Rathenau Instituut

Implementing biosecurity in (bio-)scientific research in the Netherlands

POLICY BRIEF November 2011

Dirk Stemerding, Keelie Murdock, Barend van der Meulen, Frans Brom

Published at the "Think Zone" website of the United Nations Office at Geneva for the Seventh BWC Review Conference: http://www.unog.ch/bwc/thinkzone

In December of this year, the Seventh Review Conference of the Biological Weapons Convention (BWC) will take place in Geneva, under Dutch Presidency. One of the important aims of the Review Conference is to consider policies of implementation of the BWC by the States Parties. In this policy brief we discuss major challenges for Dutch policy making focusing on the implementation of biosecurity in (bio)scientific research.

- The first challenge is to find a balance between a biosecurity regime of statutory control and scientific self-regulation. It is often assumed that this challenge may be overcome by embedding biosecurity in the established biosafety regime in the life sciences. However, we conclude that implementation of biosecurity in the framework of the current biosafety regime cannot be taken for granted and will only be possible on the basis of dedicated policy-making which takes into account important differences and tensions between biosecurity and biosafety.

- The second challenge is to keep a balance between rapid and potentially disruptive developments in the life sciences and the need for a robust and trustworthy regulatory system. Developments in the field of synthetic biology have to be considered as a major challenge in this respect. In the light of these developments, we conclude that Dutch biosecurity policy making is hampered by a lack of institutional capacity and responsibility for the monitoring and assessment of the biosecurity implications of new science and technology.

Securitisation of the life sciences

In the recent past we have seen a shift in focus of international BWC policies from threats posed by state actors to threats presented by non-state actors and bio-terrorism. Given growing concerns about potential misuse of biological knowledge for terrorist purposes, the life sciences are increasingly being considered in security terms. This also resulted in initiatives from the BWC States Parties to stimulate awareness raising among scientists of biosecurity issues. The 'securitisation' of the life sciences is not only connected with the events of 9/11 and related terrorist attacks, but also with the increasing global penetration of society by biotechnology. Biological knowledge, tools and resources are becoming more and more widely available around the world. In this context, security concerns have been raised by the recent emergence of synthetic biology. As a science which promises to make biology easier to engineer, synthetic biology may extend the availability of tools to an ever-greater number of individuals, including those who may have malicious intents.

Against this background, the Rathenau Instituut organised a workshop in October 2010, hosting a select group of Dutch scientists and biosafety and security officers and two internationally renowned biosecurity experts. The discussion in this workshop was organised around two questions:

- How does the rise of new biosecurity concerns affect the science system?
- How does the rise of synthetic biology as a new science of life affect biosecurity?

Based on the workshop discussions, relevant literature, and interviews with a number of Dutch scientists and biosafety and security officers, we highlight in this policy brief some of the major challenges for policies of implementation of biosecurity in (bio-)scientific research in the Netherlands.

Biosecurity and the (Dutch) science system

Implementation of biosecurity in the science system may be seen as requiring an integral 'web of prevention', which combines a top-down approach of statutory control with a bottom-up approach, based on community engagement. These two approaches, however, are shaped by 'regimes' which to some extent are at odds with each other. On the one hand, an (inter)national biosecurity regime involving laws and government regulations and, on the other hand, a scientific regime based on self-regulation.

A national biosecurity regime

In the context of international developments, a biosecurity regime has taken shape in the Netherlands in a comprehensive network, including various ministries, public health organisations, municipalities, research institutes and emergency services. The National Coordinator for Counter-Terrorism and Security (NCTV) is at the centre of this structure. Building on the European CBRN Action Plan, the NCTV fosters a culture of security. In the field of the life sciences it supports the development of biosecurity measures and mechanisms to prevent unauthorized access to high-risk laboratories and biological agents and to protect society against biological and bioterrorist incidents. However, the foundation and framework for biosecurity policy making are still in a developmental stage. With the intention to strengthen the Dutch biosecurity regime, the National Institute for Public health and the Environment (RIVM) has developed a comprehensive overview of biosecurity implementations and has devised a framework for organising and structuring biosecurity in the Netherlands.

A regime of scientific self-regulation

To encourage scientists to consider the potential biosecurity implications of their work the scientific community has been incited to develop codes of conduct as a non-legislative form of voluntary control. In 2007 the Netherlands Dutch Royal Academy of Arts and Sciences (KNAW) released one of the first national Codes of Conduct for Biosecurity in response to recommendations from meetings of States Parties and experts preceding the Sixth BWC Review Conference in 2006. The main objective of the Code is to raise awareness about the possibility of misuse in the life sciences and the threat of bioterrorism and to provide a set of basic principles to guide scientists in their daily activities. Rules of conduct provided by the Code include biosecurity education, research and publication policy, and accountability and oversight. Governmental funding agencies agreed to request all persons submitting a grant proposal to refer to the KNAW Code of Conduct. Although the Code has been brought to the attention of the scientific community, the KNAW no longer actively promotes its implementation and it is not clear to what extent it has brought awareness of biosecurity.

Need to overcome tensions between the two regimes

Some clear tensions can be noted between the approaches characterising both regimes. In the bio-security regime notions of secrecy and containment are an important starting point, whereas scientific self-regulation is based on the idea of maximal openness and information-sharing. Lack of awareness is the main problem from the control perspective of bio-security, while limits to academic freedom are looming large from the community perspective of self-regulation.

Both regimes however need each other. There is a general consensus that the pervasive nature of biotechnology in our society profoundly complicates any efforts to control the technology and its proliferation. Instead of only trying to control and deny access through an international arms control regime, the focus of making biology secure has to be shifted towards developing a shared responsibility, as is indicated by the notion of a 'web of prevention'. On the other hand, without sustained efforts of awareness raising, promotion of good practices, and provision of regulatory advice and oversight based on national and international rules, a regime of self-regulation may be fleeting (as the lack of continual active support for the Dutch Code of Conduct demonstrates).

The main challenge of strengthening a biosecurity culture in the science system is to find a balance between regulatory control and scientific autonomy. This challenge highlights the need for 'bridge-builders' who may facilitate the delicate task of balancing both regimes.

Biosafety regime as a bridge?
In the life sciences, biosafety is covered by a firmly established regime, based on statutory regulations for the management of GMO's. This regime is supported, nationally and internationally, by a network of Biological Safety Officers (BSO's). In the Netherlands, this network is coordinated by a national (BVF Society) platform, which promotes and facilitates the implementation of biosafety rules and regulations by providing expertise and support. BSO's are appointed in research institutions by the government with the responsibility for maintaining biosafety and in this quality they work closely together with research project leaders at the shop floor. BSO's are also a liaison between the scientific institute and the government inspectorates which monitor observance to various regulations.

Biosafety is generally considered as intrinsically related to biosecurity, or even the cornerstone of an effective implementation of biosecurity policies. The implication is that BSO's, as liaison between government and shop floor, are the obvious bridge-builders in strengthening a biosecurity culture. However, in several respects, biosafety and biosecurity remain crucially different concerns:

- Managing the risks of unintentional accidents on the one hand, and risks of intentional misuse on the other, implies different attitudes and approaches in terms of trust versus distrust, openness versus secrecy.
- Addressing biosafety concerns – 'keeping bad bugs from people' – is in the interest of researchers, while biosecurity approaches of containment – 'keeping bad people from bugs' – may limit researcher's freedom to operate.
- Biosafety concerns are relevant here and now, whereas biosecurity issues are future-oriented risks.

In the light of these differences and tensions, we conclude that implementation of biosecurity in the framework of the current biosafety regime cannot be taken for granted and will only be possible on the basis of dedicated policy-making which takes these tensions into account.

Biosecurity implications of synthetic biology

Synthetic Biology (SynBio) is an emerging area of scientific research that promises to greatly enhance the capacity of scientists (and possibly even hobbyists) to design and engineer new forms of life. It combines methods and materials from different disciplines – including biology, chemistry, physics, information science and engineering – to synthesise biological parts and build new systems or to use these parts for the redesign of existing biological systems.

One of the stated aims of SynBio is to make biology easier to engineer, that is, to make biotechnology more reliable, cheaper and faster by the use of standardised parts and the automation of skills.

Whether SynBio will achieve this aim remains to be seen, but its potential to lower the level of skills necessary to acquire or synthesise a biological agent has raised concerns about new biosecurity risks. SynBio has thus become a matter of significant interest at the BWC and States Parties are being encouraged to consider the potential security threats of SynBio within the framework of biosecurity.

Potential of SynBio to undermine the current biosecurity regime
Different strands of SynBio may have different kinds of security implications that will become relevant at different points on a future time-scale. The potential security implications of synthetic genomics – using synthetic DNA – are generally considered of most immediate concern. Synthetic viruses have already been produced in the laboratory and, given the rate at which DNA synthesis is progressing, relatively easy synthesis of some viruses is likely to be achievable within the next 5 to 10 years. In the current biosecurity regime known pathogens may be placed under strict legal and physical controls as 'select agents'. One potential misuse of SynBio would be to recreate known pathogens from available sequence information in public databases as a means to circumvent established access controls to select agents.

The (future) potential of SynBio to (re)create pathogenic agents from biological parts that as such are non-hazardous, also exposes the limitations inherent in any agent-specific threat list. The emergence of SynBio thus challenges the controls of the current biosecurity regime, creating the need for transition from an organism-centric view on biosecurity to a sequence- or gene-centric view.

New actors are likely to gain the ability of engineering life
SynBio proves attractive to researchers from a diversity of disciplines, ranging from biology, engineering, computer science to physics and mathematics. It is also a source of inspiration for an amateur – do-it-your-self – biology movement, emerging on the margins of modern biotechnology outside traditional institutional settings. Many of these new actors will lack formal education in or an awareness of biosafety and biosecurity standards and problems. SynBio thus creates the need for oversight which extends beyond the boundaries of current biosafety and biosecurity regimes.

Organising institutional preparedness
SynBio not only raises new biosecurity concerns, but also challenges the basis and scope of the current biosecurity regime. The main challenge for biosecurity policy making, internationally and in the Netherlands, is to keep a balance between a rapidly evolving and potentially disruptive science and the need for a robust and trustworthy regulatory system. To face this challenge there is a need for pro-active and reflexive practices of 'regulatory learning', focusing the analysis of biosecurity on future challenges arising from overall research trends and trajectories, rather than individual projects. Such practices call for institutional arrangements bringing together a diverse set of expertise, based on a statutory responsibility to foster institutional preparedness for new developments in science and technology and its implications for biosecurity governance.

In the Netherlands, the Commission for Genetic Modification (COGEM) has been formally assigned such a role, but only in the framework of the current GMO biosafety regime. The COGEM is not in the position to address in its advisory work issues of biosecurity. Organising institutional preparedness with regard to the biosecurity implications of new science and technology thus remains an important challenge for Dutch policy making.

Sources

The following sources have been particularly helpful in preparing this policy brief:

- UNICRI (UN Interregional Crime and Justice Research Institute) 2011, Security Implications of Synthetic Biology and Nanobiotechnology. A Risk and Response Assessment of Advances in Biotechnology. Preliminary Version (http://igem.org/wiki/images/e/ec/UNICRI-synNanobio-final-2-public.pdf)

- Seumas Miller, Michael J. Selgelid & Koos van der Bruggen 2011, Report on Biosecurity and Dual Use Research. A Report for the Dutch Research Council, 3TU Centre for Ethics and Technology (http://www.brad.ac.uk/bioethics/media/ssis/documents/Miller+et+al+-+Report+on+Biosecurity+and+Dual+Use+Research.pdf)

- Workshop Report Biosecurity at the Science-Policy Nexus: Developing a Vision for the Future, Rathenau Instituut 2010 (http://www.rathenau.nl/publicaties/biosecurity-at-the-science-policy-nexus-developing-a-vision-for-the-future.html)