkholderia pseudomallei
- Ebola virus
- Foot-and-mouth disease virus
- Francisella tularensis
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin- producing strains of Clostridium botulinum
- Variola major virus
- Variola minor virus
- Yersinia pestis

An example can be found on the next slide.

This list is also part of the U.S. Department of Commerce list.

# Dual Use Research of Concern

## Example of biennial a DURC Report

ARS	ARS	ARS	ARS	ARS	ARS	ARS	ARS	ARS
Funding Institute (Always ARS and perhaps DHS, US State Department, DoD DTRA, or commercial entity)	Activity Status (Indicate date that project becomes/inactive)	Agent	Experiment Number	Objectives	Expected Outcomes	Potential risks/possible category of DURC	Abstract	Changes in Project Design, Outcome, Risks
ARS	9/30/2016	Avian influenza		Investigate the effect of common poultry diseases on vaccine efficacy and the susceptibility of chickens to avian influenza virus	Improve vaccination strategies by elucidating the factors in the field which cause vaccine failure.	None Found	Vaccine failure of avian influenza virus in the field is not uncommon with poultry and is believed to play a critical part in the inability of some regions to eradicate the virus from back-yard and small holder poultry flocks. A major contributing factor which has not been well described is the effect of impaired immunity from ubiquitous viruses of poultry, and the effect of other common respiratory pathogens. These studies will demonstrate what the effect of these common viruses of chickens contribute to vaccine failure in the field.	None

# Contact People for DURC

Appointed Staff :

Dr. Cyril Gay, National Program Leader, Animal Health and Safety, 301-504-4786

Dr. James Lindsay, National Program Leader, Food Safety and health, 301-504-4674

Mr. Joseph Kozlovac, Agency Biosafety Officer, 301-504-4734

Will ensure oversight of all of the 15 potential DURC agents in accordance with the Government Policy.

# Export Control and Deemed Export

# Bureau of Industry and Security

- **Bureau of Industry and Security Mission Statement**
- BIS Mission: Advance U.S. national security, foreign policy, and economic objectives by ensuring an effective export control and treaty compliance system and promoting continued U.S. strategic technology leadership.

# Commerce Control List

- The Commerce Control list contains the Category, Product Group and Type of control for all EAR regulated Items.
- Items are Commodities, Software and/or Technology that might need an Export License to ship out of the U.S.

# What is an Export?

- An Export is the shipment or transmission of items out of the United States.
- There are currently 74 pages with on average 41 Items per page or in simpler terms, over 3,000 Items. These range from equipment, pathogens, chemicals, materials, parts to oils. Would anyone think Protective Gloves? Grinding Machines? Lubricating Oil are controlled? They are!

# What Is a Deemed Export?

- Release of an **item** and/or **source code** (computer code) to a foreign national in the U.S. or abroad
- The release is considered to be an export to that person's country
- Does not apply to U.S. Citizens, individuals granted permanent resident status (Green Card Holder), or protected individuals
- ARS as an agency of the Federal Government is exempt from most licensing requirements under the "Fundamental Research" exemption

# Exemption to Deemed Export

- “Fundamental Research” exemption –
- Where the resulting research information is ordinarily published and shared broadly within the scientific community.
- Running controlled equipment is fine, taking it apart to see how it works is not.
- Risk is low however, if there is any doubt check with your Tech Transfer Coordinator (TTC) or the Office of Technology Transfer (OTT).

# What is a Re-export?

- A reexport is the shipment of an ARS Item, whole or in part subject to the EAR from one foreign country to another.
- To be very clear no ARS item, proprietary or not, should ever be shipped out of the country with out an MTA! Pathogens and Chemicals controlled by EAR must be shipped with a Select Agent MTA.

# Material Transfer Agreements (MTAs)

- Why MTAs are critical?
- An MTA controls the ARS Items use and transfer!
- No ARS scientist can be in violation of the Reexport of a controlled Item or the transfer of a non controlled Item to a person on the Denied Person list, the Entity List or most importantly a Group E country if they had an MTA in place.
- MTAs are a simple process that your TTC will be happy to help you with. All MTAs for Items going out of the country will be reviewed at OTT to help protect against an export mistake.

# Person and Entity Lists

- Denied Person List, Entity List, Debarred List
- These are list maintained by BIS that change on a regular basis.
- Denied Person List is a list of people and companies whose export privileges have been denied.
- Entity List is a list of entities that have engaged in activities that could result in an increased risk of the diversion of exported, re-exported and transfer of Items to weapons of mass destruction.
- Debarred List is a list of entities and individuals that have been convicted of violating the ARMS Export Control Act.

# Country Lists

- Country Control List
- There are five country control list A, B, C, D, and E.
- A to E is basically the good to the bad to the worst. All lists are divided into categories by type of Item and use of Item. These categories are part of the Export Control Classification Number (ECCN) that is needed by OTT to review if an export license is needed and part of the application if submitted.
- Group E is the terrorist supporting countries (Iran, North Korea, Sudan, and Syria) and Cuba (Unilateral Embargo) Humanitarian exports only! *Contact OTT for any interest in exports to this group.*

# SNAP-R and the ARS Application Process

- SNAP-R is the on line application process used to provide a request to BIS.
- Once the determination is made that an export license is needed the scientist will be ask to provide some information needed for the application. One page and very short. The application process takes about 30 days for approval. There are some exemptions we can use and sometime BIS will allow the shipment without a license.
- Once the application is received the recipient will be sent a letter acknowledging they accept the terms and conditions of the license. This is part of the ARS compliance program.

# SNAP-R and the ARS Application Process...cont'd

- Once all the approvals are received an MTA will be put in place. Because it is an export of a controlled item the MTA must have the AD, NPL and Director of ARS Homeland Security (ARSHS) signatures.
- Once the MTA is signed you can work with your area safety officers for shipment.

# Some Points on the ARS Application Process

- First and most important never hesitate to contact your TTC or OTT with any questions.
- OTT has a long working relationship with BIS and can get answers to questions quickly. OTT had applied for and received over 50 Export Licenses. OTT has the most up to date information on the EAR.
- No scientist is being ask to classify an Item they want to ship with an ECCN number.
- Let your TTC and OTT do that for you.

# Reporting Mistakes/Oversights

- It is the goal of ARS to prevent any EAR controlled Items from being exported without the proper approval. The Department of Commerce however, understands that even with the best compliance program mistakes can happen and they **STRONGLY** emphasize that if a mistake is made to report it to BIS ASAP. This reporting will go a long way in the reduction in penalties that could handed out.

# Case Study

- Example:
  - A University scientist exported (shipped) an antennae, cables and an atmospheric testing device (controlled) to Pakistan Space and Upper Atmosphere Research Commission (SUPARCO) without a license. This does not seem like a major problem, correct? What was not known was that SUPARCO was on the Entity list for involvement in nuclear and missile activities.
  - Fine \$100,000

# How could the problem have been avoided/solved

- An MTA cleared and approved by your TTC and OTT.
- The Entity list is ever changing and has members in all countries!

# Application information Sheet

ARS Scientist Name, Address, Phone, Fax, and email. (Item 15)	
Research Leader's Name	
Name, Address, Phone, Fax, and email for Recipient Scientist(s). (Item 18 & End-User Appendix for multiple scientists)	
Description of Specific End-use (1440 Characters) (Item 21)	
Technical Description of Material(s) (250 Characters for each item) (Item 22j and Item Appendix for multiple items)	
ECCN (Item 22a)	
Quantity/Units (Item 22 e & f)	
Unit Price (Item 22g)	
Total Price (Item 22h)	

# Contact Information

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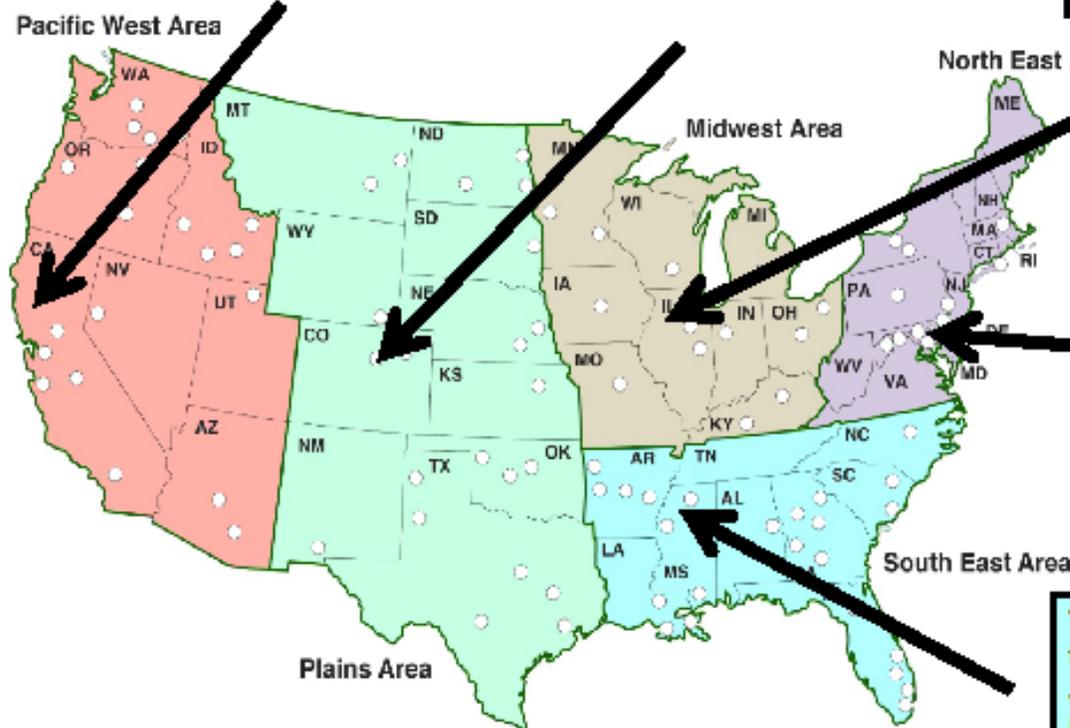
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The bold lines reflect the boundaries of the ARS geographic Areas.

