

The EU legal framework for preventing BW proliferation and promoting biosafety and security

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What is VERTIC?

VERTIC is an independent, non-profit making, non-governmental organization located in London, United Kingdom, that promotes the effective verification and implementation of arms control, disarmament and environment agreements.

VERTIC's National Implementation Measures (NIM) Programme, with funding and in-kind assistance from Canada and the United Kingdom, has been developed to assist States in understanding what measures are required at the national level to comply with the prohibitions in a wide range of nuclear, chemical and biological weapons treaties and UN Security Council resolutions and how to implement them.

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Overview of my presentation

I. Preventing BW proliferation

II. The benefits of implementation

III. VERTIC's EU legislation survey

IV. The EU legal framework: preventing BW proliferation and financing of terrorism

V. How comprehensive is the EU legal framework?

I. Preventing BW proliferation

Criminalizing the Biological Weapons Convention prohibitions

- development, production, acquisition, stockpiling, retention, direct or indirect transfers, and use of biological weapons (and preparatory activities such as attempts or financing)
- unlicensed activities involving controlled pathogens or toxins (such as anthrax, botulin toxin, Ebola, plague, tularaemia, etc.)

Enforcement measures

- Extraterritoriality and international co-operation on judicial and criminal matters
- National Authority? Stand-alone or combine with existing CWC NA
- National inspections of laboratories and other facilities where controlled pathogens may be found (there's no international inspections regime)
- Disease surveillance; response capability in the event of a natural, accidental or intentional outbreak (and co-operation among law enforcement; human and animal health officials)

Biosafety and Biosecurity measures

- Controlled agent lists based on threat to public health and safety and national security (e.g. EU dual-use lists; WHO risk-based approach; Australia Group lists for biological agents, animal and plant pathogens and dual-use technology)
- Establishing a licensing system for individuals and laboratories wishing to carry out activities with controlled agents
- Notification of loss or theft
- Comprehensive record-keeping
- Biosafety and biosecurity training for personnel
- Physically secure labs and personnel background checks
- Secure transportation (approved carriers, secure containers and packaging, labelling, shipment tracking)

Transfer controls

- Controlled agent lists (see above)
- Internal and international transfer controls through permits (that is, export and import controls)
- Customs/border controls and checks of documentation, end-use certificates, and detection equipment

II. The benefits of implementation

- States can investigate, prosecute and punish any offences, including preparatory acts, associated with biological weapons, committed by non-State actors such as terrorists
- States can monitor and supervise any activities, including transfers, involving controlled biological agents or toxins
- States will enhance their national security; public safety; and human, animal and plant health
- States with effective and adequate legislation will strongly signal to potential investors that they are a safe and responsible location for activities involving dangerous biological materials; good laws promote trade!
- States' obligations under the BWC and UN Security Council Resolution 1540 will be satisfied and they will be able to enhance transparency about their national implementation, including through the BWC CBM data exchange process

III. VERTIC's EU survey

- VERTIC reviewed the EU's legal framework for combating bioterrorism, prevention proliferation, promoting biosecurity/biosafety and enforcement (under EU Project n° 253485 - U. of Milan)
- This 'survey' – now in English, French, Portuguese and Spanish – is based on 96 criteria covering definitions, offences (and preparatory offences), jurisdiction, control lists, biosafety/biosecurity, transfers control, and enforcement
- The survey identifies the legal gaps to be addressed to prevent the proliferation of BW, promote biosafety and biosecurity and implement UNSCR 1540
- EU regulations, directives and decisions must of course be implemented through national law!

IV. The EU legal framework: preventing BW proliferation (and financing of terrorism)

- Council Framework Decision of 13 June 2002 on combating terrorism (2002/475/JHA)
- Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items
- Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime
- Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing

The EU legal framework: biosafety and biosecurity

- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work
- Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods
- Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste (does not include a definition for infectious waste!)
- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR – 2011) [NB: this agreement is not strictly speaking legislation]

The EU legal framework: GMOs

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on transboundary movements of genetically modified organisms
- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms

The EU legal framework: enforcement (1)

- Council Decision 2005/671/JHA of 20 September 2005 on the exchange of information and cooperation concerning terrorist offences
- Council Framework Decision of 13 June 2002 on joint investigation teams
- Council Resolution of 17 January 1995 on the lawful interception of telecommunications (Official Journal C 329, 04/11/1996)
- Council Framework Decision 2008/978/JHA of 18 December 2008 on the European evidence warrant for the purpose of obtaining objects, documents and data for use in proceedings in criminal matters

The EU legal framework: enforcement (2)

- Council Decision 2003/335/JHA of 8 May 2003 on the investigation and prosecution of genocide, crimes against humanity and war crimes
- Council Framework Decision of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (2002/584/JHA)
- Council Framework Decision 2009/948/JHA of 30 November 2009 on prevention and settlement of conflicts of exercise of jurisdiction in criminal proceedings
- Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime

EU legislation and member state laws/regs on the VERTIC website...



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BWC Legislation Database

Implementation of the Biological Weapons Convention

Once a State has ratified or acceded to the Biological Weapons Convention (BWC), it will be bound by the content of the BWC, and obliged to implement its requirements.

In particular, Article IV obliges each State Party, in accordance with its constitutional processes, to take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of biological weapons in its territory and anywhere under its jurisdiction or control. States Parties have agreed that the prohibition of the use of biological weapons - originating in the 1925 Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare - also falls under the scope of the BWC.

In addition, Article III requires all States Parties to refrain from transferring biological weapons to anyone and from assisting, encouraging or inducing anyone to manufacture or acquire them.

VERTIC is in a position to assist States with national legislation to implement the BWC, at no cost, under our [National Implementation Measures Programme](#).

European Union

Consolidated Version of the Treaty on the Functioning of the European Union [EN](#) [FR](#) [PT](#) [SP](#)
 Council Framework Decision 2002/475/JHA of 13 June 2002 on combating terrorism [EN](#) [FR](#) [PT](#) [SP](#)
 Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime [EN](#) [FR](#) [PT](#) [SP](#)
 Council Decision 2005/671/JHA of 20 September 2005 on the exchange of information and cooperation concerning terrorist offences [EN](#) [FR](#) [PT](#) [SP](#)
 Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime [EN](#) [FR](#) [PT](#) [SP](#)
 Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing [EN](#) [FR](#) [PT](#) [SP](#)
 Council Framework Decision 2008/978/JHA of 18 December 2008 on the European evidence warrant for the purpose of obtaining objects, documents and data for use in proceedings in criminal matters [EN](#) [FR](#) [PT](#) [SP](#)
 Council Framework Decision 2002/465/JHA of 13 June 2002 on joint investigation teams [EN](#) [FR](#) [PT](#) [SP](#)
 Council Resolution 96/C 329/01 of 17 January 1995 on the lawful interception of telecommunications [EN](#) [FR](#) [PT](#) [SP](#)
 Council Decision 2003/335/JHA of 8 May 2003 on the investigation and prosecution of genocide, crimes against humanity and war crimes [EN](#) [FR](#) [PT](#) [SP](#)
 Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States [EN](#) [FR](#) [PT](#) [SP](#)
 Council Framework Decision 2009/948/JHA of 30 November 2009 on prevention and settlement of conflicts of exercise of jurisdiction in criminal proceedings [EN](#) [FR](#) [PT](#) [SP](#)
 Council Decision 2009/316/JHA of 6 April 2009 on the establishment of the European Criminal Records Information System (ECRIS) in application of Article 11 of Framework Decision 2009/315/JHA [EN](#) [FR](#) [PT](#) [SP](#)
 Council Decision 2009/371/JHA of 6 April 2009 establishing the European Police Office (Europol) [EN](#) [FR](#) [PT](#) [SP](#)
 Council Decision 2002/187/JHA of 28 February 2002 setting up Eurojust with a view to reinforcing the fight against serious crime [EN](#) [FR](#) [PT](#) [SP](#)
 Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items [EN](#) [FR](#) [PT](#) [SP](#)
 Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods [EN](#) [FR](#) [PT](#) [SP](#)
 European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR - 2011) [EN](#) [FR](#) [PT](#) [SP](#)
 Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [EN](#) [FR](#) [PT](#) [SP](#)
 Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste [EN](#) [FR](#) [PT](#) [SP](#)
 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [EN](#) [FR](#) [PT](#) [SP](#)
 Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) [EN](#) [FR](#) [PT](#) [SP](#)
 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms [EN](#) [FR](#) [PT](#) [SP](#)
 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [EN](#) [FR](#) [PT](#) [SP](#)
 Regulation (EC) No 1846/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms [EN](#) [FR](#) [PT](#) [SP](#)

V. How comprehensive is the EU legal framework? BW criminalization

- The term ‘biological weapon’ is not defined in the EU legal framework
- The 2002 framework decision on combating terrorism requires member states to criminalize activities involving biological weapons, including development, manufacture, acquisition, possession, transport, supply and use (transfers may be covered by supply)
- threats to commit acts with biological weapons are prohibited under the 2002 decision on terrorism, and natural *and* legal persons must be punished for any BW crimes
- financing terrorist acts, including ones with BW, is prohibited by the directive on money laundering and financing of terrorism; this must be implemented in national law

How comprehensive is the EU legal framework?

Biosafety and biosecurity

- the EU directive on worker safety defines ‘biological agent’ and includes annexes with classification lists for pathogens
- the EU legal framework includes measures to *account for* use and transport but not production and storage of pathogens and toxins; there are also measures to *secure* their use, storage and transport but not their production
- certain physical protection measures are required, but an authorisation system (for working with pathogens) is not required nor is disposal explicitly covered
- GMOs are comprehensively regulated by the EU legal framework; this regime must be implemented through national laws

How comprehensive is the EU legal framework?

Transfers control

- the 2009 EU regulation on transfers of dual-use goods includes annexes of controls lists including for pathogens and toxins
- this same regulation requires EU Member States to promulgate laws and regulations for:
 - export licensing
 - a licensing authority (through customs agencies)
 - end-use controls
 - catch-all control
 - intangible transfers
 - transit control and control of brokering (but not re-export or import controls)

How comprehensive is the EU legal framework? Enforcement

The EU has a broad legal framework in place requiring member states to enact legislation covering:

- investigations
- surveillance
- warrants
- legal co-operation and assistance with other EU member states (also in relation to terrorism under the 2002 decision)
- national inspections and law enforcement/public health official co-operation are not expressly included in the EU legal framework

Questions?

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