



Strategic Export Controls in the EU

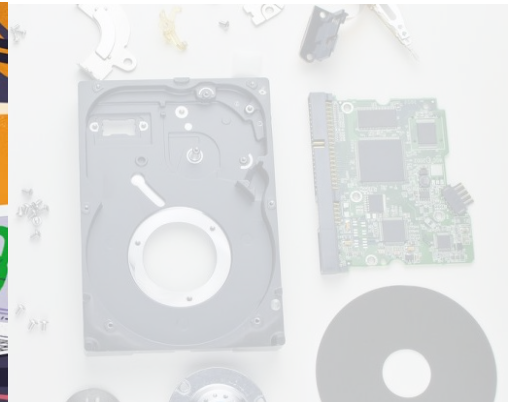
Guusta Visser, Customs Attache

Carina Bottema, Expert Dutch Central Licensing Office





Dual Use aspects for academia and research institutions







Responsibility in export control

COMPETENT AUTHORITIES

Policy making and implementing rules. Granting authorisations and monitor the export control on strategic goods.

BUSINESS/ RESEARCH COMMUNITY

Compliance with the applicable legal requirements. An Internal Compliance Programme (ICP).

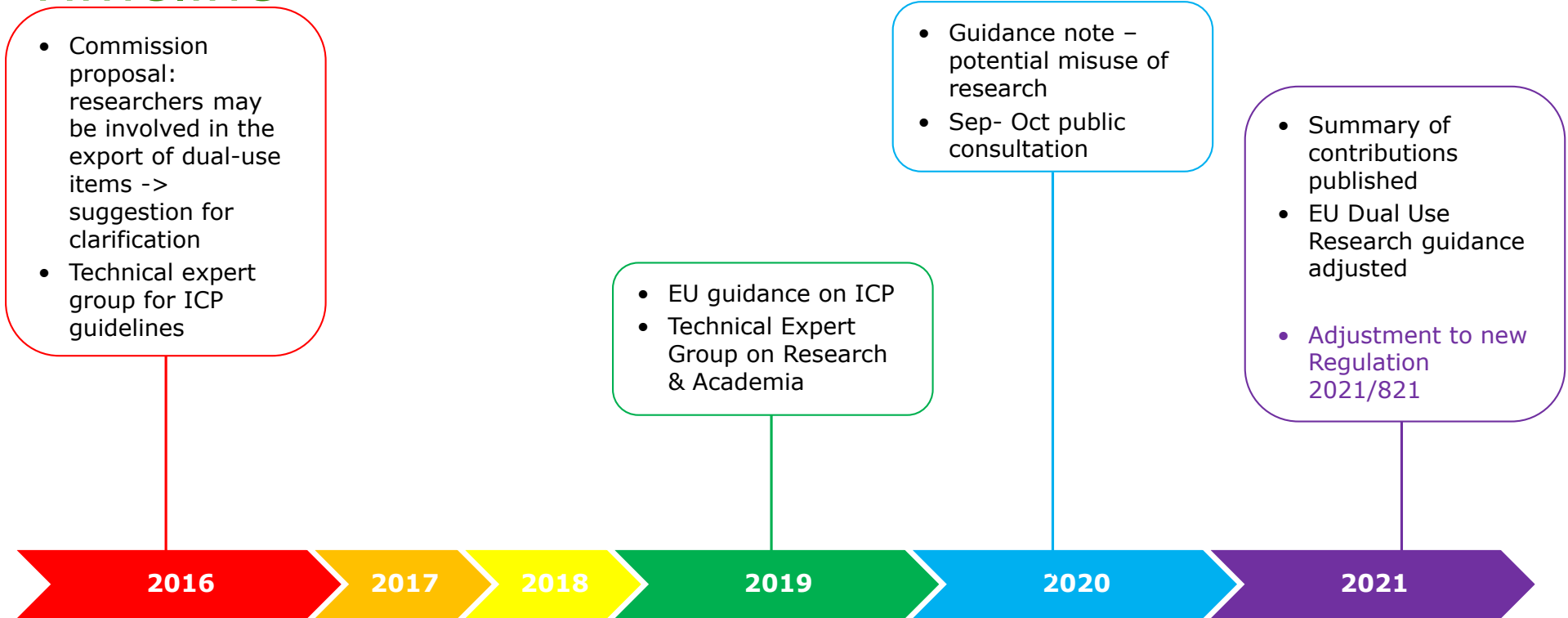


Awareness is empowering

- Rita Wilson -



Timeline





Goal of the guidance

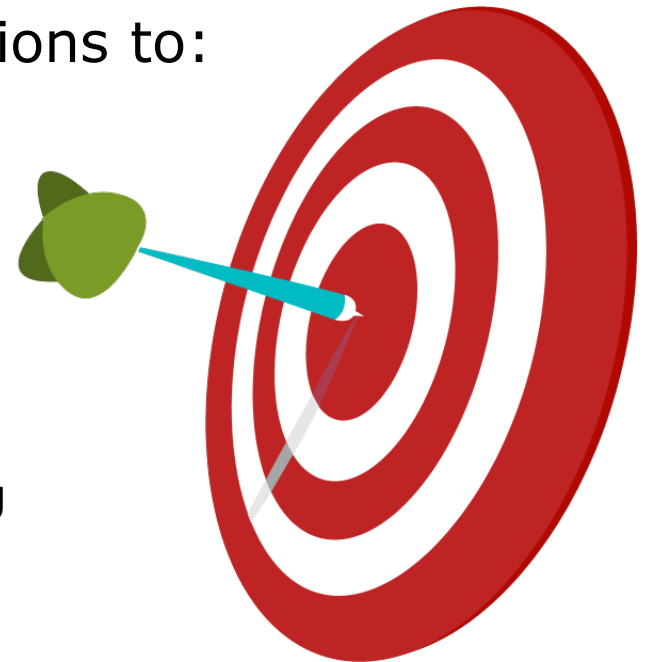
To help researchers and research organisations to:



identify, manage and mitigate risks



facilitate compliance with the relevant EU and national laws and regulations





1

How research organisations can be affected by EU and national dual-use export control regulations and how commitment to compliance

2

Awareness information to researchers, including the basics of dual-use export controls and the potential impact on research related activities

3

Specific guidance on how to set up and review an Internal Compliance Programme.

4

Overview of the regulatory framework for dual-use export controls

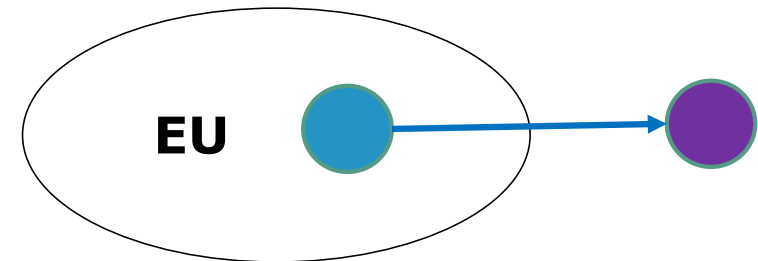
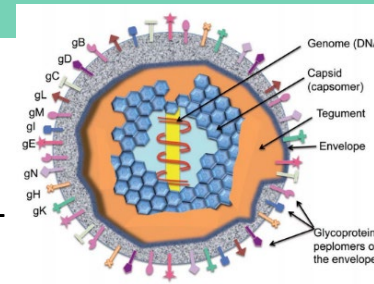
Vaccine development



Example 1

Exporter: University of Medicine (EU country - EU1)
Product: 10 ml vial of pseudorabies virus – suid herpesvirus 1
 ○ Causes Aujeszky's disease in life stock
End user: National State Center of Veterinary medicine
(Country in Asia Pacific - AP)

End use (stated on EUC):
Titre determination of Aujeszky's disease virus in Porcilis® Begonia vaccine as part of random testing according to Law "On Circulation of Medicinal Products". (validatory purposes)





Class

Product Categories:

Vaccines

End

Species:

Pigs

Open

vac

Pol

lice

Porcilis[®] Begonia

Freeze-dried live attenuated vaccine against Aujeszky's disease. Per dose: At least 10 exponent 5.5 TCID₅₀ of Aujeszky's disease virus strain Begonia. This strain neither synthesizes thymidine kinase (tk-) nor the glycoprotein 1 (gE-).

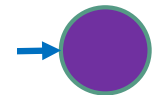


ways:

either in the
cluding living
oculated or

Aujeszky's

notoxins".



INDICATIONS: Immunization of pigs against Aujeszky's disease (pseudorabies).

DOSAGE: Reconstitute with the use of either standard Unisolve or adjuvanting Diluvac Forte. 2 mL/dose by deep IM inj. Vaccination program: Fattening pigs - Administer when pigs are at least 14 wks old. No revaccination is needed. Risk of early infection, pigs can be vaccinated before that age but should be revaccinated at age of at least 10-14 wks, although not earlier than 2 wks after first vaccination. Breeding pigs - Basic vaccinations, as for fattening pigs. Repeat vaccinations 4 mos interval, 3 times yearly.

PRECAUTION: Vaccinate only healthy pigs.

PACKAGING: 10 doses, 50 doses.

Tests for certification



Example 2

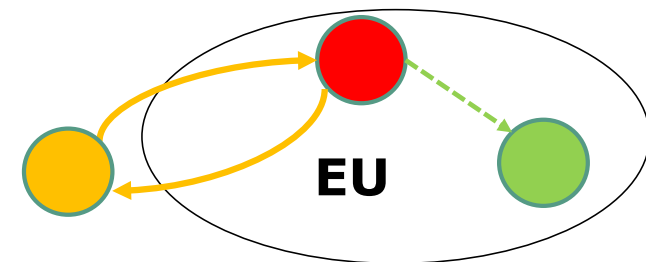
Analyser for traces of explosives – specially designed for use by customs on airports

Product made by *Trace Tech Ltd.* (country in Asia Pacific - AP)

Temporary import for tests – *Tulip TechTests* (EU1)

Output: report sent to company issuing certification marks (EU2)

System is sent back to *Trace Tech Ltd.* (AP)



Tests for certification



Example 2

System = 1A004

The report: information on the libraries classified as 1E002.g (NLR to **EU2**)

Pollquestion: who should apply for a license for re-export (**AP**)?

Tulip TechTests recognised dual-use

- o based on ICP

Trace Tech Ltd. authorises subsidiary in **EU1** requesting license

1A004

Protective and detection equipment and components not specially designed for military use, as follows:

d. Electronic equipment designed for automatically detecting or identifying the presence of "explosives" residues and utilising "trace detection" techniques (e.g., surface acoustic wave, ion mobility spectrometry, differential mobility spectrometry, mass spectrometry).

1E002

Other "technology" as follows:

g. "Libraries" specially designed or modified to enable equipment to perform the functions of equipment specified in 1A004.c. or 1A004.d.

