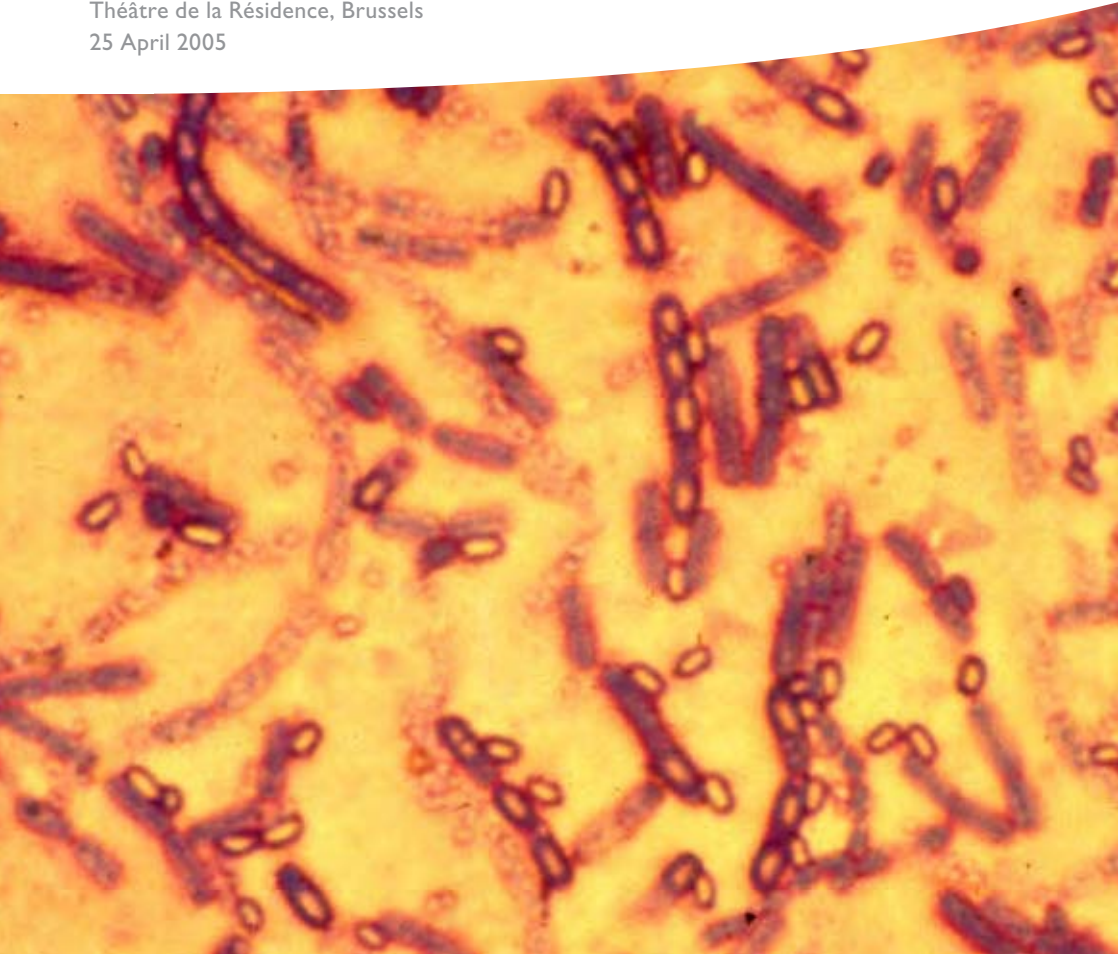


A report of the fourth meeting of the New Defence Agenda's Bioterrorism Reporting Group co-organised with the Chemical and Biological Arms Control Institute (CBACI)

Countering Bioterrorism:

How can Europe and the United States work together?

Théâtre de la Résidence, Brussels
25 April 2005



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Introduction

by Giles Merritt

The NDA is proud to present the third of its Bioterrorism Group reports. Some 80 experts from both sides of the Atlantic gathered in Brussels on April 25 to discuss common strategies to counter bioterrorism. The trustful partnership between the NDA and the Chemical and Biological Arms Control Institute (CBACI) provided the basis for a frank discussion that is part of a continuing process of creating a transatlantic dialogue on bioterrorism.

The nature of the bio-threat is that counter-measures cannot be developed by the EU or US alone; it is a joint problem that needs joint solutions. The meeting showed that there are still many hurdles to be overcome before we can arrive at a common strategy. The NDA Bioterrorism Reporting Group will continue to gather key players to push the debate inside Europe, and also looks forward to strengthening transatlantic ties.

This report offers a summary of the debates, together with additional contributions from speakers. The main purpose of these reports is to offer recommendations that can push the political process forward towards the adoption of a global and commonly accepted counter-bioterrorism strategy.

The impact of these NDA meetings reflects the willingness of participants to take an active part in the discussions. This report is intended to circulate new ideas to the NDA's network of experts, and offers an opportunity to register their support for its recommendations. I should therefore like to thank NDA's supporters and encourage interested parties to contact us with their views on future topics that they feel need attention.

Giles Merritt

Director, New Defence Agenda

Introduction

by Michael Moodie

It has become common place to note that the promotion of domestic security must be conducted on a global basis. It is nevertheless true. The security challenge posed by the potential misuse of the life sciences is beyond the capability of any single state to address on its own. Failure to contain an infectious agent in any single place could result in an attack widening across the globe. The need to provide essential countermeasures stems from the fact that the problem does not recognize international borders, and that solutions are beyond the resources of any single country.

The United States and Europe must work with each other if they are to meet this challenge and foster more secure societies. Unfortunately, the biological challenge is relatively new, and neither a commonly accepted view of the problem nor a shared strategy or set of policies to respond effectively characterizes perceptions on the two sides of the Atlantic. Significant differences continue to exist about both the nature of the challenge and the appropriate set of policy responses.

These differences must be overcome. Europe and the United States have successfully countered threats to their shared interests and values by developing a strategy that identified enough common ground in which to work together. There was no shortage of disagreements, but the shared (if not unanimous) views of the problem of

common policy concepts and assumptions, similar language for communicating, and a mutual set of policy tools proved invaluable in overcoming differences and building an enduring security architecture. That sort of collaborative perspective now must find a place in the biological arena.

The Chemical and Biological Arms Control Institute was honored to co-sponsor with the New Defence Agenda the dialogue between Europe and the United States that is reflected in these pages. We believe that it made an important contribution to better understanding and the creation of a foundation on which we must continue to build cooperative efforts. We look forward to working with the NDA on additional efforts in the future.

Europe and the United States need each other today no less than in the darkest days of the Cold War. The challenge is as difficult, if not more so, and the ground on which we must operate is often unfamiliar. But if we continue to learn from one another, to work together, and to appreciate the outcomes that collaboration will yield, we will be in a much stronger posture to meet the dangers ahead.

Michael Moodie

President, Chemical and Biological Arms Control Institute

Recommendations

Seven Recommendations following the 4th meeting of the NDA's Bioterrorism Reporting Group on 25 April, 2005*

- Conduct a joint risk assessment to determine the plausible risk envelope for bio-terrorism that will guide planning and resource allocation decisions;
- Based on the risk assessment, identify the priority requirements and capabilities necessary to implement an integrated bio-defence strategy that incorporates elements of deterrence, prevention, preparedness, and consequence management/mitigation;
- Improve interoperability between core bio-defence and security agencies to combat threats to transatlantic security;
- Agree upon a protocol and strategy for counter-measures, delegate leadership areas and define responsibilities before an act of bio-terrorism;
- Harmonize national European policies to strengthen bi-lateral and multi-lateral counter-terrorism and proliferation cooperation at the European as well as international level;
- Adopt a more integrated transnational approach to public health security, bio-terrorism and emerging disease preparedness, detection, surveillance, containment and response;
- Increase the selection of counter-measures and capability sharing; develop formal mechanisms to share lessons learned.

* The recommendations stemming from the NDA Bioterrorism Reporting Group are developed after each meeting based on the discussions held and the suggestions brought up on the day. Recommendations are then floated to a wide pool of bioterrorism, security and defence experts to sign on to.

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*The signatories of these recommendations
have signed in their personal capacities and
do not necessarily represent the views of the
organisations they represent.

Additional recommendations from experts in the field

Here are some of the additional recommendations the NDA received after distributing its recommendations to experts in the field:

- Develop technical and regulatory approaches for radically accelerating the development of biodefence drugs and vaccines to counter bioengineered threat agents for which effective prophylactics and therapeutics do not currently exist;
- Improve European capabilities in the area of bio-defence based on NATO core assets as CBRN capabilities and on EC initiatives as RAS-BICHAT and promote closer cooperation between EU and NATO in this area;
- Promote and conduct regular transnational training courses and exercises using if necessary NATO and EU established mechanisms and structures in this area as well as relying on their expertise;
- Focus on source prevention, emphasise the importance of the Bio Convention in third countries, guide the experts in these countries and criminalise acts against the Convention;
- Develop an effective public information campaign that prepares the public regarding the threat and measures that may be needed following an event as part of the crisis management response and the consequence management in order to maintain any affected areas of the critical national infrastructure.

Programme of the April 25 meeting

Session I: Can we develop a transatlantic response to bioterrorism?

The recent Atlantic Storm simulation exercise showed the United States and EU Member States are not prepared for a bioterrorism attack. With US and EU biodefence programmes varying markedly, can the Atlantic alliance develop suitable defences together? Are differences in EU and US programmes based purely on threat perception, or are other critical factors involved? What are the similarities and differences between European and American programmes and do gaps in scope and scale, priorities and strategy weaken transatlantic defence cooperation? As past preparedness programmes were developed around state-run bio programmes, will the potential increase of sub-state actors affect our attempts to control biological weapons development and use? If the EU should strengthen its homeland security infrastructure, does that mean developing something similar to the US Department of Homeland Security's National Response Plan?

INTRODUCTION:

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Michael Moodie, President, Chemical and Biological Arms Control Institute

PANELISTS:

Georges Benjamin, Executive Director of the American Public Health Association

David Franz, Senior Scientist at the Midwest Research Institute and former Commander at USAMRIID

Annalisa Giannella, Personal Representative of the High Representative for matters of non-proliferation, Council of the European Union

Erika Mann, European Parliament and European representative to Atlantic Storm

Brigadier Ian Abbott, Director Policy and Plans Division, European Union Military Staff

Session II: What future for bio-defence industry and technologies?

As the EU develops its policies to prevent bio-terrorism and strengthen public health security, what role will technology play in the identification and detection of pathogens and agents? What is the future of the European biotechnology sector and its specific bioterror applications? In which defence technology areas should the EU and US be consolidating technology acquisition and are advances in the life sciences affecting the ability of bio-defence companies to counter bio-terrorism? Are there sufficient opportunities for collaboration, sharing of information, the exchange of lessons learned and best practices between the EU and the United States on issues of civilian bio-defence? How should the US and EU industries work together to avoid duplicating research?

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Frank Rapoport, Partner, McKenna Long & Aldridge

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Executive Summary

Bioterrorism - a potent mixture of “infectious disease and intent”

The latest Bioterrorism Reporting Group meeting was hosted jointly by the NDA and CBACI, an example of excellent EU-US collaboration. If there was one conclusion that could be drawn from the meeting itself, it was that such teamwork had to be duplicated in the actual fight against bioterrorism. Not that the event lacked ideas, as these were ever present. But there were few signs of real co-operation and the spectre of different “threat perceptions” was forever hovering in the background.

CBACI's **Michael Moodie** set the scene by arguing that on bioterrorism the traditional transatlantic partnership did not exist insofar as there was neither a shared perception of the challenge or an agreed strategy for dealing with it. He had heard a lot of talk but seen little action. Moodie was supported by MEP **Erika Mann**, fresh from the *Atlantic Storm* exercise, who thought that current US – EU co-operation was fragmented. Mann wanted a more coherent approach to be developed. The Polish Embassy's **Stanislaw Janczak**, however, delivered the most damning comment. He simply stated that the US and the EU had to start to communicate.

Perhaps the other fundamental problem identified was that of accountability on

the European side. The US has obvious advantages in comparison to a 25 member state - and expanding - EU, but NDA Director **Giles Merritt** felt moved to ask who was accountable on the matter of addressing Europe's bioterrorist threat. That was also a question of much interest to the US participants and it was left to the Council of the EU's **Annalisa Giannella** to answer the Henry Kissinger question – “If I want to pick up the phone and talk to Europe, whom do I call?” Giannella did not have the number and argued instead that the new Constitution would deliver clearer lines of responsibility.

Another thorny issue under discussion was that of public health information systems. The EU Military Staff's Brigadier **Ian Abbott** wanted accountability to be defined in that area, while Mann called for the responsible authorities to show EU's citizens they were in control and that political management was in place. Not that the problems were limited to Europe. The American Public Health Association's (APHA) **Georges Benjamin** described an American public health system that had made significant progress but still had laboratory facilities “in a state of disrepair”, an ageing workforce and a struggle with the private sector to attract the right level of staff.

As for the threat itself, Moodie, Virginia Polytechnic Institute's (Virginia Tech) **Randall Murch** and Romanian Ministry of Defence's **Florin Paul** all wanted the same level of attention focused on re-emerging infectious diseases as was currently being placed on bioterrorism. Moodie's view is that the bio challenge must be seen as a spectrum of risks that spans naturally occurring risk such as infectious disease on one end to potential deliberate misuse on the other. The NTI's **Mark Smolinski** was currently dealing with that particular situation, finding it difficult to explain to his colleagues in the developing world why there were no resources available to fight malaria and TB, whereas the US government was promising billions of dollars via the BioShield programme to combat anthrax, smallpox, and other potential bioterrorism agents.

With Murch reasoning that scientific knowledge was racing ahead at an enormous and unprecedented pace, it was left to CSIS's **Gerald Epstein** to conclude that "a flexible responsive adaptive programme" had to be developed. He added that it would be "a major challenge for both the US and Europe".

As for the future, the Midwest Research Institute's **David Franz** agreed that collaboration at existing levels was insufficient. He wanted a "species neutral" approach and much greater exploitation of the genomics revolution. Franz had no simple solution but he had a rallying cry for US-EU collaboration – bioterrorism was "a mixture of infectious disease and intent" and it had to be fought.

Session I

Can we develop a transatlantic response to bioterrorism?

New Defence Agenda Director **Giles Merritt** opened the meeting by stressing the importance of the NDA's new partnership with the Chemical and Biological Arms Control Institute (CBACI). The transatlantic element was vital in any discussion on bioterrorism, otherwise, Merritt conceded, one would be "fumbling around in the dark". Looking forward to a lively day's debate, Merritt passed the floor to **Jill Dekker-Bellamy**.

the more fundamental and subtle areas of risk communication, threat perception, approach and response. She reasoned that threat reduction, arms control and non-proliferation were all opportunities for the US, Canada and the EU to strengthen their collaboration. Dekker-Bellamy raised other key issues, such as:

- who will lead the response?
 - ◆ the US, Canada or the EU?
 - ◆ the one with the most resources?
 - ◆ the one with the best communication system?

- how will the various agencies and institutions interact with one another?

Where to begin?

Dekker-Bellamy explained that the purpose of the meeting was to better understand the challenges faced in preparing for and responding to terrorism and the unconventional weapons use by terrorists. She saw problems in creating a transatlantic partnership if the issues were approached from different perspectives, with different goals and different capabilities.

Looking ahead to the second session, Dekker-Bellamy said that all governments were forced to confront several vital issues. These included the ability:

- to stop acts of bioterrorism
- to quickly communicate health and security information
- to co-ordinate not only between agencies but also among governments
- to improve detection methods, where technology would play a critical role

Describing the recent Atlantic Storm exercise¹, Dekker-Bellamy said it had revealed not only inadequacies in the preparedness for a smallpox outbreak and lack of vaccine stockpiles, but also

¹ See conclusions at <http://www.atlantic-storm.org/analysis/initial.html>



Room for improvement

In his introduction, **Michael Moodie**, President of the Chemical and Biological Arms Control Institute, focused on the need to improve international collaboration. After making an unfavourable comparison between the current transatlantic situation and that existing during the “Cold War”, he bemoaned today’s lack of a “*shared intellectual infrastructure*”. Outlining his thoughts, Moodie described this infrastructure as one that should contain:

- a shared view of the problems faced
- sufficient common ground to allow collaboration
- common concepts and assumptions
- mutual terminology
- shared tools – military, diplomatic and economic

Such an infrastructure had been useful when the transatlantic partners had disagreed and Moodie called on international bodies to work together to develop one to meet today’s challenges. He added some suggestions as to how this might be achieved:

1. **Thought processes must be changed:** because the misuse of life sciences cannot be eliminated, bioterrorism is a risk that has to be managed.
2. **All risks to be examined:** the deliberate misuse of life sciences must be seen as part of a broad spectrum that includes re-emerging infectious diseases, laboratory accidents, etc.

3. **A single-factor approach is not sufficient:** the issue must not be over-simplified, there are various actors, agents, modes of operation, targets (human, plant or animal, etc.).
 - a. it is necessary to develop a range of responses to combat varying threats
4. **Though permanent, the risk can be diminished:** via a multi-faceted approach (e.g. norm building, deterrence, prevention, preparedness, consequence management & mitigation).

Moodie concluded that a much wider-range of players had to be integrated into the process, some of whom were not traditionally used to working in an area that had a security focus. He added that the environment was “fiscally-constrained”, so international cooperation was critical. Priorities had to be set and this required a high degree of coordination, understanding and common approaches that had so far been lacking.

“we do not have a common intellectual infrastructure and it would well behoove us to develop one”

The principles of public health preparedness

Georges Benjamin, Executive Director of the American Public Health Association, described the state of US public health preparedness, based on four principles:

1. **A knowledge-based approach to combating bioterrorism:** based on experience (as the US has suffered anthrax and salmonella attacks)
2. **The necessity to fight a combination of “evil individuals and bad organisms”**
3. **Nature is the most dangerous terrorist**
4. **The work of the public health authority has moved centre stage: it is now more visible and, by necessity, more proactive.**

Benjamin said that great concern existed in regard to emerging diseases, such as monkeypox² and pandemic flu, and he confirmed Moodie’s comments that the public health community was one that was “uncomfortable” about working in a security mode.

Benjamin said the US public health authority was building-up its infrastructure - defined as “people, training and tools”. Linking the first two items, he described the shortage of trained scientists and the need for structural reform (such as detection methods and in public information systems). Benjamin also stressed the need to build relationships before a crisis occurred and described preparedness as going “from chaos to controlled disorder”.

² Monkeypox is a rare illness that causes rash, chills, and fever. It is caused by the monkeypox virus, which belongs to the same family of viruses as smallpox but is not as deadly. (<http://www.sutterhealth.org/>).

A list of lessons learned

David Franz, Senior Scientist at the Midwest Research Institute and former Commander at USAMRIID, looked at the history of bioterrorism and listed some of the lessons learnt:

1. It is harder to protect civilians in everyday life than military personnel on the battlefield.
2. Not all microbes are created equal.
3. Biological and chemical threats must be treated differently
4. Bioterrorism is a mixture of “infectious disease and intent” (“a rallying cry for transatlantic co-operation”).
5. Biotechnology advances will have an impact – with both good and bad consequences.

Reviewing the bigger picture, Franz saw areas where the community faced serious challenges, as there is:

1. too much faith in “air monitors and gadgets” to issue warnings
2. not enough integration of animal and human public health issues – Franz recommended a “species neutral” approach
3. too great a focus on vaccines as counter-measures for unknown threats (shelf-life, regulatory and liability issues make these very expensive)

4. a lack of attention to non-specific counter-measures and therapies and exploitation of the genomics revolution is not being sufficiently exploited
 - a. the basis of a possible transatlantic “Manhattan” project to further examine human immune systems – to improve the resistance of populations
5. more reliance on deterrence to balance preparation for response
6. more collaboration – at national and international levels

Franz saw no simple solution. It requires a **balanced approach** between technical and non-technical (societal and human behavioural) solutions, between hard power and soft power (“difficult in the US’s two-party political system”) and in international relationships.

Quoting Edward R. Murrow, who said, “It’s the last three feet between people that make the difference”, Franz concluded that the human aspect of communications was vital.

A need for intellectual infrastructure

Erika Mann, MEP and European representative to Atlantic Storm, described “**Atlantic Storm**” as an extraordinary exercise. She agreed with Moodie that there was a need to develop an **intellectual**

infrastructure, as communications were poor. Mann stressed the need for consistent and regular contact between the related communities (technical staff, the politicians) and supported the idea of a **matrix**. This could contain the available tools, scenarios, critical factors, priorities, actions to be taken, etc. It also implied that an agreement on common terminology was critical, together with a definition of common concepts and tools. But there were other vital issues - what were the various roles and responsibilities for nations, neighbouring states and international organisations?

Turning to Europe, Mann saw differences between the state of readiness of EU member states (stockpiles of vaccines for example), so priorities had to be set in advance. Different scenarios had to be considered (would some borders be closed? what part of the infrastructure was critical?). Overall, her message was that the process had to be fully inclusive – to involve the US, the EU and its neighbouring countries, and further afield.

Wanted: Public information policies

Brigadier Ian Abbott, Chief of Policy and Plans Division at the European Union Military Staff, served as Director of Capabilities in the UK Cabinet Office responsible for contingency and continuity planning and consequence management

during the events of 9/11 and the subsequent actions to cope with the new threats. He was deeply involved in dealing with the “White Powder” attacks in the UK that followed the Antrax attacks in the US. Beginning his talk, he looked first at the consequences of a “white powder” attack. As background, he explained that there had been over 200 events in the UK following the US Antrax incidents, that required serious investigation and engagement of the emergency services.

Abbott focused on the effect induced, the crisis management requirements, the consequence management issues raised and the remedial measures identified. Above all, he identified the centre of gravity is for the public to maintain confidence in the national government. This implied:

- **Finding effective national and international public information policies:** that strikes a balance between proactive (without scaring the public) and reactive measures
- **Engaging the private sector:** critical services have moved to the private sector and the need to be competitive has introduced “**Just in Time**” rather than “**Just in Case**” methodologies (i.e. no reserve stocks in the supply chains).

In conclusion, Brigadier Abbott wanted governments, and relevant parties from the public and private sectors, to develop, understand and practice crisis management procedures and to have effective and resilient

business continuity plans in place (to maintain essential services as part of the Critical National Infrastructure for society at large).

Setting the scene for debate

NDA Director and co-moderator **Giles Merritt** argued that the political and administrative machines of complex western societies had to be set in gear. To this end, Merritt had some questions for the assembled experts in regard to transatlantic relations:

1. **Who is working with whom?** (the US government, the EU, NATO, the European Commission, member states – were these relationships multilateral, bilateral?)
2. **What does working together mean in practice?** (is it sharing ideas, intelligence, stockpiles of vaccines, expertise – all of these?)
3. **In which areas are transatlantic links not working effectively?**
4. **How can the need to communicate with the general public be made a central issue?** Merritt was concerned that some 200 white powder attacks in the UK had gone largely unreported; how open should public announcements be?
5. **How could legal powers and frameworks be introduced consistently across member states?**

Resources, budgets & security clearance

The Western European Union's **Paolo Brito** saw many similarities between the US and Europe in terms of public health approaches, except that the European Commission had no federal powers. He saw problems with declining public health budgets and a shortage of trained scientists, with the need for security clearance exacerbating the situation. In response to Brito, the Commission's **Jan Peter Paul** said that research funds would be doubled for the 7th Framework Programme.

Georges Benjamin commented that a great number of the US' public health laboratory facilities were in a state of disrepair. Painting a gloomy picture, he stated that between 25% and 50% of public health staff would retire in the next five years. There was therefore an urgent need to hire skilled workers familiar with new technologies, a problem worsened by the fact that public health authorities had to compete with the (highly paid) private sector.

David Franz said it was hard to staff new laboratories. This problem was being heightened by the need for background security checks for staff working on "select agents". Note (1): It was later confirmed that full security clearance was only required for employees working at the US Department of Defense (DOD) and the US Department of Homeland Security (DHS). Note (2): Franz later added that the need for such security

checks might place barriers in the way of US–EU collaboration and Moodie opined that the US reaction could be seen as "over the top".

Agro-terrorism, accidents and infectious diseases

Brito was concerned about "agricultural warfare" at a time of reduced control at US ports and a possible expansion of the EU to include "grey zones" such as Moldova, Ukraine, etc. Paul added his fears about: the uncontrolled spread in Africa (impacting several countries) of the Marburg³ virus, and the accidental distribution of the H2N2 virus by the Centers for Disease Control and Prevention (CDC)⁴. On the subject of agro-terrorism, Franz regarded this as an attack on the economy. His worse fear was an outbreak of Foot & Mouth disease (FMD) that could lead to economic costs of tens of billions of dollars in the US. Franz knew that consequence management planning was ongoing at the state level but he saw a need for more consolidated US national efforts.

Scenarios & simulations

The Stockholm International Peace Research Institute (SIPRI)'s **Richard Guthrie** responded to Moodie's call to

³ The virus appears to be native to central Africa and the first reported cases were from scientists exposed to infected monkeys.

⁴ The CDC has since said it was not responsible for the distribution of the H2N2 virus (see <http://www.cdc.gov/flu/h2n2backgroundqa.htm>). During the debate, Benjamin made the same comment.

prepare for the full spectrum of biological risks by arguing that the problem was even broader. A crisis might start with a terrorist attack, but it could soon expand to include flooding, loss of power and other complications across a wide area. He argued that the "Atlantic Storm" exercise was too complex and that it would be more effective to develop a number of small scenarios. Once these had been successfully concluded, exercises on a larger scale could be envisaged.

Benjamin was equally practical. Any infrastructure that was required had to be built on existing foundations, as people did best what they did every day. He suggested that "everyday events" be used to test facilities, as developing large-scale fictitious scenarios brought no benefit. Benjamin also suggested the people who would be involved in the genuine alerts (police, security, public health authorities) should be the ones running the scenarios, rather than senior politicians.

The role of the military

In the context of the development of a common infrastructure, *Defense News'* **Brooks Tigner** wanted to know how military authorities planned to share information with the civilian community. That was not a decision for the military said Brigadier **Abbott**, but rather one for the government of each individual member state. It was also impossible for the military,

with their limited resources, to protect civilians without the full collaboration of the civilian "blue light" services. Abbott added that governments were accountable to their citizens and "openness and education" were important tools which should be used to inform and shape people expectations in order to be prepared.

Collaboration – the key

Frank Rapoport, a Partner at McKenna Long & Aldridge, agreed with Mann that collaboration between neighbouring countries was vital. He explained that the US was working closely with Canada, a country with a vibrant biotech industry, as it had new solutions for anthrax, smallpox and tularemia⁵. The BioWeapons Prevention Project's **Jean Pascal Zanders** saw collaboration being difficult in Europe, due to nationalistic views being paramount in an EU context.

Tigner wanted more definition of terms such as *intellectual infrastructure* and *matrix* as the international community was already acutely aware of bioterrorist threats (with their monitoring information centres and laboratory standards).

In response to Merritt's and Tigner's questions, **Erika Mann** was certain that transatlantic co-operation was insufficient. It was fragmented and incoherent. Expanding on her ideas for the development of an

⁵ Tularemia, or rabbit fever, is a bacterial disease associated with both animals and humans.

intellectual infrastructure, Mann said that this would be a fundamentally different concept that would not aim to give clear and precise answers to the problems of bioterrorism, but would lead to much improved collaboration – and ultimately to results. She added that the aforementioned *matrix* would be a snapshot of today's situation that showed the state of readiness (geographically, tools, preparedness, contacts, etc.) and weak areas (in the EU and in the US).

Both the *intellectual infrastructure* and *matrix* would require ongoing communication and collaboration, as it was essential to build on the developed expertise. Only in this way could the authorities show citizens that they were in control and that political management was in place.

Michael Moodie thought that the very need for the meeting showed that the US and EU were not working together sufficiently. Some actions were underway but many actors on the US side were frustrated as they did not know whom to contact in Europe. He also reasoned that NATO had been sitting on its hands in regard to bioterrorism. On the positive side, Moodie saw that the G8 had committed itself to a bioterrorism work plan, the Health Security Action Group (G7 plus Mexico) had plans underway and the WHO and InterPol were launching initiatives. But he repeated that the traditional transatlantic partnership did not exist; there had been a lot of talk but not much action.

The Polish Embassy's **Stanislaw Janczak** had been present at *Atlantic Storm*. In his opinion, the US and the EU had not yet started to communicate. Messages were not passed between European and US authorities. There had to be communication methods set-up now, to be used in the case where biological agents were released.

Brigadier **Abbott** thought that many of the day's questions were symptomatic of a general problem, in that there was no effective public information system in place that achieved a balance between preparing rather than scaring the various populations. He also agreed that it was necessary to build on existing practices and identify who was ultimately accountable. In addition, Abbott did not want scenarios to be invented, there were enough genuine accidental cases that could be used – and whether by accident or design, the results were the same. We need to consider the effects and then be able to conduct crisis response and consequence management procedures simultaneously.

CBACI's **Michael J. Powers** responded to Merritt's comment re the US's fragmented approach. He argued that the DHS saw money as the answer – it was working towards creating a single integrated system for managing emergencies. However, this was a contentious issue at state and local levels. Powers also commented on the logistics problems involved in distributing vaccines once such a need had been identified. This was also a responsibility of the public health authorities.

Merritt noted that while the US had a durable, tried and tested political system, this was not the case in Europe. He agreed with Abbott that there was a real problem of accountability, with Brussels being a town where argument between subsidiarity and centralisation were faced every day. However, the threat was current – and Merritt wanted to know who was in charge when it came to countering bioterrorism. That was the problem to be addressed – sooner rather than later.

The EU's view

Annalisa Giannella, Personal Representative of the High Representative for matters of non-proliferation, Council of the EU said she was responsible for the prevention of WMD proliferation and had an "understanding" with the Counterterrorism Co-ordinator Gijs de Vries, especially in the area of bioterrorism. To answer Merritt's question, she had faith in the approval of the new Constitution (together with the creation of a joint external action service – bringing together the Council Secretariat and European Commission services together with diplomats seconded from national diplomatic services), which would facilitate the co-ordination of counter-bioterrorist activities.

In terms of US and EU collaboration, Giannella recommended closer ties on compliance and verification in the biological area in the following areas:

Intellectual Infrastructure

Composition

- *Consisting of experts, scientists, politicians, the cyber community, etc.*

Objectives

- *To develop a shared view of the problems faced*
- *To develop shared terminology and tools (military, diplomatic and economic)*

Scope

- *Global (not limited to the US and the EU)*

- The development of a common *threat assessment* (initially between the EU and the US)
- **Greater compliance;** the US and the EU could assist third countries in drafting legislation in order for them to comply with the Biological and Toxin Weapons Convention (BTWC);
 - ♦ as no model legislation exists, the US and EU could try to establish some "models" and then work in synergy in their bilateral assistance programmes to third countries.
- **Improved verification and control:** members should regularly submit "Confidence Building Measures" (CBMs) but responsibilities are unclear
 - ♦ Giannella suggested the creation of a "small unit" under the BTWC, that could examine CBMs and be a contact point for non-aligned countries

- ♦ Giannella also bemoaned the lack of a verification protocol; she wanted a code of conduct for laboratories and ways of raising awareness between scientists
- ♦ another element was the need to retain the expertise of The United Nations Monitoring, Verification and Inspection Commission (UNMOVIC), as the UN needs expertise to be available on request

Giannella also noted that the idea of an Advisory Scientific Board had recently been launched. This could follow the latest developments in bioterrorism and alert the decision-makers. Giannella recommended that the US get involved, together with industry, under the BTWC framework.

Q&As for Annalisa Giannella

Moodie intervened to say he did not think that the US would welcome the retention of UNMOVIC expertise as it might be seen as a “back door to verification”. It could be rejected for the same reasons that the protocol negotiations had failed. But Moodie saw a future for a body that reviewed ongoing scientific developments and the possible implications of the misuse of biology. He thought that could fly in Washington.

Giannella agreed it was a sensitive area and added that the EU might well seek

discussions in regard to how UNMOVIC’s expertise could be retained. She welcomed Moodie’s comments regarding the Advisory Scientific Body and added that she would take that idea forward.

Merritt agreed with Giannella that industry had a role to play and that it had to be involved in the policy-making process in the face of bioterrorism threats. However, he was not sure how it could be achieved. Giannella thought that it would be natural (with the Review Conference approaching) for national authorities to contact industry to see what it could do in terms of improving compliance and control.

Michael J. Powers commented on the need for model legislation to help third parties and thought there could be much debate and discussion on the content (simple compliance with the BTWC obligations or pathogen control and bio-security). He was not sure however if a single model could be applied to all countries. On this issue, Giannella thought that several models might well be needed. However, she was starting from scratch, as it was not clear about the existing legislation in the EU member states. A joint action with the Organisation for the Prohibition of Chemical Weapons (OPCW) was taking place to draft legislation. But for biological weapons, nothing existed. An OPBW was needed – and why couldn’t preparatory work take place with the US?

Jean Pascal Zanders commented on different threat perceptions in the US

and in Europe. He felt that the EU looked at bioterrorism as a public health issue whereas the US saw it as a matter of national security. He wondered how this influenced the thinking on both sides of the Atlantic.

On threat perception, Giannella said the EU had to update its thinking and then “compare notes with our American friends”. While agreeing with Zanders, she felt that the US as well had initially regarded bioterrorism as a health issue. The important thing was to create a threat assessment and keep it regularly updated.

Zanders was also concerned that Moodie had implied that a body that reviewed ongoing scientific developments would be sufficient. Moodie said he had been misunderstood. The US administration had

simply said that the approach inherent in the BWC protocol was not workable. They preferred a “working group, expert group, work programme” approach. The Review Conference was important, and ideas were coming forward but the underlying scientific environment was changing fast.

Paul commented that China would be training one million scientists per year. He thought that companies would continue to move their laboratories to China and India and that these two countries had to be involved in any future agreements and discussions. Giannella thought the EU could do that, as the security dimension (non-proliferation) was being developed in negotiations with third countries. The EU was constantly changing its methods of co-operation and was including security issues in all trade negotiations.



Session II

What future for bio-defence industry and technologies?

Project BioShield

Providing some background to “Project BioShield”⁶, co-moderator **Frank Rapoport** of McKenna, Long & Aldridge described the US government’s necessity to engage the pharmaceutical industry in the fight against bioterrorism (against anthrax, smallpox, tularemia, etc.). This had been greatly facilitated by the SARS outbreak. As a result, Rapoport forecast that there would be an enormous “pharmaceutical biodefence public health infrastructure” within five years.

The “BioShield” initiative streamlined the FDA approval process so that the government could purchase drugs before they had FDA approval. In essence, it was a way of getting the pharmaceutical industry on the government’s side – a new development according to Rapoport, and one that he recommended that Europe should consider.

Rapoport explained that therapeutics (cures) were seen as the correct approach, rather than vaccines, as people were unhappy about the latter course of action. Moving to the larger “BioShield 2” legislation, Rapoport said it expanded the government’s ability to

buy drugs or counter-measures, not only to pathogens but also to counter infectious diseases (such as avian flu or pandemic flu). It also includes funding for the construction of the necessary biosafety level 4 (BSL4s)⁷ facilities.

The power of scientific knowledge

Randall Murch, the Associate Director for Research Program Development at Virginia Tech, and former Director of Advanced Systems and Concepts Office at the Defence Threat Reduction Agency, with nearly 23 years of service in the FBI, saw opportunities for US – European scientific co-operation not only to fight bioterrorism, but also to combat current and emerging infectious diseases in the human, animal, plant and food supply chains. Stressing the need to understand how nature was evolving, he looked to technologies that would help the protection, clean-up and re-population of the environment.

Murch argued that scientific knowledge was racing ahead at an enormous and unprecedented pace, bringing opportunities to combat disease and help in the fight against

bioterrorism. Referring to the resulting and complex “dual-use research”⁸, he reasoned that it had scientific, technological, ethical, moral, legal, political and policy implications. Despite the difficulties, he saw this as both a challenge and an opportunity for the US and Europe to work together.

Murch identified several joint areas for collaboration, where he wanted a more systematic approach to developing, executing and measuring initiatives. This process would include:

- the definition of problems of mutual concern
- the analysis of questions and problems (from US and European perspectives)
- the identification of priorities and gaps
- the design of solutions

Overall he wanted to move from “thought to action” by developing executable plans, and he suggested that the NDA might be a good starting point for such discussions. He therefore recommended the implementation of flexible, robust and adaptable systems – both human and technological – on a transatlantic basis, in order to achieve full collaboration across four key communities: public health, agriculture, law enforcement & public safety and intelligence.

It was necessary to show these four communities that they are interdependent and then move on to full interoperability.

Murch did not want to wait for a crisis. He wanted a systems approach to crisis response management and he felt the NDA could provide structure in this area. Murch also wanted a state of “full readiness” and a set of coherent standards was required - to which agencies on both sides of the Atlantic could aspire.

A call for regional stockpiling

Florin Paul, Deputy Surgeon General in Romania’s Ministry of Defence, was also at pains to stress that he was including the spread of infectious diseases in his definition of bioterrorism. As he was concerned about the capability of any single organisation to be responsible in the event of a biocrisis, Paul wanted regional authorities to be able to take decisions. On the subject of industry involvement, he had been impressed by Rapoport’s explanation of how the US government had gained the pharmaceutical industry’s support. Within Europe, there was a similar issue, as he was concerned about the production of “orphan drugs”⁹. Someone – in Europe - had to take the risk and provide necessary funding.

Addressing the issue of bioterrorism in practical terms, he saw local authorities having a role to play at the tactical level. However, when it came to strategic discussions, he

6 On July 21, 2004, President Bush signed into law Project BioShield, which provides new tools to improve medical countermeasures protecting Americans against a chemical, biological, radiological or nuclear (CBRN) attack. (from <http://www2.niaid.nih.gov>).

7 A biosafety level 4 (BSL4) lab allows researchers to safely handle small samples of infectious disease microbes for vaccine development or for diagnosis of patients suspected of being infected.

8 It was assumed in this case (and later in the debate) that dual use meant research that was both a) security & defence related and b) for commercial purposes, in the realm of public health.

9 Definition from the FDA website: The term “orphan drug” refers to a product that treats a rare disease affecting fewer than 200,000 Americans. The Orphan Drug Act was signed into law on January 4, 1983. Since the Orphan Drug Act passed, over 100 orphan drugs and biological products have been brought to market.

wanted the “requirements in the field” to be fully defined before important decisions were taken. For example, on the subject of stockpiling, Paul saw many issues to be tackled if it was decided to create regional stockpiles. It would be necessary to agree on:

- the location of the host country and the responsible body for coordination
- customs clearance and transportation issues (to avoid delays)
- treatment of the stockpiled products (each nation’s medical and pharmaceutical regulations)
- the delivery of the products in an emergency
- financial matters (costs, reimbursement)
- the security and safety of the stockpile
- cultural, linguistic, religious, legal and other matters

This was only one example, but Paul felt it was one where US – European collaboration could be useful. He preferred that Europe took a regional approach when facing the issue of bioterrorism as Europe is not structured as the US with a single federal administration.

Difficulties

Gerald Epstein, Senior Fellow for Science and Security in the Homeland Security Program at the Center for Strategic and International Studies (CSIS), took up Giannella’s point concerning threat perceptions, as it was the nature of the threat that both

motivated society to invest in biodefense and shaped the nature of the resulting program. He regarded the issue as fundamental and said it was clear that there was no consensus on the issue of threat perception.

It was therefore difficult to define either the necessary resources or the structure of the programme to be developed. Epstein highlighted the problem, linked to the issues of threat perception, the gap between proven and clearly foreseeable technical capabilities (in the realm of bioterrorism) and the limited scale of attacks actually undertaken. With the business world’s increasing interest in biotechnology, and the widespread international diffusion of the technology, he reasoned that it would be more difficult to develop accurate intelligence: the signal being sought (i.e., evidence of a malicious program) is very hard to detect, and the background noise in which it would be hidden (i.e., legitimate commercial and scientific activity) is exponentially increasing.

Epstein also argued that even if he had perfect knowledge of today’s situation, (i.e. the identity, location and intentions of those who had the capabilities of committing bioterrorist attacks), it would be impossible to predict the future threat, as the technology was advancing so rapidly and the time necessary to develop a hostile program is less than that required to develop countermeasures. He regarded this mismatch as making it impossible to base a biodefence program on specific intelligence information. Money is well spent on

combating smallpox and anthrax because those two agents pose exceptionally serious threats, but the list of additional agents that might be used in an attack was endless and even the US could not afford to develop expensive countermeasures against very many of them. Epstein concluded that both the US and Europe faced a major challenge – the need for a “flexible responsive adaptive programme”.

Communications

The Israeli Centre for Disease Control’s **Manfred Green** wanted to improve communication about the issue. This would reduce the impact of bioterrorism and there would be many interested parties, including the vaccine manufacturers. He recommended that a joint (US and European) programme be created to conduct research on the development of “common risk communication techniques”.

The NTI’s Acting Vice President for Biological Programs, **Mark Smolinski**, picked up the issue of risk communication. He had a responsibility to communicate the US’s decisions to people in developing countries. Smolinski found it difficult to explain the emergence of the BioShield programme (that was funding the pharmaceutical industry to fight Class A and Class B agents¹⁰) whereas there had been many demands for the US to assist the pharmaceutical companies to

develop products to combat malaria and TB. The perception was that the US did not care about the threat from emerging diseases.

Answering Smolinski’s question, **Gerald Epstein** looked to future legislation that would augment the Bioshield program, and that would allow therapeutic agents and vaccines to be developed that would combat the spread of infectious diseases in addition to those to be developed to counter bioterrorist attacks. Thus funds from federal projects would be available to fight diseases like malaria and TB in the developing world. However providing government funding to benefit drug development efforts in the pharmaceutical industry would not be popular with many in the Congress. Epstein saw the need for careful legislation that did not arbitrarily distinguish between public health and biodefense, as the ability to differentiate between public health and bioterrorist threats would get harder in the future. **Richard Guthrie** introduced a “highly-charged political issue” by asking what constituted a public health emergency. In the past, former Health and Human Services Secretary Tommy G. Thompson had been ready to sign a patent waiver following (just) five deaths in the US. Guthrie wanted common standards (for the definition of a public health crisis) to be agreed on a global basis. On a related issue, he asked for common health standards on illnesses and diseases to be defined (so that, for example in the developing world, the need for basic hospital care could be set against the need to monitor outbreaks of infectious diseases).

¹⁰ Class A agents include anthrax, smallpox, plague and tularemia; Class B agents include the more common food-borne agents Salmonella and E. coli.

Laboratory procedures

The German Collection of Micro-organisms (DSMZ's) **Christine Rohde** wanted more efficient "registration, documentation and reporting" of laboratory practices within the BTWC. She called for such practices to be placed under the control of the WHO and the UN. Rohde argued that the biodefence industry and biodefence research, which she regarded as "health protection research", should be under the WHO's "neutral" control.

George Benjamin had grave doubts about the WHO's capability to act as the world's public health authority. As its funds were severely limited, the WHO would need a massive injection of resources and an improved infrastructure in order to play a meaningful role in the process.

The European Commission's **Barbara Rhode** called for stricter controls on clinical trials conducted in the developing world, as these were becoming more fashionable. She was especially concerned about the effect on the local population, as in some cases it was their only method of receiving hospital treatment.

Threat assessments / intelligence gathering

While stressing their importance, **Frank Rapoport** disagreed with Epstein's views on threat assessments, as they were

currently being conducted in the US under the leadership of the DHS.

With reference to Epstein's comments on information gathering, **Randall Murch** suggested that the intelligence communities had to adapt their methods. They should utilise more open source¹¹ and human intelligence, the latter being "the best way to collect information."

Epstein stressed that intelligence was important but one had to understand its limits. Agreeing with Murch that different methods are required, he pointed out that one problem is that the scientific community and the intelligence community need to work together in ways that are unfamiliar, and likely uncomfortable, to both of them.

The Landau Network's **Maurizio Martellini** wanted improved information sharing, perhaps funded by a public-private partnership, which could lead to a databank of knowledge (of infectious diseases) and even to University-based educational courses.

Being practical

Florin Paul wanted to keep things practical and reasoned that you had to prepare for problems that actually existed, such as the threat of malaria or TB. The results of such outbreaks would be similar to a bio-crisis

and he saw two key requirements: an early detection system (very expensive if this was in real-time) and a surveillance system.

Stanislaw Janczak wanted a co-operative approach to be developed in the case of mass casualties. Assuming a worst case scenario, that meant the spread of contagious disease. In that case hospitals would be closed down. Janczak therefore argued for priority to be given to first responders, i.e. medical staff attending the victims so that quarantine and isolation procedures could be conducted effectively.

A security matter or public health?

On the subject of whether bioterrorism was a matter for the security services or the public health authorities, Epstein argued frankly that the US would never have approved the funding for BioShield if it had been seen as a public health issue (and hence essentially commercial in nature). In his opinion, the US government had major problems with commercial organisations requesting funds for (federal) purposes, whereas in Europe, defence and security projects often had government connotations.

Wrapping up, **Michael Moodie** said that although it was important to communicate, one first had to be sure about the message to be conveyed. He was not yet convinced that the message was understood, nor who should provide it or the actual identity of

the audience. Moodie felt that there was much work to be done in order to achieve concrete results.

Giles Merritt was more positive, expressing himself happy with the results of the day's debate as it was sending the attendees away with more questions than they had brought to the table. Looking to the future, he said he would welcome NDA involvement in a European follow-up to the *Atlantic Storm* exercise. However, it should look at a totally new set of questions, from a primarily European perspective.

After listening to the day's debate, Merritt concluded that Europe was one of the problems. For example, it had no idea of the financial resources required to combat bioterrorism. In his opinion, EU policy-making on counter-terrorism could not be left to the Europeans. Likewise, US policy-making could not be left to the Americans. It was a joint problem that had to be tackled together.

Merritt was keen to repeat the day's exercise, perhaps with a thorough examination of bioterrorism and counter-terrorism. It was vital to continue to solicit American views and experience, as the US would always be ahead of Europe due to its single-government structure.

¹¹ "Open Source" intelligence, such as that in newspapers, Internet sites, books, magazines, and foreign radio broadcasts. (<http://www.globalsecurity.org/>)

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Agilent 2100 Bioanalyzer

The Agilent 2100 BioAnalyzer uses microfluidic lab-on-a-chip technology to provide rapid (< 3 min/sample) qualitative and quantitative information on DNA, RNA, and proteins in biological samples. Biological pathogens can be detected and identified using the 2100 bioanalyzer after specific DNA sequences from the chosen pathogens are amplified by polymerase chain reaction (PCR) using selective primers.

The primary advantage of the 2100 bioanalyzer relative to other PCR based detection methods, such as real time PCR, is that the 2100 bioanalyzer allows for multiplex detection assays that can simultaneously interrogate collected samples for many different types of bacteria and viruses. A multiplex assay enables a laboratory to routinely test for up to 16 PCR products in a single analysis vs. up to 4 products using Real Time PCR. This results in dramatically reduced operating costs as well as a more efficient workflow



Invitrogen PathAlert Kit

PathAlert™, a kit for detection of *B. anthracis*, *Y. pestis*, *F. tularensis*, and *Orthopox*, meets the challenging requirements for sensitivity, specificity, throughput, and cost. Based on PCR technology and proprietary novel modifications to reagents and primers, the kit includes a universal internal positive control for self diagnosis, selected dual target loci for sample detection, and corresponding engineered external positive controls for pathogen specific false positive readings when using the PathAlert system. Using the PathAlert multiplex-PCR kits with the Agilent 2100 bioanalyzer, the system can monitor multiple DNA targets and a series of internal controls in the same analysis without the multiplexing constraints imposed by conventional real-time PCR.



Analysis:

“The EU is not a United States of Europe.”¹²

Jill Dekker-Bellamy

Bio-Defence Consultant, New Defence Agenda

Within a wider international framework, the transatlantic relationship is a key asset in preparing to meet the challenge posed by the threat of unconventional weapons use and mass casualty terrorism. Differences in perception can play a significant role in whether or not the transatlantic relationship moves forward and the partnership is strengthened or if it

becomes static and fails to address common security interests. This session examined not only differences in capability, interests and objectives to counter bio-terrorism but our ability to overcome real and possibly long-term differences to achieve mutual public health security goals. Europe has experienced terrorism for decades but until the Madrid mass transit bombings in March of 2004 the type of terrorism was largely limited to known national groups utilizing conventional terrorist weapons.

¹² Stevenson, Johnathan, “How Europe and America Defend Themselves,” Foreign Affairs, Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

The use of biological agents even by a national group has the potential to cross borders making unconventional weapons use not only a European wide problem but an international one. The prospect of Al Qaeda targeting European territory will make the need for vigorous European territorial defence acute, this in turn will stimulate a natural convergence of European and American agendas.¹³ Given the recent enlargement of the European Union security challenges such as Chechnya and instability in the Transcaucas may become intensified security issues over the next decade. Network terrorism and the use of unconventional weapons in this context is clearly a critical transatlantic issue.

Gaps in capability and resources on both sides of the Atlantic have served to shape threat perceptions. How can the United States and the European Union better understand not only differences in approach but an appreciation for unique capabilities each side brings to the table? The concept of 'homeland security'¹⁴ and establishment of institution(s) specifically consolidated after 9/11 is an accepted US approach, it is not however a common European level position where subsidiary must be consistently be factored in to action. Homeland Security covers such a converse area of protection across a field of designated US threats where European initiatives are defined and

structured on a more national basis so the concepts usefulness for Europe may not prove highly applicable in a wider transatlantic dialogue. Moreover initiatives taken at the European level often go by unnoticed by the US, who, with a unilateral approach, tries to impart best practices to nations with vast experience with terrorism and well versed in countering transnational threats.

State sponsors of terrorism and terrorist networks such as Al Qaeda represent transnational threats very different to the type of threat posed by traditional European terrorist groups such as the IRA or even Hamas. With potentially thousands of members and no interest in bargaining with the United States or its allies Al Qaeda seeks to inflict mass casualties possibly with weapons of mass destruction.¹⁵ It is impossible to imagine Osama bin Laden's followers apologizing for inadvertently killing Americans...as Hamas did, after a suicide attack on Jerusalem's Hebrew University in August of 2002.¹⁶

Although acts of Arab national terrorism on US soil is a relatively new experience in the United States, France, has recently shown greater concern about mass casualty attacks and unconventional weapons use.¹⁷ Moreover both Europol and Interpol have seen budgets added for bio-terrorism

and transnational threats. Interpol has launched a bio-terrorism section. With its well established institutions Europe is perhaps in a unique position to confer best practices to the United States both in terms of multi-lateral engagement, human intelligence¹⁸ capability needed to track terrorist recruitment and activity in Europe and internationally, investigative jurisdiction and preventative diplomacy which can serve to strengthen defences against 21st century security threats. Recently a number of Member States have coordinated their intelligence which resulted in the capture of several individuals trying to refine Ricin into some kind of weapon and the capture and detention of Islamic terror suspects in the Madrid transit bombings.

*"September 11 demonstrated that America's security is organically linked to Europe's vulnerability to infiltration by terrorists."*¹⁹

Are we addressing the right issues in the transatlantic context?

While the focus of the April 25th session was squarely set on "Homeland Security" and to a lesser degree proposing crisis management strategies, arms control and counter-proliferation methods, problems

with determining *if* bio-terrorism is a threat and *how best* to strengthen the transatlantic partnership to counter it were somewhat obscured. Undoubtedly intelligence capabilities are essential to first determining threats then appropriately responding to WMD and the threat of unconventional weapons use by terrorists. Significant US intelligence failures in a number of key areas give cause for concern within the European Communities.

The European approach, far from creating a homeland security sector, generally maintains even distribution of human resources and builds upon science and technology.²⁰

Title VI instruments capture a much wider field of security concerns than merely terrorism; it covers both police and judicial cooperation in criminal matters an inter-governmental arena of cooperation within the EU in which the European Commission shares the right of initiative with EU Member States.²¹ Last year, the EU announced it would step up cooperation between the intelligence agencies of its 25 member states. The move is part of the EU's response to the terrorist attacks in Madrid and recognition of the potential for unconventional weapons use. "The threats we are facing today are not national threats -- terrorism -- they are international threats.

13 Ibid., Stevenson, 2003.

14 Homeland security consists of all military activities aimed at preparing for, protecting against or managing the consequences of attacks. [] It includes all actions to safeguard the populace and its property, critical infrastructure, the government and the military, its installations and deploying forces. RAND

15 Stevenson, Johnathan, "How Europe and America Defend Themselves," *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

16 Ibid., Stevenson, 2003.

17 Ibid., Stevenson, 2003.

18 Ibid.

19 Stevenson, Johnathan, "How Europe and America Defend Themselves," *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

20 Solana, Javier, "EU Takes First Step toward Joint Intelligence Capability", *EU Business*, 9, June 2004. URL: http://www.eubusiness.com/topics/European_Council/EUNews.2004-06-09.3325

21 Den Boer, Monica, "9/11 and the Europeanisation of Anti-Terrorism Policy: A Critical Assessment", Groupement D'Etudes et de Recherches Notre Europe, Jacques Delors, Policy Papers No. 6, September 2003.

Therefore, to put together the intelligence which is international with intelligence which is national will be a very important step forward in the coordination of the European Union [counterterrorist measures].”²² To what extent is threat perception and our capability to determine next generation unconventional weapons use *accurately*; dependant on a wider array of capabilities? Has US superiority and reliance on science and technology obstructed not only threat perception but response? Where technical capability gaps exist between the EU and US who make for an unbalance relationship, analytic capability and resource management by specific US intelligence agencies factors into how Europe perceives the transatlantic relationship and can essentially build trust to counterbio-terrorism and the threat of WMD.

“A profound lack of American interagency coordination, [] prompted soul-searching in existing US law-enforcement and intelligence services and the creation of the Department of Homeland Security. France’s highly effective intelligence coordination system -- centered in the Secretariat Generale de la Defense Nationale and spanning the executive and judicial branches -- was itself the product of administrative disarray in French counterterrorism in the 1980s and therefore merits close American study.”

Johnathan Stevenson

Understanding Differences: Threat Base or Comprehensive planning

Europe’s perception of the threat posed by terrorism, even after September 11, 2001 has remained intrinsically different from America’s -- perhaps justifiably so; both Europeans and Americans understand that the war in Afghanistan and new law-enforcement and intelligence cooperation have not stopped al Qaeda.²³ Engagements in Afghanistan and Kosovo have arguably reshaped terrorism and added impetus to movements previously considered non-aligned. The recognition of the use of WMD or biological weapons by terrorists and state sponsors and US policy orientation to prevent it did not simply emerge out of 9/11. These policies were well underway during the Clinton administration.

The September 11th attacks were planned nearly two years prior to the event. We cannot discount the possibility of another mass casualty attack possibly with biological agents in the future. Where U.S. homeland security strategy is now driven by potential consequences, European security tends to pivot on probabilities; most European governments, accordingly, have continued to approach terrorism as predominantly a problem that can be assessed and dealt

with on an emergent basis, after particular threats have arisen.²⁴

Should we discuss bio-terrorism in the transatlantic context at all when Member States and the United States must get their own houses in order first and the international community as a whole must be fully engaged? Unfortunately the intersecting of bioterrorism and our understanding of transnational threats is too great a problem and too diverse in scope to wait until everyone is ready. An open border Europe where the free flow of commerce, people and animals coupled with transnational criminal syndicates working across our Community in direct contact with terror organizations means tighter security legislation must be enacted. While it would be ideal to approach bio-terrorism preparedness on a state by state basis where each nation builds its own resources and capabilities, a mass casualty event with a biological agent likely to cross borders and cause panic means this is no longer a practical option. The nature of biological weapons necessitates engagement in both dialogue and actual preparedness planning in the transatlantic community simultaneously in order to meet the challenges we will face at the international level.

Although the meeting did not address NATO, could NATO provide the conduit for closer dialogue on biological weapons

prevention and preparedness? NATO structures might, in theory, help fill the gap by coordinating efforts at counterterrorism and homeland security; indeed, the alliance has already established five concrete counterterrorism instruments: a mobile lab for analyzing nuclear, biological, and chemical (NBC) weapons; a prototype NBC response team; a virtual “center of excellence” for NBC weapons defense (consisting of a standing, Brussels-based system of intranet links among national study centers and their experts); a biological and chemical weapons defense stockpile; and a disease surveillance system.²⁵ Perhaps it is within the transatlantic context that NATO should play a more visible role in helping to coordinate preparedness and response planning as the Member States who comprise it already collaborate at a well integrated and consolidated level within the transatlantic framework. NATO’s formidable capabilities could be an asset in assisting NATO Member States and coordinating with the United States in delegating resources.

The World Health Organization would be a likely institution for emergency public health planning and provide non-stockpiled vaccines and therapeutics in the event of a global pandemic. [To prepare for bioterrorist attack, many nations have integrated bioterrorism response strategies into their public health care systems.]

22 Solana, Javier, “EU Takes First Step toward Joint Intelligence Capability”, *EU Business*, 9, June 2004. URL: http://www.eubusiness.com/topics/European_Council/EUNews.2004-06-09.3325

23 Stevenson, Johnathan, “How Europe and America Defend Themselves”, *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

24 Stevenson, Johnathan, “How Europe and America Defend Themselves”, *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

25 Stevenson, Johnathan, “How Europe and America Defend Themselves”, *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

Nations and international organisations with the best capability will likely be called upon to mount a response, to lead during an international crisis. Forming a coalition now offers the best chance of appropriate and consolidated preparedness and response in the event of a major bio-terrorist event.

From Non-Proliferation to Counter Proliferation: developing a transatlantic risk management strategy

Making progress in the area of non-proliferation and disarmament is clearly a priority for the Member States and EU institutions as expressed in the newly emerging EU Strategy on WMD defined in the EU Security Strategy and the two documents mentioned in the Thessaloniki conclusions: the 'Basic Principles' and the 'Action Plan to implement the Basic Principles for an EU Strategy against the proliferation of weapons of mass destruction.' Achieving a single Common Foreign Security Policy budget line on 'non-proliferation and disarmament' would be an important measure of this commitment and serve to build on the achievements of the Community in this area.²⁶

Limits of the non-proliferation regime prompted the US and ten allies, including

26 Quille, Gerrard, "EU Member States Pledge 5 Billion Euros to Tackle WMD Proliferation", *European Security Review*, International Security Information Service, No.20, December 2003. URL: <http://www.isis-europe.org/ftp/Download/EU%20Member%20States%20pledge...WMD%20proliferation.pdf>

the UK, France and Germany, to adopt the Proliferation Security Initiative (PSI) which aims to prevent the transport and delivery of weapons of mass destruction.²⁷ The PSI's objectives and working methods have been set forth in a simple one-and-one-half-page political statement, the "Statement of Interdiction Principles," issued by 11 states on September 4, 2003, in Paris. In so doing, these 11 founding participants—Australia, France, Germany, Italy, Japan, the Netherlands, Poland, Portugal, Spain, the United Kingdom, and the United States—vowed to step up their efforts to interdict WMD-related shipments in the transport phase, whether by land, air, or sea.²⁸ The Proliferation Security Initiative is however only one tool in a suite of needed interventions to prevent the possible use of WMD and in a wider sense an act of bio-terrorism. It does serve as a practical mechanism for transatlantic engagement.

War Game Scenarios: imperfect but necessary?

War-game scenarios are often based on 'worst-case.' Critics of Atlantic Storm, Global Mercury, Dark Winter and other war-games based on a Category A pathogen outbreak, often propose such gaming is not realistic and conducted to sow the seeds of panic or

27 Verdirame, Guglielmo, "The Case for Forcible Counter-Proliferation", *The Nixon Center*, 2005. URL: <http://www.inthenationalinterest.com/Articles/Vol3Issue4/Vol3Issue4Verdirame.html>

28 Winner, Andrew, C., "The Proliferation Security Initiative: the New Face of Interdiction", *The Washington Quarterly* The Center for Strategic and International Studies and Massachusetts Institute of Technology, (Spring) 2005. URL: http://www.twq.com/05spring/docs/05spring_winner.pdf

at the minimum, increase defence spending on CBRN counter terrorism preparedness. With little to replace it however, what should nations do to test vulnerabilities and ramp up capabilities? EU Member States and the international community experience cyclical outbreaks of Avian Influenza and Classic Swine Fever among other major zoonotic disease outbreaks in close herd density nations such as those found across the European Union. Might this not present smaller scale opportunities to define gaps in planning and regulation and prepare for a range of bio-terrorism events which have the potential to impact public health security and, veterinary and economic security.

In 2001, when the Netherlands suffered a relatively limited outbreak of foot and mouth disease, statutory issues over authority immediately emerged between European Union regulation on designated quarantine indicators, vaccination policy, and transport and border closure. Belgium and Germany closed their borders, immediately halting all trade; the Netherlands initially instituted a three Kilometer quarantine around infected farms while states such as Germany insisted on a 10 Kilometer radius, Dutch veterinarians began vaccination in direct violation of EU law at that time (the law has now been revised to allow for vaccination with six month restrictions on trade). If nations challenge EU authority and regional discrepancies obstruct timely response for emergency animal disease crisis how will they cope with a highly orchestrated deliberate disease outbreak of a Category A

pathogen such as smallpox? This is a limited example of the impact naturally occurring zoonoses and the consequences lack of emergency disease crisis planning can have during a real-time outbreak.

If indeed this had been smallpox one would have to consider what the possibilities might be regarding statutory jurisdiction covering a range of policy and regulatory areas not to speak of the lack of practical emergency disease containment and response planning. The Bio-Terrorism Reporting Group has been convened specifically to discuss policy planning for Category A pathogen threats or the group of diseases considered suitable for biological warfare. However within the wider framework of emergency disease planning natural and deliberate zoonotic disease outbreaks and general threats to public health security, the transatlantic partnership would be well served by sharing lessons learned over wider public health emergencies. Although war games may not reflect the full spectrum of issues we would likely face during such an event, they are perhaps imperfect means of highlighting the more glaring failures of policy and capability gaps. The most efficient way of assessing our capabilities in light of non conventional terror threat is to carry out simultaneous action on several levels: deterrence (though in the case of terror, effectiveness is questionable), prevention, and preparations for responding to the fallout of an attack should one occur.²⁹

29 Stevenson, Johnathan, "How Europe and America Defend Themselves," *Foreign Affairs*, Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

As zoonotic and emerging diseases pose a greater and greater challenge to public health authorities and international health security how can we hope to counter deliberate disease (bio-terrorism) when we do not even have regulations covering notification of Class A and B zoonoses which pose a direct public health threat?

A Real Time Public Health Security Crisis: Risk Communication, Response and Preparedness?

“Syndromic diagnosis—[is] nothing but a big charade, by the time you start getting blips in emergency rooms, it’s too late.”

Dr. C. J. Peters, former head of the CDC’s top security lab.³⁰

The Marburg outbreak³¹ in Uige province, although a presumed natural occurring

outbreak of disease, seems to be slipping by without much notice or concern over its potential spread even as it moves closer to major cities where international travel could present real risks to public health security. This would seem to be a good opportunity for transatlantic dialoging on common biological threats just as the SARS-CoV outbreak was a wake-up call to western governments to enhance surveillance and response capacity. Transitional states, developing states and failed states should be serious considerations when we assess our defences against biological terrorism and basic emerging diseases. Although few economic interests are at stake in Uige province the potential spread of a Category A Viral Hemorrhagic Fever is alarming. While the US, Canada and Europe consider how to work together to prevent the spread of disease the outbreak of Marburg seems to have slipped from the radar.

Unlike recent Avian Influenza outbreaks across Asia which posed a significant economic and potential public health threat, the Marburg outbreak which as of May 6th claimed more than 277 lives, with 316 persons infected has reduced economic significance but potential public health security risks. The first cases in Uige were reported last October in 2004 since then there has been a steady increase in the infection rate and fatalities. In early April, nine people were placed in isolation in Italy following contact with an infected person who died. In Portugal two suspected cases (people who had arrived

from Angola) were investigated by the WHO and determined not to be infected with Marburg. International health threats and bio-terrorism must be responded to in a much wider, integrated context. As of 13, May (2005) there were reported 8 people dead in the Congo from symptoms similar to Ebola or consistent with a Viral Hemorrhagic Fever. Ebola’s worst outbreak in 1995 killed more than 250 people in the Congo. Cuvette region suffered 120 fatalities from Ebola the same region where the 8 casualties have thus far occurred.

Emerging and reemerging disease must arguably be included in public health planning for emergency and deliberate disease management; a structure complimentary to most public health systems. An integrated approach to vaccine and therapeutic investiture must have a dual function both to serve normal disease outbreaks as well as potential deliberate disease epidemics. The transatlantic relationship could be positioned to strengthen these areas critical to shared public health security policies.

Viral Hemorrhagic Fevers and other Category A bio-warfare agents such as Anthrax do occur with some regularity throughout many parts of the world. They pose a significant health risk and should be considered in a wider bio-defence public health protection strategy. Unlike smallpox, there is no treatment for VHF’s and their classification as bio-warfare agents should be taken into account when structuring public health

security preparedness. Although agro-terrorism and food-borne zoonoses pose a serious threat to public health with the exception of genetic modification and an advanced delivery system most would not have the same kill ratio as a VHF or other Cat.A fully weaponized disease.. From an economic standpoint which unfortunately often takes precedence over public health security, food-borne zoonoses or agro-terrorism would be devastating, there are however often treatments

Angola: Marburg Hemorrhagic Fever Outbreak: Minor Emergency no.05ME021; Bulletin No 3; Reported		
Cases from October 2004 to April 2005		
Month Year	Cases Reported	Deaths Reported
October 2004	3	3
November 2004	4	4
December 2004	7	7
January 2005	20	20
February 2005	31	30
March 2005	53	47
April 2005>20 April	148	133
Total	266	244

This represents a fatality rate of 91.7%³²

available and the symptoms are generally not as severe as the crash and bleed out phase from VHF, smallpox or blackpox.. How effective are current tropical disease management strategies in the EU? What regulations are in place to test for Marburg at international airports across Europe today? Should we be concerned that such an outbreak is not only occurring but not

30 Gottlieb, Scott, “Wake up and Smell the Bio-Terror Threat”, Homeland Dangers, *The American Enterprise Institute*, January/February 2003. URL: http://www.taemag.com/issues/articleid:17342/article_detail.asp

31 Marburg hemorrhagic fever isn’t as much feared as its cousin Ebola hemorrhagic fever. But in fact, they’re hard to distinguish [Clinically they are associated with similar disease symptoms, but the 2 viruses do not cross-react antigenically and are easily distinguishable by serology and RT-PCR assay. - Mod.CP]. In both cases, victims bleed to death, often from every orifice and every organ. Few infections are as deadly. That’s why the WHO, the US Centers for Disease Control and Prevention, Health Canada and the medical aid group MSF (Medecins sans Frontieres) are rushing to Angola. The international response to the outbreak in Angola began one month ago, on 22 March. The features of Marburg hemorrhagic fever, and the conditions in Angola, have been an extreme test of international capacity to hold emerging diseases at bay. The outbreak in Angola is the largest and deadliest on record for this rare disease, which is presently showing a case fatality rate higher than 90%. For comparison, outbreaks of the closely related Ebola hemorrhagic fever have shown mortality rates ranging, according to the virus strain involved, from 53% to 88%. World Health Organization

32 International Federation of Red Cross and Red Crescent Societies, Angola: Marburg Hemorrhagic Fever Outbreak: Minor Emergency no.05ME021; Bulletin No 3; 25, April, 2005. URL: http://www.ifrc.org/cgi/pdf_appeals.pl?05/05ME02103.pdf

being overtly communicated to the public by public health authorities responsible for protecting European citizens?

*“As we face the possibility of designer agents, facilitated by advances in biotechnology, we must reconsider our current extremely conservative and cumbersome system for development and production of vaccines. ... Failure to prepare is not an option; the potential impact of biological terrorism on our society is too great.”*³³

Dr. David Franz and Dr. Lance Gordon, co-chairs of a national working group convened by the Chemical and Biological Arms Control Institute (CBACI) to develop a national bio-defense vaccine strategy.

Policies for Preparedness

Before September 11, only six European countries – France, Germany, Italy, Portugal, Spain, and the United Kingdom – had specific counterterrorism laws (as distinct from ordinary criminal codes).³⁴ Some of these six have since strengthened their laws still further or improved enforcement; other countries such as the Netherlands, which did not have such laws or counterterrorism programs, have enacted and implemented

them.³⁵ Bio-terrorism is a security and public health issue which is not necessarily true of emerging or pandemic diseases.

Although preparing for bio-terrorism requires national investment in a range of capabilities (i.e. surveillance, diagnostics, capacity) and a suite of security based counter measures one of the primary means available to us is the use of vaccine and therapeutics as a deterrent. Creating a national vaccine strategy with comprehensive legislation to ensure public health security is a significant advantage against the use of disease as a weapon of mass destruction. In this respect the United States has made tremendous strides toward insuring public health protection. As war scenarios have tended to demonstrate the need to plan for such an event is critical even if nations disagree on the exact extent and nature of the threat.

The incubation period (1 day to 2 weeks) associated with most biological agents between exposure to the infectious agent and the onset of symptoms is unique among weapons types; preparedness can make all the difference to the outcome of a bio-terrorist attack. Unlike weapons with more immediate effects such as explosives, there is the possibility to mitigate the effects through counter-measures including rapid detection, treatment with antibiotics, therapeutics and/or vaccines

and quarantine.³⁶ As Akerman and Moran contend in regard to the technical ability of terrorists to engage in future acts of biological terrorism, some experts contend that previous technical obstacles to obtaining or developing biological weapons has eroded, and biological weapons capability is most likely within the reach of at least a certain subset of terrorist groups. The group most commonly cited as being likely to “overcome the technical, organizational and logistical obstacles to WMD³⁷ is the Al Qaeda network, which is reported to be pursuing several types of WMD including biological weapons. The transatlantic relationship in identifying common threats, preparing to respond and contain disease outbreak could not be more critical. Since well over 30 previously unknown infectious agents (including several new hemorrhagic fever viruses and new highly virulent strains of streptococci) have been identified since 1973, it is imperative our public health infrastructure and surveillance systems be structured to recognize both naturally occurring and intentionally released infectious agents.³⁸

For most European Member States launching programmes solely for countering bioterrorism is not an option as it may be for the United States. Rather, improving capacity

fully consistent with current public health security policy is preferable. To this end, the European Union has endeavored to increase its surveillance of disease outbreaks via its network approach. As Julius Weinberg states, “Many of the European networks have shown that by combining data from various different countries they can detect events that would not have been detected any other way, such as for the Legionella and Salmonella networks.” (Weinburg admits, however, that the system failed to achieve a consistent response across different countries to the H5N1 influenza strain.)³⁹ Weinberg advocates the use of “effective generic public health systems” that deal routinely with a range of infectious diseases - not specific bioterrorism-response systems - because “you actually don’t know what the next bioterrorism event is going to be.” “You can build endless P4 facilities against the day that someone releases a very virulent pathogen, but laboratories have to be doing something in the meantime.”

*“Even if al Qaeda focuses only on American installations in Europe, should its operatives use WMD, the consequences will be grave for the population at large. These factors suggest that with respect to homeland security, Europeans and Americans will remain dependent on one another.”*⁴⁰

33 Chemical and Biological Arms Control Institute, “CBACI Releases ‘Roadmap’ for National Vaccine Strategy”, press release, 29, September 2004. URL <http://www.cbaci.org/press/release8.htm>

34 Stevenson, Johnathan, “How Europe and America Defend Themselves,” *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

35 Ibid., Stevenson, 2003.

36 Akerman, Gary and Moran, Kevin S., “Bioterrorism and Threat Assessment”, *The Weapons of Mass Destruction Commission*, No.22, Stockholm, Sweden, November 2004. URL: <http://www.wmdcommission.org/files/No22.pdf>

37 Simon, Steven and Benjamine, Daniel, “America and the New Terrorism”, *Survival*, Vol. 42, No.1, Spring 2000 pp. 59-75. URL: <http://www.eusec.org/su00011e.pdf>

38 Cassell, Gail, Testimony on the Department of Homeland Security, *American Society of Microbiology* July 9, 2002.

39 Clayton, Julie, “Europe in Disunion about Proposed Disease Center”, *BioMedNet*, 3 May, 2002. URL: <http://www.vaccinationnews.com/DailyNews/May2002/EuropeDisunionInfect.htm>

40 Stevenson, Johnathan, “How Europe and America Defend Themselves,” *Foreign Affairs*. Council on Foreign Relations, March/April 2003. URL: <http://www.foreignaffairs.org/20030301faessay10340-p20/jonathan-stevenson/how-europe-and-america-defend-themselves.html>

Conclusion

Rapid advances in life sciences and the anticipated developments in biotechnology, genetic engineering, and other advanced technologies not only have the potential to produce new drugs for serious diseases, but also pose tremendous security risks for fear that terror organizations may exploit the technology to cause diseases, epidemics, and other biologically related damage.⁴¹ Several counter-measures for responding to bio-terrorism are complimentary to basic public and veterinary public health security. Building capacity to respond to natural outbreaks of disease, research on emerging and re-emerging diseases including Category A biological warfare agents such as Viral Hemorrhagic Fevers offers a number of benefits. However in the EU building capacity among the member states must still be increased to better partner with the international community. Europe still has only a few locations to perform pox diagnostics. In an outbreak where rapid processing may be necessary according to Matthias Niedrig, of the Robert Koch Institute, even 50 to 100 samples would be problematic in terms of a quick diagnosis. What should be our goal then within a wider international framework for developing counter-measures to bio-terrorism? Although the transatlantic debate took in a wide field of related areas narrowing the debate to bio-terrorism instead of terrorism was less transparent.

41 Friedman, David, "Preventing the Proliferation of Biological Weapons: Situation Overview and Recommendations for Israel", *Strategic Assessment* Vol. 7, No. 3, Jaffee Center for Strategic Studies, Tel Aviv University, December 2004. URL: <http://www.tau.ac.il/jcss/sa/v7n3p5Fri.html>

The transatlantic discussion on perception of threat and counter-measures to interdict an act of bio-terrorism at an early stage reflected general criteria similar to that proposed by the American Society of Microbiology essentially that we need to:

- Develop an integrated set of strategies;
- Prevent nations from acquiring bio-weapons in the first instance,
- Dismantle existing programs and capabilities where proliferation has already occurred;
- Deter the use of biological weapons, and,
- Ultimately, put in place countermeasures that can rapidly detect and effectively defend against such use.

In the long term, the only way to defend against bioterrorism is through a combination of constant surveillance, accurate diagnostics to identify threats as early as possible and continuous innovation to provide high quality vaccines and drugs that can be useful against any attacks that do occur.⁴² Research related to bioterrorism is inextricably linked to that of naturally occurring infectious agents and development of new antibiotics, antivirals, diagnostics and vaccines; the research and development of technologies for bio-defense should be synergistic and not duplicative.⁴³

42 Cassell, Gail, Testimony on the Department of Homeland Security, *American Society of Microbiology* July 9, 2002.

43 Cassell, Gail, Testimony on the Department of Homeland Security, *American Society of Microbiology* July 9, 2002.

Brigadier Ian Abott, OBE Director, Policy and Plans Division European Union Military Staff

I welcome the opportunity to place this complex subject in context and to give some impression of the consequences arising from this form of threat. We know for some individuals, organisations and governments this subject and the asymmetry aspect in the contemporary threat spectrum are not new. We all acknowledge that public discussion and thinking on this subject was precipitated by the events of 11 Sep 2001. But possibly we need reminding that in addition, there were 'anthrax' attacks that took place in October of 2001 in the US and were copied as "white powder" attacks in other countries. I do not want to be drawn on whether a national or a foreigner conducted the attack; significant though that might be to the threat profile. Instead, I wish to **concentrate on the effect induced**, the crisis management required, consequence management issues raised and remedial measures identified as these areas seem to me to offer the best potential to harness your views in order to address today's meeting.

As a model to orientate our thinking I ask you to consider what might be involved in a "white powder" attack which, for background, happened several hundred times in the UK in the year following the anthrax attacks in the US and generated over 200 events that required serious investigation and engagement with the emergency services.

Although the numbers were very high, even one "event" can be highly disruptive. The following description is over simplified but gives an example of some of the factors and sequences involved. Several hours and days are lost as part of the identification and clean up tasks are undertaken. Rooms, computers and papers are not available. People are stripped, their clothes, car keys, money and credit cards are quarantined. **Minds are affected; public perceptions are shaped.** The blue light emergency services are initially totally committed. What the substance is and where it is are unknown. CBRN contamination suits and breathing apparatus hinder progress. The weather, and particularly the wind strength and direction, plays a significant part. A hot zone, with inner and outer cordons is established. First aiders, hospital A&E departments, pharmaceutical laboratories, police, fire and military capabilities are engaged. The population from the areas directly affected and then downwind of the cordon are affected and moved. Then once clear, and remember it took over one year to declare all of the papers clear of infection after the anthrax contamination, more time is needed to regroup and reconstitute the emergency services capability and readiness to respond again.

And this brings me to a key element. Confidence, I firmly believe that **the centre of gravity in a democracy is the maintenance of public confidence in the government.** In open societies

this brings an associated challenge of engagement with the public over the threat, crisis management procedures, plans and Consequence Management Capabilities. Establishing and maintaining confidence involves several lines of development. Some of which I will briefly cover now.

The first is Public Information. Effective Nation and international Public Information policies are key but they appear to suffer from oscillating between sharing information or scaring the target audience. In many countries now questions are being raised on the legality and suitability of national counter terrorist measures introduced after 11 Sep 2001. It seems that it is very difficult for democracies to find policies, strategies and procedures that are pragmatic and achieve a balance between being proactive or reactive.

Another key factor is the engagement of the private sector. For many European States, the last 60 years can be categorised as the conversion of a nation state from being organised for total war to one that is best orientated to meet the challenges and opportunities provided by democracy and free trade. As a result, services that were once considered as critical to the maintenance of government control and power, have changed ownership and have moved into the private sector. The situation though becomes more complex as government and corporate influence has been eroded as market forces and the search for competitiveness have introduced

“Just in Time” rather than “Just in Case” methodologies and practices. This means that there is very little or no reserve in the national and international supply chains. For instance, I recall a case where a global energy plc found it was unable to move its oil products as it did not directly employ the drivers of its fuel tankers nor did it own the vehicles that carry their logo as they are leased from another company. Elsewhere we see a taxi drivers strike at the airports in the Balearic Islands cause charter aircraft to be grounded on the American West Coast. Consequently as the world has become more interconnected and societies more complex, there has been a growing vulnerability to natural and man made “shocks”.

Trade patterns, commercial practices, legislation and multinational contracts have produced a global web that binds us all. And this brings me to my last key ingredient. I believe the terminology Weapons of Mass Destruction (WMD) is misleading - even the expression CBRN may be unhelpful as I look inside my son's fridge at university and think the cultures growing there on his food and drink indeed warrant being considered as a risk to life!

But returning to the expression WMD, instead, I consider the challenges we face now are best analysed and managed as being **weapons or actions that seek mass effect**. From national examples I am convinced that the **more novel the event, the more it will stimulate a**

reaction, shape public perceptions and so influence political thinking, policy and strategy. We appear to be immune to some losses; regrettably hundreds of lives are lost every day on the roads, aircraft are lost. But the Tsunami, the gas attack on the Tokyo Tube system and the Anthrax attacks in the US seize the mind. Consequently we must consider new and novel forms of attack and prepare our minds and those of the decision makers and public. Returning to the centre of gravity; the terrorist will be successful if the government loses public confidence. I think the Madrid bombing was a pertinent example of my thesis. Consequently governments and relevant parties from the public and private sector must develop, understand and practice crisis management procedures, have effective and resilient Business Continuity Plans to sustain for the maintenance of essential services for the public and private sectors and society at large. This planning should begin with what effect has been produced, and what capabilities and actions are needed in order to return to normality as quickly as possible.

Hopefully this reminder of some of the associated factors involved will help place the subject and your deliberations in context in order to address the aim of today's meeting.

Georges C. Benjamin, MD

Executive Director

American Public Health Association

Strengthening Public Health: Homeland Defense

Four important principles are guiding current efforts to strength the U.S. public health system. First, our knowledge on bioterrorism is based on experience. The U.S. has experienced at least two bioterrorism incidents in the past twenty years: the Rajneesh's use of salmonella as a food contaminant in 1984 and the series of unattributed anthrax mailings in the fall of 2001. Second, the practice of public health has fundamentally changed as a result of multiple factors. Third, there is evil in the world. Malicious actors can seek to use dangerous organism with the goal of creating mass- fatalities or mass disruption. Finally, having said that, nature is the most dangerous actor in that outbreaks of new and reemerging infectious diseases are occurring as a result of man's interaction with and use of the environment.

These four factors are converging to create a new operating environment for the practice of both medicine and public health. In the past, public health practitioners and the public health system were largely invisible to the public. With the emergence of infectious disease as a known threat to security, public health has become increasingly prominent as the front line of defense against this

threat. As a tool of security and defense, public health has become a 24/7 operation with the goal to provide immediate results. This has also meant that public health is increasingly intertwined with “big P” politics and fundamental debates about national budgets and budget allocations. Where public health in the past focused on well-planned, well-defined public information campaigns focused on public education and prevention, this new environment is taxing the system with too much information and an inability to speak with “one voice and one message”. Last, and perhaps most importantly, the practice of public health has by necessity become increasingly global in scope, to keep pace with the global nature of threats to public health.

Two issues have placed public health at the center of national and homeland security and are producing this new operating environment. The first is concern about the threats posed by emerging diseases. This includes the re-emergence of infectious diseases: perhaps as a result of lapses in public health, evolutionary changes in the organism that helps it to overcome existing vaccines and treatments, or the reintroduction of dormant diseases resulting from environmental changes. This includes the possibility of pandemic flu, sporadic outbreaks of hemorrhagic diseases, hantavirus, etc. It also includes the emergence of completely new and previously unseen infectious diseases; including those created by nature like SARS and new organisms created by human

ingenuity like the highly deadly form of Monkey pox created by accident in an Australian biotechnology facility.

The other factor placing public health at the center of national and homeland security is the danger of bioterrorism and biological weapons. As a direct result of the terrorist attacks of September 11, 2001 and the anthrax mailing in the autumn of 2001, security dominates the national agenda. The possibility of biological weapons use by terrorist organizations and nation-states has risen to the top of listed threats to national security and homeland security. Strategies for responding to the threat of bioterrorism have emphasized elements of prevention and protection. Increasing the capacity of the national public health system to respond effectively to an outbreak resulting from biological weapons use is the cornerstone of the national strategy to defend the nation against biological weapons. Importantly, the results of these capacity building efforts also provide the nation with the cornerstone of defense against all infectious diseases – including naturally occurring outbreaks.

There are multiple challenges to ensuring the public health system of the 21st century can respond to the full range of infectious disease threats. Effectively managing the growth to ensure it provides real improvements in capability is critical. Increased spending on public health must be used effectively in building and sustaining key elements of infrastructure. This includes

hiring new people, providing education and training opportunities for staff, providing the tools they need to operate in this new environment, and supporting infrastructure – things like new facilities and new linkages with non-traditional partners like the law enforcement community. To be successful, creating a public health system for the 21st century requires structural reform at local level and increased investments into basic in public health research. It also requires sustained investments to increase capacity and changes in the way Federal government provides funding to state and local public health agencies.

To provide the necessary defense, investments in public health must enhance response capacity across all levels of government; Federal, state, and local. The capacity to respond is comprised of several elements. These elements include:

- Prevention;
- Disease detection and the ability to discern unusual patterns of disease;
- Epidemiological investigation to determine the extent and cause of the outbreak;
- Laboratory testing to confirm the disease agent;
- Provision of information regarding the outbreak to key stakeholders;
- Provision of treatment and the ability to contain the outbreak through focused public health intervention;
- Links with external supporters and partners; and

- Recovery from the immediate and long-term effects of the outbreak.

Federal, state, and local governments have been investing in the public health system significantly in the period since the events of September 11th, 2001 and the anthrax mailings of the same year. A key question for the public health community, political leaders, and public at large is “are we prepared?”. In other words, has investment in public health capacity building efforts provided the capabilities the nation needs to protect itself from bioterrorism, biological weapons, and the broader range of infectious disease threats? The answer is more complicated than a simple “yes” or “no”. Preparedness is a process, and not a point in time. The direction of this process is determined largely by answering the question of “preparedness for what?”. It is the complexity of the challenge posed by infectious disease – the number and variety of disease causing agents, the potential for the use of disease as a weapon, and possibility of new and unknown diseases created by nature and man – that make the achievement of true preparedness difficult if not impossible. Rather than thinking about creating a public health shield against infectious disease, our goal should be the creation and maintenance of a public health system that can translate the chaos of disease outbreaks into controlled disorder.

What are the results of on-going efforts to build up the U.S. public health

infrastructure to date? The public health system has become less reactive – catching up to events, and increasingly proactive. Preparedness and infrastructure building efforts have produced rapid, frequent, and broad-based communication among and between Federal, state, and local public health agencies. It has also increased communication with external partners and supporters. Recognizing the global scope of the infectious disease problem, there is an increasingly global approach to public health. As the public and political leaders have focused on the public health community to provide information and answer their questions about health and infectious disease, knowledgeable and capable spokespersons are being developed within the public health community. Investments in people, facilities, and technology are producing new science at record speed. Public health is using all available systems and resources to their full potential. Finally, and most importantly, we know that recent improvements in the public health system and its associated infrastructure have saved lives!

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Threat Perceptions, Threat Assessments, and US/EU Cooperation in Biodefense

I'd like to talk about two factors that will have a very important effect on the degree to which the United States and Europe will be able to cooperate on biodefense: our relative perceptions and assessments of the threat. The degree to which bioterrorism and biological weapons are perceived to be significant security threats will affect each party's willingness to invest resources in biodefense, and the nature of each side's threat assessment will help structure that side's biodefense program. Of course it is not necessary for the United States and Europe to have identical threat perceptions and threat assessments in order to successfully collaborate - political history is replete with situations where parties, having different overall perceptions (not to mention values and objectives), have worked together in some area of common interest. But given that countering biological threats is too large and too inherently international a problem for any one nation or group to solve alone, it is important that we arrive at some common understanding of what it is we need to do together. However, deriving threat assessments - let alone coming to agreement on them - is complicated both by

the (fortunate) paucity of actual historical or intelligence information regarding biological threats, and by the limitations that we would face in using such information even if we had it.

Limitations of Historical Analysis. The enormous gulf between what might be possible in the future and what has been seen in the past in terms of biological attacks leaves room for widely disparate differences in perceived threats. Indeed, few areas besides biological threats have so great a disparity between the proven capability to do harm, and the number of actual attacks. We know for sure that biological weapons, when prepared for effective dissemination in large enough quantities, can kill over large areas. The capabilities to place many thousands of lives at risk were demonstrated decades ago. Although these programs drew on the resources of nation-states, half a century of advances in biotechnology - one of the most rapidly advancing realms of human endeavour - goes a long way towards making these capabilities available to non-state groups. We know that the technology, materials, and expertise required to produce biological weapons are available to those terrorists who are sufficiently motivated and skilled to pursue them; essentially all the equipment, materials, and expertise have legitimate application or are available to be found (although they will not all be typically collected in any single place). And we know that enemies exist who are eager to kill in vast quantities. What we are not sure of is why we have not yet suffered

major biological attacks. Maybe not enough of today's terrorists took high school biology. Tomorrow's will - and their high school biology classes will be much more potent than today's. We cannot bet our countries that whatever restraints have kept terrorists from pursuing biological weapons will persist indefinitely. Indeed, it would be very dangerous to assume that the future will look like the past when both terrorist capabilities (in terms of technologies that may become accessible to them) and terrorist intentions are dramatically changing.

Limitations of Intelligence Analysis. But the problem is even worse than that. Even if we had perfect intelligence information about the current state of the bioterror threat - if we knew the intentions of every person seeking to do harm with biological agents, and we knew perfectly exactly what they were capable of - we would not necessarily know how to structure a biodefense program that may take years to develop countermeasures. Said another way, exactly how close terrorist groups are right now to the capability to conduct a major biological attack matters if we want to know how likely it is that such an attack will take place in the near future. However, looking at the several years that our defensive preparations will take to implement, the details of today's threat are less important than the realization that the rapidly increasing capability, market penetration, and geographic dissemination of relevant biotechnical disciplines will inevitably bring weapons capabilities within the reach of those who may wish to use

them for harm. If it takes close to a decade to develop and license a new therapeutic or vaccine, it is not today's threat but the threat a decade from now that we need to counter. And given how much easier it is to pose a threat than to counter one, the threat ten years out may not even materialize until eight or nine years out. So we have a fundamental problem in principle in trying to base today's countermeasures programs on today's intelligence information.

I don't want to sound like I am saying that intelligence is useless - it is critically important that we use every available means to disrupt, interdict, or prevent ongoing efforts to develop and use biological weapons. However, as we look further out into the future, intelligence will be less and less useful as a tool for planning our long-term defense strategy.

Implications for Biodefense. At the same time, given the vast array of possible ways in which bioscience and biotechnology can be used for harm - and the certainty that new science and new technology will further expand those possibilities - we cannot design defenses to counter every possible mode of attack. We have to prioritize our investments. Some initial priorities seem clear - a few specific threat agents, such as anthrax and smallpox, are so dangerous that it is worth developing specific remedies for these, even if all that accomplishes is to bump terrorists into using something else. If they don't use anthrax or smallpox, we've gained a lot. But one can't work down lists

of potential threat agents very far, spending the kind of resources that have been required to develop such "point" solutions, before any conceivable biodefense budget gets exhausted.

In the long run, the only way to match finite resources against a seemingly infinite set of threats and vulnerabilities is to develop a vibrant, flexible, and responsive biodefense system - one that can respond to threats as they materialize. This is a challenging task - we don't necessarily have the basic science and technology in hand that will be necessary for such an approach, let alone the financial commitment, logistical support, and regulatory mechanisms that will also be required. But we will certainly improve our prospects of putting such a system in place if the United States, Europe, and other scientific and technological powers are all able to contribute effectively to the task. And to recap my earlier remarks - it isn't necessary that we all view the threat identically. But unless we both share some common sense of urgency, and have commensurate views on certain elements of how to respond to it, we will find it difficult to make much collective headway.

David R. Franz, DVM Midwest Research Institute

The Evolution of Thought on Biological Defense in the United States

Pre-1990: A back-burner concern

In 1969, the United States unilaterally halted its offensive biological weapons (BW) program. In 1972, it signed the Biological Weapons Convention (BWC). In 1975, it ratified the convention. When President Nixon decided to stop the offensive program, his statement had explicitly directed the continuation of defensive programs against biological threats. In reality, the United States relegated development of BW defenses to relatively low priority. Research on biological weapons detection capabilities essentially stopped detection in the 60s. For much of the period, the United States maintained a small (ca. \$15-20M/yr) medical countermeasures research program housed at the U.S. Army Medical Research Institute for Infectious Diseases or USAMRIID at Ft. Detrick, MD.

Many assumed the ban on biological weapons had eliminated much of the BW threat. Although a suspicious outbreak of inhalational anthrax occurred in the Soviet Union in 1979 and there was concern regarding the possible use of toxin weapons by the Soviets in Cambodia shortly thereafter, we did little to improve our defenses.

Of course, this was a serious mistake. For much of the period until the late 1980s, the United States knew little of the enormous Soviet BW program; a program the Soviets actually scaled up throughout the 80s after they ratified the BWC.

The United States and the Soviet Union continued to openly possess large stocks of offensive chemical weapons (CW) during much of this period. As a result, the United States continued to develop medical and non-medical countermeasures to CW agents. Adding to the low priority place on biodefense, we assumed our passive chemical protective gear - gas masks, protective suits, etc. - would provide adequate protection against the poorly understood biological threat.

This period could be characterized as one of naïveté and intelligence failure.

1990-1998: Only protecting the military on the battlefield

The 1991 Gulf War triggered new interest in chemical and biological weapons defense within the Department of Defense (DoD) - particularly in passive biological defense. Revitalized biodefense efforts mobilized at Edgewood Arsenal, Dugway Proving Ground, and at Fort Detrick. Edgewood and Dugway focused on environmental detection, physical protection and decontamination. Ft. Detrick, primarily through USAMRIID, focused on the developing and testing of vaccines, drugs, and diagnostics.

During this period, the doctrine of nuclear, biological and chemical (NBC) defense was viewed as an interrelated whole. Experts in chemical detection - where we already had significant capabilities to warn troops before concentrations reached toxic levels – were retooled to detect “chem-bio” agents. Drawing largely from the experience of chemical weapons defense, the concept of “detect to warn” sensors and protective clothing were adopted as the likely solution to the “bio” problem as well as CW defense. Seven to eight years of basic research and field testing of sensors and protective scheme produced the realization that “bio” was fundamentally different from “chem.” and “detect to treat” might be the best achievable result for the near term.

In the area of medical countermeasures, the DoD medical tech base developed 10-15 new vaccine candidates, but took them only through pre-clinical testing (most in non-human primates). DoD research efforts also developed vastly improved diagnostics and reference laboratory identification capabilities that included chain of custody and forensics support. These capabilities were exploited extensively during the numerous “anthrax hoaxes” occurring during the late 1990s.

By 1997, the entire US budget for biodefense had reached \$137M. All of that resided within the Department of Defense. The U.S. Centers for Disease Control and Prevention (CDC) was involved peripherally given its public health mission and was

essentially unfunded for biodefense. With its nuclear stockpile mission reduced, the U.S. Department of Energy (DoE) began collaborating with DoD laboratories on biodefense research. DoE personnel was placed in key DoD leadership positions relating to BW defense. The complex of national (DoE) laboratories began contributing its expertise to biodefense research projects.

Some in the international community were suspicious of U.S. intentions related to the increase of our biodefense R&D effort, our continued work with dangerous pathogens and toxins, and our unwillingness to agree to any type of enforcement regime or legally-binding protocol. This “post-Iraq” period was characterized by increased awareness of the battlefield threat and the widely held belief that physical countermeasures were the key to protection of the force. Until 1998, little program activity concern focused on providing civilian biodefenses.

1998-2001: Protecting civilians and seeking public health “buy-in”

As a result of the Sarin gas attack in the Tokyo subway, the bombing of the Murrah Federal Building in Oklahoma City, and the 1993 attempt to topple the World Trade Center, government officials and non-government experts began expressing growing concerns that terrorists would acquire and use weapons of mass destruction. In 1996, pushed by a mandate and funding provided by Congress, the Department of

Defense began the first national program to provide training and equipment to local first responders to improve their ability to respond to terrorism incidents involving the use of weapons of mass destruction.

In the event of an actual terrorism incident in the United States, the Federal Response Plan and other policy documents provided primary responsibility for crisis management (investigation, security, prevention, etc) to the U.S. Department of Justice (DoJ). These same documents and policies assigned primary responsibility for consequence management (decontamination, search and rescue, medical care, site clean up and restoration, etc.) to the Federal Emergency Management Agency (FEMA).

Until the fall of 1998, these domestic prepared efforts reflected the military’s perspective that the response to a chemical incident would be similar to a biological incident. Until this point in time, “bio” was perceived by many to be a new form of “chem” and therefore the response to a bioterrorism incident was largely a public safety response on a HAZMAT response template, not the public health threat that it is. That perception changed gradually as public health experts in and out of government were growing increasingly concerned that preparedness programs failed to understand the nation’s public health system would be the “front line” of defense against bioterrorism. These experts called for increased resources to support public health capacity building, but

the political support for such programs was lacking until President Clinton read Richard Preston’s “The Cobra Event,” a fictional account of domestic bioterrorist activity.

As a result, the U.S. Department of Health and Human Services (HHS) was given approximately ca. \$150M to develop a civilian biodefense capability. These dollars funded laboratory upgrades, education and a fledgling national pharmaceutical stockpile. The increased role of public health in national defense probably resulted from the general change in our appreciation, not of the magnitude of the threat, but the character of the solution.

With the start of a public health-focused civilian biodefense program (several years after the sarin chemical attacks on the Tokyo subway and a string of “anthrax” hoaxes that started in 1997), officials and experts within the Department of Defense were thinking more about biological terrorism in our cities than biological warfare on the battlefield. The DoD’s budget for environmental detection programs and the medical tech base budget doubled in 1998 to approximately \$40-50M annually. However, neither the complexities nor the costs of advanced development of medical countermeasures (vaccines) were well appreciated. Vaccine candidates remained in the tech base and years from licensure by the Food and Drug Administration. The DoD’s actual mission did not have a clearly defined mission during the response to domestic bioterrorism event, and our non-

military security agencies were not focused on biological terrorism defense.

In the international policy arena, the U.S. increased efforts to encourage criminalization of biological weapons development and use and to expand international norms condemning the use of biology for other than legitimate purposes.

During this period, the United States had started to appreciate and understand the nature of the biological terrorism threat against our civilian population, and that the nation's public health infrastructure was an important part of our defenses against this threat.

2001-2004: Serious national preparation

The events of 2001 prompted many new biodefense initiatives within the US, more outside the DoD than within. Following the 'anthrax letters' and the five deaths by resulting from inhalational anthrax, the US Government became serious about preparation for a bioterrorist attack against our population. USAMRIID, having prepared to support forensic identification in the late '90s, processed more samples than any other laboratory immediately post October 2001. DoD experts supported biological defense programs in the Department of Health and Human Services (DHHS) and the Department of Homeland Security (DHS) as they scrambled to ramp up.

The '03 President's budget specifically for biodefense soared to \$5.8B. Of this amount,

the National Institutes of Allergy and Infectious Disease (NIAID) – part of HHS's National Institutes of Health - received \$1.75B for medical countermeasures research and development and vaccine production; a larger percentage funding increase for bioterrorism defense than it had received during the HIV-AIDS pandemic that started in the '80s. Importantly, NIAID harvested the best of the DoD tech base vaccine candidates of the 90s and moved the next generation anthrax and smallpox vaccines into advanced development and production. CDC grants to state and local public health agencies increased substantial to further improve the national public health system. These funds supported hiring and training of additional staff within state and local public health agencies, planning activities, improving physical infrastructure – particularly information technologies, and to develop a national network of Federal, state, and local public health laboratories.

In March of '03, the Department of Homeland Security (DHS) was formed to consolidate Federal anti-terrorism assets and programs — including several biodefense activities — within one department. DoE's laboratory programs, managed by DHS, increased their role in non-medical biological research and development while the DHHS expanded its tech base medical programs, to include construction of high-containment laboratories regionally within academic centers. At the same time, DoD's medical and non-medical tech base budgets for biodefense remained relatively flat.

In the end, the transition from thinking about and preparing to counter a biological TERRORISM threat, vs. a traditional biological WARFARE threat, had been difficult.

2005-Present: Settling in for the longer term

After a rush to harvest real and perceived "low-hanging fruit" the relatively quick and easy capability improvements in the area of civilian biodefense and a boom in the number of bioterrorism 'experts', the nation is beginning to better understand the complexity of the biodefense challenge. As a result, we are refining our approach to protecting our population.

A basic appreciation for the differences between "bio" and "chem" was a huge step forward. It led to our initial awareness of the central role of the public health bioterrorism preparedness and response. But, even with that understanding, we continue to focus on very specific medical countermeasures and relatively simple, but expensive, aerosol sensors in cities to warn of attack. In the post-9/11 surge of biodefense activity and funding, many government officials believed technical muscle alone would provide sufficient protection. Now, we are realizing that more complex and more difficult counter-measures are needed.

In recent months, we have started to "step to the side" to review and chart the way ahead. The core of the problem – biology - has several unique characteristics:

- Potentially extremely small footprints (the weapon and the lab or production facility within which it is produced);
- IOs of suitable agents available in nature thus not 'outlawable';
- Low-tech (or no-tech) is required for use, especially in the case of the contagious agents;
- Vulnerable human, animal and plant populations exist in our free societies;
- Best available medical defenses against potential threats – vaccines - must for the most part be given prophylactically and there may be more behavioral issues than technical because vaccines carry their own, if minimal, risk;
- Regulatory barriers to developing medical countermeasures are significant and cost and many of the products have a relatively short shelf lives;
- Specific intelligence regarding the threat is extremely difficult and the real risk of this low-likelihood but potentially very high-impact event is almost impossible to measure.

As the difficulty of the task sinks in, we are now considering solutions that are 'broad spectrum' in nature. Examples include research on non-specific immune modulators rather than very specific 'one-bug' vaccines and the involving citizen-

teams in response rather than depending on emergency professionals alone. Both of these approaches could move the population bell curve to the right: one regarding its immune status and the other its behavioral response in a health crisis following an incident or introduction of disease. Both are excellent proposals, but not quick or easy fixes.

After an initial rush to technical solutions, there is now more talk of the non-technical: building international understanding and norms regarding the potential abuse of biotechnology, cooperation in deterrence and response, joint education and awareness programs and integration of species-neutral disease surveillance internationally. This evolution in thinking about biodefense is not occurring in the U.S. alone. A number of nations have recognized the unique challenges of the biological threat and the importance of an approach that significantly improves cooperation and coordination between public health and medical, law enforcement and first responder communities at the local, state, federal and international levels.

We are learning several key lessons. The problem of bioterrorism is continually changing and evolving, and is not amenable to simple technical solutions. Preparing specifically for each agent or even each incident is too expensive. The potential for abuse of biology will likely become greater in the future. Finally, protecting our citizens without strong international cooperation in technical and non-technical areas may be impossible.

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Though gaps and complexity exist between European and U.S. on biosecurity and bioterrorism, I strongly suggest that there are a number of areas for potential cooperation and collaboration between the two parties. I tend to think of problems and challenges as “opportunities”.

In my view, whatever we decide to do together in these areas should best be couched under the broader rubric of addressing the challenges of current, emerging and new infectious diseases against human, animal, plant and food targets. There are numerous opportunities for the United States and Europe to work together now and into the foreseeable future. Our common goal must be to provide our citizens and visitors with the best possible array of defenses against infectious diseases and their expression as outbreaks, epidemics or pandemics – regardless of their origin.

Joint pursuits should include focused initiatives in areas including policy development; research, development, testing, and validation programs; common systems for knowledge management, technology transfer, and training; and joint planning and exercises. We should endeavor to make these initiatives as scalable, maneuverable and transportable as possible. The interrelationships and

crossovers between (human) public health, animal and plant health and protection, and food safety with security are obvious and have been addressed by numerous experts over the past several years. In keeping with the charge I have been given, I will address areas of collaboration in science and technology, but of course broader implications will be recognizable.

In this regard, concerted collaboration between the United States and Europe within a productive, structured agenda can produce “grand leaps” in the broader fight against infectious diseases:

- Understanding the basic biology of infectious microorganisms and biotoxins;
- Seeking deep knowledge of pathogenicity, host-pathogen interactions and host response;
- Detecting, characterizing and modeling the disease process;
- Monitoring disease emergence, spread and persistence;
- Understanding biological diversity and its implication to disease;
- Protecting, reversing, mitigating and recovering from exposure or disease;
- Cleaning up and repopulating contaminated environments; and
- Attributing and reconstructing the causes, effects and sources of disease outbreaks.

Scientists, policymakers, and the public are increasingly aware of the extraordinary speed and content of discoveries in the

life sciences and technologies. The ability of the life sciences community to exploit this knowledge is extraordinary and is a permanent feature of our common future. The diversity and magnitude of current and future advancements in the life sciences may potentially provide considerable benefits to health and medicine, increase the resiliency of the human population as a whole, and make the use of infectious disease weapons increasingly obsolete by providing robust protections. Logically, humanity wants to push ahead these entirely legitimate scientific activities in order to these enormous medical, agricultural, and environmental benefits. But, the same science and technology can be used for and contribute to malevolent purposes – namely the misuse of advancements in the life sciences to improve on the use of disease as a weapon.

This forces us to face a “grand challenge:” how to ensure the benefits of advances in the life sciences while containing the potential misuse for these advances for malevolent ends. The United States and Europe need to jointly tackle this complex matrix of the “dual use” of the life sciences with commitment, creativity, and persistence. In my view, Europe and the United States should begin a process of methodically working together on the many dimensions of this problem set: scientific, technological, ethical, moral, legal, political and policy to lead the global community into new constructs and concepts for improving risk anticipation, preparedness, response and management.

I also suggest that we begin this partnership by identifying, agreeing upon, and validating specific areas of mutual concern through a methodical and rigorous approach at the tactical (focused, short-view) and strategic (broad, long-view) levels. This approach would enable us to identify and validate priorities, gaps, needs, challenges, and opportunities. It would also provide the ability to place the results of our joint efforts in the appropriate operational context - against likely, well founded, plausible scenarios - for analysis, planning and training purposes. In short, we have to design and implement a "systems analysis" approach to developing and pursuing a range of joint initiatives to improve our defenses against infectious disease. Such an approach would include:

- Thoughtfully and carefully stating provocative, penetrating questions or problems we both hold in high priority;
- Methodically and rigorously analyzing these questions, problems or scenarios from both the European and U.S. perspectives;
- Identification and validation of shared priorities, gaps, needs and opportunities;
- Conceptualizing and designing joint solutions sets;
- Developing strategies and plans to execute;
- Measuring success and outcomes; and
- Investing in processes for capturing and sharing lessons learned.

Meetings and seminars such as NDA's Bioterrorism Reporting Group are helpful

for a variety of reasons, but they go only so far in developing an agenda for joint action. We must begin to build a process whereby we can persistently work through differences between the United States and Europe, and achieve true collaboration and cooperation on those matters we agree. Systems analysis enables us to address three key questions:

- Where are we now?
- Where do we need to be?
- How are we going to get there, if we are able to?

This approach will provide us with the means to pursue robust, adaptive, and enduring systems solutions to complex and evolving challenges.

There are two specific areas where the United States and Europe can work to "operationalize" mutual collaboration and cooperation. First, we need a system or mechanism for Joint Crisis Response, Coordination, and Management for both natural disease outbreaks and intentional releases of disease. We need to commit to implementing shared human and technological systems that will enable full and rapid coordination and management of the crisis and consequences incidents affecting both sides of the Atlantic. This system requires close communication and collaboration between four key, interdependent communities: public health, agriculture, law enforcement, and intelligence. Our goal should be to create a fully interoperable, organizational

model that applies the capabilities of each community at the right time and measures across the continuum of incident anticipation through recovery. In working jointly, this model requires each of the four to work jointly between communities and across the Atlantic.

This process would lead us to the next area for collaboration and cooperation - achieving Full Readiness. Transatlantic "readiness" flows from our work, and hopefully, successes in developing a system for Joint Crisis Response, Coordination and Management. This area needs a jointly developed and validated set of performance standards in use on both sides of the Atlantic that guides efforts to build capabilities.

We cannot wait for a major or even catastrophic crisis before developing these cross-discipline and trans-Atlantic linkages. Working jointly, we need to be focused and innovative in developing and implementing joint structures, methods, capabilities, pathways, tools and techniques to **before an event fact**, not during or afterwards. A systems approach to planning and preparation would be helpful in forcing us to deal with complexities with which we might not be able to otherwise realize, understand, or contend. It would also allow us to reach true systems solutions rather than personal preferences or temporary point solutions developed "on the fly." It would assist in the creation and validation of standards of performance that would allow us to cut across our political, social,

and cultural systems to achieve the state of operational capability we seek.

In the end, the New Defence Agenda or some other European entity must will step forward and provide the European side of a trans-Atlantic bridge that links the United States and Europe in the development of defenses against infectious diseases and biological weapons. Global health, resiliency, preparedness, and biosecurity can only be achieved through global partnerships.

Dr. Florin N. Paul
Deputy Surgeon General,
Medical Directorate
Ministry of National Defence, Romania

Opportunities For Collaboration & Sharing Of Experience On Biodefence

Nothing is so frightening and terrifying like terrorism and bioterrorism. They are the biggest threats that we have to face in these times.

It is not my intention to focus on the causes that generate the wide range of terrorist attacks. We are very well aware that our tasks are to inform and to prepare our community, to face and to respond properly to the threat.

All figures show us that a community itself cannot react and respond efficiently in the

case of a crisis or accident. We only need to remind ourselves of the picture of the earthquake in Turkey three years ago or the tsunami in December 2004. The fear and pressure that the SARS outbreak posed on the international community in 2003 is more or less the picture of what could happen during a biological crisis.

Could somebody predict how a manmade biological crisis following a bio-attack with modified pathogens would develop?

From my perspective it is almost impossible.

Allow me to consider, from a practical point of view, that a terrorist attack is a crisis that occurs suddenly and unexpectedly, like a technological or natural accident; this approach makes things a little bit smoother than a real attack and probably not so terrifying for ordinary people. We have to keep in mind that panic and fear are the two facts that dramatically change the behaviour of people. This is one of the terrorists' main aims, to disturb the very normal life and reaction of people and their community. This approach is suitable, especially for a biological attack that mimics the natural outbreak. The difference is in the number of sick people at the beginning of the event, and when the pathogen involved is genetically modified, classical treatment and preventive measures are more or less inefficient.

This approach has other benefits, such as better involvement of public health

authorities or negotiations with the private sector of pharmaceutical companies.

There are many discussions on international and regional cooperation in many fields. One of the most important fields, having indeed a very long projection and very long term effects, is protection and countermeasures for bioterrorism. Sometimes the subject is avoided or kept as "confidential". On other occasions, developing countries request the transfer of technology from democratic and developed countries to build their own capabilities for detection and production of specific equipments, vaccines, drugs. In such cases, leaving aside the economical aspects, confidence in partner countries is essential.

From my very personal perspective there are two key elements in prevention and medical response to a bio-crisis: the early detection, ideally real time detection, and stockpile of drugs and vaccines.

The early detection of an attack is an extremely complex process that requires not only high technology but also well educated and trained personnel, good planning, appropriate funding and last but not least, a real network in the area of responsibility.

The other field in which cooperation and partnership must be built is the stockpiling of medicines, medical equipment, vaccines etc.

The issue of stockpiling becomes more complex when there is a common will of

countries to build a regional stockpile. Countries that do not have enough funds to establish their own stockpile may jointly organize a regional one. First of all a regional stockpile must meet the requirements of all involved parties.

Issues that should be considered are:

- the host country;
- customs requirements and transportation, focused on emergency delivery, to avoid any delay;
- agreement on the stockpiled products, regarding each nation's medical and pharmaceutical regulations and common agreements on this issue;
- agreements and regulations about the purchasing and delivery of the products in emergency;
- common consent on who coordinates the activity;
- agreement on financial matters (costs, reimbursements);
- security and safety, maintenance and renewal of the stockpile;
- cultural, linguistic, religious, legal and other matters that may affect the efficiency of such an attempt.

Bearing in mind the experience that the USA has in the field of stockpiling, it would be very useful to develop projects for different regions of Europe in this respect.

In conclusion, there are no doubts that collective efforts and regional and international cooperation are the

cornerstones of an efficient, protective and countermeasure-focused policy against biological terrorism and terrorism itself.

Frank Rapoport
Christopher C. Bouquet
Scott Flukinger⁴⁴

The Project Bioshield Act of 2004: Lessons learned for Europe

Weeks after the 9-11 attacks in the U.S., a still-unknown perpetrator mailed weapons-grade anthrax to Congressional offices in Washington, D.C., and to several media outlets on the U.S. East Coast. Five people died and seventeen others became gravely ill. The event exposed the inadequacy of America's public health system to respond to a man-made epidemic, particularly one involving agents of such lethality as anthrax. As one expert testified to a Senate committee after the attacks, "We must understand that public health is now an essential aspect of national security."⁴⁵

Following the anthrax attacks, the government undertook intensive new

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⁴⁵ Terrorism Through the Mail: Protecting Postal Workers and the Public, United States Senate, joint hearing before the Comm. on Governmental Affairs and the Subcomm. on Int'l Security, Proliferation & Fed. Services, 107th Cong. (2001) (Testimony of Tara O'Toole, MD.) available at <http://govt-aff.senate.gov/103101otoole.htm> (Last visited March 4, 2005)

efforts to counter the bioterrorism threat. Indeed, between 2001 and the end of 2004, federally-funded civilian biodefense programs in the U.S. totaled nearly US \$14.5 billion.⁴⁶ In Fiscal Year (“FY”) 2005 alone, America is expected to spend approximately US \$7.6 billion on biodefense programs.⁴⁷ During his 2003 State of the Union Address, President Bush first proposed that Congress enact legislation to stimulate the development of countermeasures to protect against bioterrorism. In response to this call, the Senate passed its version of The Project BioShield Act of 2004 (“BioShield” or the “Act”) on May 19, 2004, and the House likewise adopted the Senate’s bill on July 15, 2004. The President signed the bill into law on July 21, 2004.

The Act has an ambitious policy goal: to create a new biodefense industry to expeditiously develop and produce medical countermeasures and related products and services to secure the U.S. homeland against bioterrorism. Specifically, the Act amends the Public Health Service Act⁴⁸ to create five tools for promoting commercial involvement in biodefense:

- I. it provides the Secretary of the Department of Health and Human Services (“HHS”) with **streamlined authorities to promote the research and development**

of drugs and other products needed to protect Americans in the event of a bioterrorist attack;⁴⁹

2. provides for “**calls**” for **development of specific countermeasures** that include a commitment that the Secretary of HHS will recommend to the President funding of procurement upon first development of a countermeasure that meets certain criteria;⁵⁰
3. authorizes the procurement of countermeasures for the nation’s stockpile using the **Special Reserve Fund**;⁵¹
4. provides that in the event of a national emergency, the government is authorized to **make available new and promising treatments prior to approval** by the Food and Drug Administration (“FDA”);⁵² and, finally,
5. provides for streamlined and **simplified acquisition procedures** for the procurement of countermeasures for select bioterror agents, like smallpox, anthrax and plague.⁵³

While BioShield was an important step in the creation of a new biodefense industry, industry reaction to the Act has been muted, partly because the government has not taken full advantage of its new legal authorities and partly because the scope and incentives of BioShield are somewhat limited. BioShield is limited in two respects.

First, BioShield limits the use of the Special Reserve Fund to the purchase of drugs, biological products and medical devices applicable to treating a limited range of potential terror agents, including biological, chemical, nuclear and radiological agents. Second, the provisions of BioShield under which the government may commit to recommend funding for successfully developed countermeasures provided only a limited incentive to companies to enter the biodefense market. These provisions merely indicate that in the future the government may provide more assurances to industry of a market for countermeasures than government has provided in the past.

New biodefense legislation now under consideration by the 109th Congress seeks to address these industry concerns. This legislation would broaden the definition of countermeasures that may be procured with the Special Reserve Fund to include detection technology, diagnostics and research tools. In addition, the countermeasures may also be used to counter public health threats posed by naturally occurring infectious disease, such as the pandemic flu. Moreover, the legislation under discussion would provide powerful tax and patent incentives to companies seeking to enter the biodefense industry. Finally, the legislation would also offer liability protections to the biodefense industry. This issue was not addressed in the BioShield debates and, currently, federal law only provides limited protections for developers of countermeasures for

biodefense in the event of an actual terrorist attack.⁵⁴

BioShield is notable both for the uniqueness of the challenge they attempt to address and for its ambitious scope. The initiative created an opportunity for Congress, the legal community, agency program managers and the industry to apply innovations in U.S. government contracts law practice to an entirely new sector. However, initial implementation of BioShield has raised some questions about the government’s commitment to create this sector, necessitating a new round of legislative initiative. The “lesson learned” for Europe is: “get it right the first time”. Rather than taking a piecemeal approach to promoting the development of countermeasures to bioterrorism, Europe should act boldly.

46 Ari Schuler, *Billions for Biodefense: Federal Agency Biodefense Funding, FY2001-FY2005*, Vol. 2, No. 2, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science, p.86 (2004) [hereinafter, Schuler]. See, <http://www.liebertonline.com/doi/pdf/10.1089/153871304323146388> (Last visited March 4, 2005)

47 Id.

48 42 U.S.C. § 243 et. seq.

49 See *Id.* § 319F-1.

50 See *Id.* § 319F-2(c)(4).

51 See *Id.* § 319F-2(c)(7).

52 21 U.S.C. § 360bbb-3.

53 42 U.S.C. § 319F-2

54 Publ. Law No. 107-296, § 862.

Future programmes of the NDA Bioterrorism Reporting Group

October 2005

Critical Infrastructure Protection and Intelligence: Is European bioterrorism preparedness up to par?

Are national governments ready to defend critical infrastructure and is a European level approach necessary?

Collecting and sharing data that provide an understanding of the operating status of critical infrastructure, key assets, and major events will allow for the detection of anomalous changes in operations and activities. Evaluating critical infrastructure protection provides an understanding of potential targets of terrorist activities to allow better interpretation of data that may point to terrorist targeting of critical infrastructure, key assets, and major events. Is a net centric approach to critical infrastructure protection viable during a deliberate disease outbreak? Do we need to streamline the current data sharing systems to better track criminals and terrorists who may divert or acquire Category A biological warfare agents? The session looks at SIS Plus and its limitations. Which areas are the most crucial and the most vulnerable during a biological attack?

- Civil military approaches to the threat of catastrophic unconventional weapons: what interactions and deviations?
- Which states pose the greatest threat for unconventional weapons deployment and how can we defend against this?
- Are EU policies in place to prevent critical infrastructure failure?
- How do we target and prevent states from sponsoring unconventional weapons?
- Are there losses in integration?
- What policies do we need to ensure infrastructure protection during a major bio-terror event?
- How well integrated are our resources and capabilities?

C4I: What advantage does integrated intelligence policy and technology procurement in today's market have on interdicting bio-terrorism or bio-warfare?

As the European Union continues to strengthen its security and defence position, intelligence capability plays a critical role in defending against WMD and more specifically biological weapons diversion, acquisition and procurement by terrorists and states. Changes in European operational and strategic initiatives such as post-war engagement in Iraq and Afghanistan will necessitate the need for an increased and consolidated intelligence capability. The seeming failure of the US intelligence community to accurately assess Iraq's biological weapons programmes highlights the increasing need for Europe to increase and integrate its intelligence capabilities to independently assess the threat of biological terrorism. Europe's lagging investment in procurement leave it vulnerable for sensitive tasking and operational engagement of forces, what must be done now to prepare for fourth generation warfare and asymmetric bio-terrorism? How can the EU develop the technical and skill base to ensure European security both within the EU and abroad?

- What role should European C4I capabilities play in preventing and detecting potential acts of bio-terrorism or warfare?
- Civilian versus Military Intelligence tasking is there common ground for bio-defence?
- Identification of challenges facing the European C4I industry;
- How has preparing for net-centric warfare altered the European C4I markets and what effect is this likely to have on bio-defence?

January/February 2006

The Biological and Toxin Weapons Convention at a Crossroads: Principles, Policy and the Future of Enforcement

The BTWC was the first disarmament treaty to ban an entire class of weapons in both peacetime and during the engagement of war. This meeting will address Verification (Past, Present and Future), and outline critical issues on the 2006 agenda. Heads of European delegations to the Convention will be invited to attend. Rapid advancements in the life sciences merit caution over novel security threats which might arise from biological

research, how openly should results be communicated? Are some basic research projects too 'contentious' to pursue? NDA will debate the principles, practicality and potential for implementation of a universal code of conduct and make recommendations to all key stakeholders.

Bioterrorism and to a wider extent CBRN terrorism also involves a number of other essential communities: public health, science, academia, industry, organizations and security agencies. Given the national security and non-proliferation regimes which are often in conflict, which institutions are better placed to make hard-line calls and develop security policy? Is the NGO community, not having access to intelligence information, capable of making informed 'decisions' on bio-defence? Are there appropriate mechanisms for essential exchanges of information? Who should set security policy on biological and unconventional weapons regimes? Is there a problem with governmental transparency? Is the non-proliferation agenda and arms control defined by national players or NGOs?

April 2006

WARGAME scenario: BLUE MERCURY

The NDA is developing a table top war game exercise for the European Communities. Blue Mercury will highlight the impact of unconventional weapons proliferation and the likely effect of a bio-terrorist attack on the European Community. A biological agent located in an unstable region outside Europe has been transferred into Europe by plane and European leaders are faced with coordinating responses to an outbreak within the EU while contributing to a more global effort to resolve the arisen crisis abroad.

Drawing on NDA's pool of experts in the field, it is anticipated high-level officials will play the part of national leaders. The game is designed to emphasize the European role in prevention and response to unconventional weapons use and to gain wider understanding of the need to strengthen the prohibition against the use of disease as a weapon of mass destruction by state parties. This scenario would be positioned as a day-long event.

About the New Defence Agenda (NDA)

At the suggestion of NATO's Jamie Shea, Deputy Assistant Secretary General for External Relations, Public Diplomacy Division, Forum Europe established the New Defence Agenda in early 2002 to provide a common meeting ground for defence and security specialists from NATO and the EU that would meet on a regular basis.



Now the only Brussels-based platform for debate devoted solely to defence and security issues, NDA's International Conferences, Press Dinners and Monthly Roundtables bring top EU and NATO officials together with senior figures from governments, defence industries, the military, academia and press. The NDA also serves as a networking centre of defence-related think tanks and experts around Europe.

The aim of the NDA is not to replicate more academic research-based projects but to give greater prominence to the complex questions of how the EU and NATO policies can complement one another, and to stimulate reaction within the international press.

One of our prime objectives is to raise the profile of defence and security issues among the Brussels-based international press. To encourage more in-depth coverage of these topics, the NDA holds regular, informal dinners for journalists.

The NDA's Advisory Board is made of some 20 prominent defence experts drawn from a cross-section of government, politics and industry and is patroned by Jaap de Hoop Scheffer, Javier Solana, Benita Ferrero-Waldner and Franco Frattini.

The CBACI Commitment



Since 1993, the Chemical and Biological Arms Control Institute (CBACI) has worked to address 21st century security challenges, with a special but not exclusive focus on the elimination of chemical and biological weapons. A nonprofit, private policy research organization, CBACI fosters its mission through an innovative program of research, analysis, technical support, and education. Within its global network of policy makers in government, industry, the scientific community, the media, and other critical constituencies, CBACI provides a unique strategic perspective and effective policy options on contemporary security challenges

Ahead of its time...CBACI has

- Identified chemical and biological terrorism as an emerging threat – even before the attack in the Tokyo subway in 1995
- Sponsored the first major conference on CBW terrorism in Washington
- Launched its Health and Security Program well before HIV/AIDS was identified as a national security challenge

Leading-edge...CBACI has

- Conducted one of the first studies of U.S. preparedness for a domestic bio-terrorist attack based on an innovative threat assessment methodology and requirements based analysis
- Promoted a new “intellectual infrastructure” to address the biological challenge, including novel conceptual building blocks and analytical tools
- Advocated new partnerships among critical constituencies, not least of which is the sustained engagement of the life sciences industries in addressing emerging challenges

Global in scope and operation...CBACI has

- Created a 27-member International Research Advisory Council with experts from around the world
- Sponsored or participated in activities in more than two dozen countries, including Australia, Belgium, Canada, Germany, Hungary, Israel, Japan, Kuwait, Malaysia, and Singapore.

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The New Defence Agenda would like to thank its partners and members for their support in making the NDA a success



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FOLLOWING THE INTEREST GENERATED IN PAST NDA EVENTS AND THE ENCOURAGEMENT OF THEIR PARTICIPANTS, THE NDA DECIDED TO CREATE A VENUE FOR MORE FOCUSED DISCUSSIONS ON THE AREA OF BIOTERRORISM. THE BIOTERRORISM REPORTING GROUP WILL ALLOW THE DISCUSSIONS NOT ONLY TO BE TAILORED TO THE EVOLVING DEVELOPMENTS IN THE BIOLOGICAL FIELD BUT MOST OF ALL, THE RESULTING REPORT WILL ACT AS A CATALYST FOR THE POLITICAL WORLD.

There is no question of the need for policies directly focused against the use of biological agents as weapons. The use of disease as a weapon of mass destruction (WMD) is considered a low probability, high consequence event. However, if such an event were to occur, the consequences would be so severe that preparatory action must be undertaken to prevent it. Although biological weapons are often grouped together as agents of mass destruction, biological weapons vary significantly from chemical and nuclear munitions. Biological weapons and materials have the capacity to silently infect thousands of people, destroy agriculture and infect animal populations.

Of all the classes of WMDs, biological weapons remain the most vulnerable to diversion while also being the most difficult to detect. Unlike the Chemical Weapons Convention and the nuclear Non-Proliferation Treaty, which have full verification regimes, the Biological and Toxin Weapons Convention does not. This leaves the development and potential use of bio-agents entirely unchecked. It is therefore imperative governments begin to address the serious threat biological terrorism poses to the EU and the international community.

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