European Biopreparedness and Baxter H5N1 contamination issue

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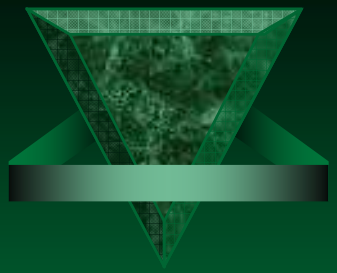
Security is the condition (perceived or confirmed) of an individual, a community, an organisation, a societal institution, a state, and their assets (such as goods, infrastructure), to be protected against danger or threats such as criminal activity, terrorism or other deliberate or hostile acts, disasters (natural and man-made)



(Bio)preparedness

- Integrated Border Management
- CBRN (Chem., Bio., Radio., Nuclear) incidents
- Critical infrastructure -Building and Construction
- Critical infrastructure -Energy supply
- Security of the Supply Chain
- Security of Water Supply
- Defence against terrorism
- Emergency services
- Reduction of crime risks in products and services

Be a virus, see the world

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.7.2007
COM(2007) 399 final

GREEN PAPER
ON BIO-PREPAREDNESS

The term "preparedness" is used in a generic way covering all aspects such as prevention, protection, first response capacity, prosecution of criminals/terrorists, surveillance, research capacity, response and recovery. The term will also cover the steps taken to minimise the threat of deliberate contamination of the food supply through biological agents and to protect against biological warfare.

European Bio-Network *
EBN

Private Sector | **PPP – Public / Private Partnership** | **Public Sector**

Biotechnology Industry

EuropaBio
European Association for Bio-Industries

EBSA
European Biosafety Association

EFB
European Federation of Biotechnology

YEBN
Young European Biotechnology Network

ESCMID
European Society of Clinical Microbiology and Infectious Diseases

EMBO
European Molecular Biology Organization

Pharma Industry

EFPIA
European Federation of Pharmaceutical Industries Associations

EBE
European Biopharmaceutical Enterprises

Food Industry

CIAA
Confederation of the Drink & Food Industries of the EU

Defense Industry

ASD
Aerospace and Defence Industries Association of Europe

Security Industry

EOS
European Organization for Security

ESRIF

European Security Research & Innovation Forum

Epidemiological & Health communities

European Institutions

European Commission

DG JLS
DG SANCO
DG RELEX
DG RESEARCH
DG ENTERPRISE
JRC
- ISPC

Bioresearch Institutes

Academic Institutions

Border Control

WCO
World Customs Organization

FRONTEX [1]

Member States

National Authorities

Public Health:
Human
Animal
Plant

CIVI Protection

Risk Prevention & Response

Intelligence Community

Law Enforcement

ICPO - Interpol
International Criminal Police Organization

EUROPOL
European Police Office

Advisory Board

ESRAB (2004-2006)
European Security Research Advisory Board → **ESRIF**
European Security Research Innovation Forum

EU Agencies

ISS
European Institute for Security Studies

ECDC
European Center for Disease Prevention & Control

EDA
European Defence Agency

EMEA
European Medicines Agency

EFSA
European Food Safety Association

[1] **FRONTEX** European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union

EU Projects

PASR (2004-2006)
Preparatory Action for Security Research → **ESRP (2007-2013)**
European Security Research Programme

BODE
Biological Optical Detection Experiment

BIO3R
Bioterrorism Resilience Research Reaction

AEROBATICS
Assessment of the quantity, identity, viability, origin and dispersion of airborne micro organisms for application in crisis management tools

ANTHRAX-EURONET
European research networking activities to develop safe products and policies to protect our citizens for the threat of anthrax attacks and other agents of bioterrorism

IMPACT
Innovative Measures for the Protection Against CBRN Terrorism

EUROINFECT-NET
A Network of Networks

United Nations
- Counter-Terrorism Committee
- Department for Disarmament Affairs (DDA)
- United Nations Environment Programme (UNEP)
- United Nations Educational, Scientific and Cultural Organization
- World Commission on the Ethics of Scientific Knowledge and Technology
- Food and Agriculture Organization (FAO)
- United Nations Industrial Development Organization (UNIDO)
- Institute for Disarmament Research
- Pan American Health Organization
- World Health Organization (WHO)
- Department of Communicable Disease Surveillance and Response

NATO
- Weapons of Mass Destruction Center
- Security Through Science Programme

OECD
- The International Futures Programme
- Directorate of Science, Technology, and Industry

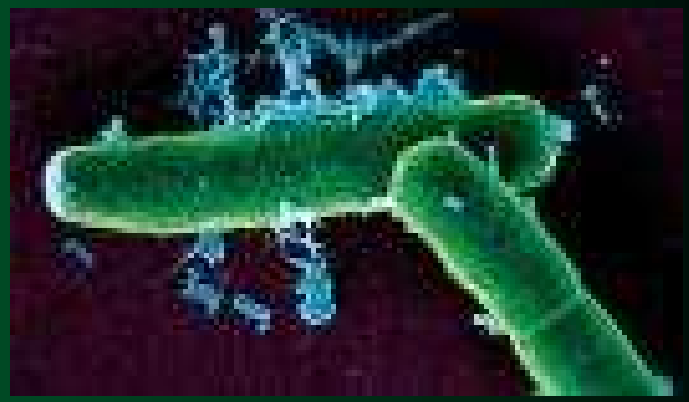
OIE
World Organization for Animal Health

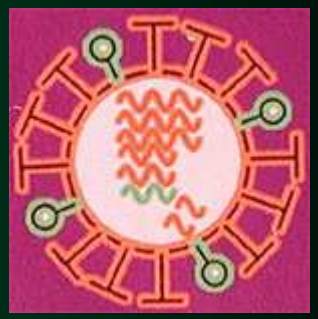
GHSI
Global Health Security Initiative

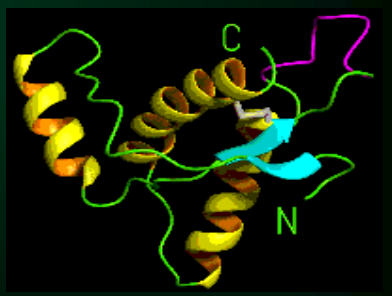
* The EBN would be an advisory structure which would pull together European expertise on Bio-Preparedness from different sectors – the research community, private and public sectors (including the security and intelligence community, civil protection authorities and first responders).

Biological Risk Spectrum

- Naturally Occurring
- Accidents/Misadventure
- Lack of Awareness
- Deliberate Misuse
- The challenge is not just weapons or classifying some agents as dangerous pathogens



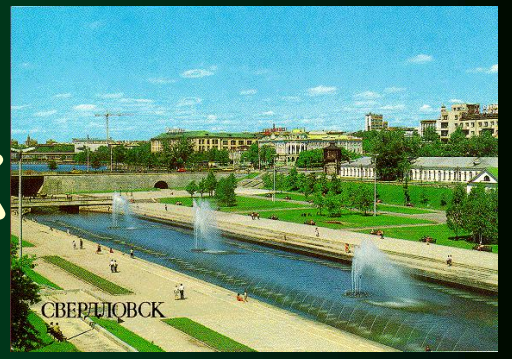




Anthrax as a bioweapon

- Sverdlovsk, Russia 1979
  - Accidental release from anthrax drying plant
  - Human error
  - 96 human cases
    - All downwind
    - 66 (68?) deaths

Lessons from Sverdlovsk



- An incredibly small quantity of a substance can have an enormous impact
- Human error is possible
- Poor communication among responders in the aftermath of a release (intentional, accidental, or natural) will increase fatalities
- Poor communication with the affected community will increase fatalities

Lessons: Envelope anthrax madness

- Co-incidence with Sep/11 terroristic attack on Twins
- Mild biological impact
- Role of public media
- Huge psychological superstructure, fear
- Overload of lab capacity

Baxter H5N1 event

- contamination of an experimental live attenuated influenza A(H3N2) challenge virus with live A(H5N1) virus in a commercial research setting (Orth, Donau)

The Czech experience

- H3N2 nasal vaccine candidates in ferrets trial
- Approved by Board of Ministry of Industry and Trade (no danger pathogen)
- 31st Jan 2009 – Start of the trial (5+5 ferrets, BSL2)
- 6th Feb 2009, 17:00 - Trial stopped on sponsor´s request
- 6th Feb 2009, 18:56 – e-mail info on H5N1 contamination (section of ferrets stopped, Tamiflu to contacts-13 exposures)

The Czech experience

- 9th Feb 2009, 10:55 – End of trial and complications reported to regional veterinary inspection
- 9th Feb -10 Feb 2009 – hospital examination of contacts
- 11th Feb 2009 – The first info in Austrian press
- 17th Feb 2009 - ECDC recognized problem based on monitoring of Slovakian press
- …

Baxter H5N1 event

- Contaminated material distributed into 4 countries (Austria, Czech Republic, Germany, Slovenia)
- Exposure: lab animals, staff
- Material not for human
- Countermeasures (sampling, observation, testing, Tamiflu) since certain time appropriate
- No human casualties

however…

Lessons learned

- Human error
- ?GLP
- Initial reluctance in commercial information channels
- Potential – reassortant incident with high impact
- Substantial delay in informing local, national authorities and ECDC, WHO, EC as well
- Gaps in legislation
- Unclear responsibilities
- Careful event evaluation – outcomes not to stop research

Questions??