Safeguarding advances in the life sciences

The International Council for the Life Sciences is committed to becoming the authoritative source for identifying and managing biological risks

Terence Taylor

Enhancing public health and safety against biological threats arising from natural or man-made causes is an overwhelming challenge for traditional governance structures. The rapid advances in the life sciences—although clearly bringing enormous benefits to public health—similarly raise concerns among governments, scientists and the public about potential risks and abuse. As seen in the 2003 SARS outbreak, increased transnational activities in trading, tourism and, in particular, air travel now allow infectious diseases to spread around the world in days. Ethical limits, owing to advances in such areas as genomics and stem-cell research, are perceived to be under pressure. Similarly, security experts find it difficult to assess the potential implications of biological research, be it deliberate misuse by terrorists and government-run weapons programmes or a lack of awareness by individual scientists.

What is needed is an international and multidisciplinary effort to assess in full the risks involved and to identify methods to manage biological risks effectively. Communicating the results of risk assessment in a balanced and objective way is of equal importance, to ensure that public confidence in science is not undermined, and that sensible and practical regulations

are developed and implemented where needed. Moreover, such an effort must be conducted at an international level with active participation—if not leadership—from the scientific community. The International Council for the Life Sciences (ICLS; Washington, DC, USA) was created specifically to help achieve this objective.

The full spectrum of biological risks, ranging from emerging infectious disease to premeditated misuse, represents an urgent and global challenge for governments and intergovernmental organizations (Fig 1). Life-science research and its commercial exploitation are essentially international in nature. They bring important benefits to medicine, public health, the food industry, agriculture and industrial processes; at the same time, potential risks to public safety and security from deliberate misuse or negligence are not adequately addressed nationally or internationally. To realize the full humanitarian and economic benefits from the advances in the life sciences, it is essential that these risks are properly identified, understood and effectively managed.

However, governments are struggling with the policy, regulatory and security implications of life-science research and its application. The extraordinarily

...security experts find it difficult to assess the potential implications of biological research...

protracted—and ultimately unsuccessful—attempt to negotiate a verification system for the Biological and Toxin Weapons Convention (BTWC) is but one example of the difficulties of intergovernmental action. Even when negotiations eventually result in an agreement, the process itself can take so long that political events, let alone scientific and technical progress, have moved on to such an extent that many of the agreement's most important and valuable elements are outdated or overtaken.

It should be noted, however, that despite the failure to reach an agreement, many viewed the annual meetings after the Fifth Review Conference of the BTWC in 2001 as useful. Several meetings brought together experts on specific topics, such as epidemiological surveillance, codes of conduct or national legislation, and attracted representatives from the life-sciences community who had been reluctant to enter the debate. Another benefit came to government officials working on the many facets of this challenge—public

Fig 1 | Spectrum of biological risks

EXTRACT FROM THE ICLS CHARTER

For the full Charter, see www.iclscharter.org.

Extraordinary advances in the life sciences and their applications have brought enormous benefits to public health, medicine, agriculture and industrial processes. It is essential that the full humanitarian and economic benefits from these advances continue to be realized. To do so, it is vital to develop a global mechanism that can act as an authoritative source of objective consideration and analysis of the benefits of these advances and related risks. It is especially important that any such risks be first identified, understood and effectively addressed. Any effort to do so must be international in nature and led by the life-science community, including private industry, academia and other non-governmental institutions.

The speed of current developments in the life sciences often surpasses national and international governmental efforts to put in place legal and regulatory policy. Often, the lack of international uniformity in the evaluation of these risks impedes the development of beneficial scientific advances. As the life-science community is at the leading edge of these developments and their dissemination worldwide, it is well-placed to assist governments and the public by contributing directly to the international effort to deal effectively with the global identification and management of biological risks to public health, safety and security.

To promote this necessary culture of responsibility in the life-science community, its leaders from around the world have agreed to create an international entity called the International Council for the Life Sciences (ICLS).

THE CHARTER

An International Council for the Life Sciences ("the Council") is hereby established that will:

- Create a self-sustaining global organization for the life-science community to contribute to improved quality of life and enhanced public safety and security;
- Promote engagement of the life-science community worldwide on issues of public safety and security;
- Facilitate effective partnerships between the

various elements of the life-science community, including private industry, academia and government; and

- Serve as an authoritative source of objective consideration and analysis of global biological risks in relation to advances in the life sciences and their application.

Mission

The mission of the Council is to help ensure global public health, safety and security by safeguarding the opportunities offered by advances in the life sciences and their application through the promotion of best practices, standards and codes of conduct.

What the Council will do

To accomplish this mission, the Council will facilitate essential and timely contributions to national and international policy development through a cooperative effort to reduce biological risks through their identification and management by:

- Proactively engaging industry, academia, governments and the public to enable accurate communication and understanding of the benefits and biological risks arising from advances in the life sciences;
- Operating as an independent organization designed to cooperate closely with national governments, international inter-governmental organizations, academia, private companies and non-governmental organizations; and
- Promoting the widest possible membership among the life-science community.

Membership

Membership of the Council is open to private entities and academic institutions participating in the life sciences that will fulfil their obligations in accordance with the mission of the Council. Members should develop the means of implementing the Charter in their own organization in accordance with local laws and regulations.

CHARTER COMMITMENTS

To promote the mission of the Council, members undertake to:

International and National Laws and Regulations

Observe, promote and cooperate to help develop effective national and international

laws, regulations, and policies in relation to the life sciences in support of the mission of the Council.

Personnel

Exercise the highest standards in the recruitment, training and management of personnel during and after employment, with special attention to those individuals with access to information, materials and technology that could have significant adverse effects on public health, safety and security if misused or not employed safely and appropriately. Members of the Council will be expected to have a code of conduct for their staff to promote the objectives of the Charter.

Information

Ensure the security of information by observing relevant international and national laws and regulations in handling information, which could have a significant negative impact on public health, safety and security; and also to contribute to developing, in cooperation with governments, effective and responsible procedures for the release of such information into the public domain.

Safe and Secure Operation of Facilities

Observe the highest possible standards for the safe and secure operation of all facilities, including materials in transit, in the interest of public health and environmental safety; and to contribute to the development of more effective international and national laws, regulations, guidelines, policies and standards in this regard.

Governance of Research and Development Activities

Take full account of public health, safety and security considerations when planning and conducting research and development activities and to support and contribute to effective and responsible international and national entities engaged in developing and promoting codes of conduct in this regard.

Risk Evaluation and Mitigation

Facilitate the development of measures to evaluate and mitigate the risks arising from the misuse of the life sciences and cooperate to support an international response in cases of major natural biological outbreaks.

health, defence, security, basic research and development—as these meetings allowed them to communicate with their colleagues in foreign governments. In essence, the meetings provided a forum for interested parties to convene regularly to debate topics of interest. That said, the effectiveness of traditional governance structures to counter the threat posed by

biological weapons without direct input from the life-sciences community will no doubt be limited.

The BTWC is not the only multilateral forum focusing on biological risks. The World Health Assembly and the UN Security Council have passed resolutions directly relevant to reducing biological risks, namely those related to the misuse of

the life sciences from both a safety and a security point of view. Preventing the deliberate misuse of the life sciences by terrorists and promoting good biosafety practices make major contributions towards enhancing global biological safety and security. Efforts must be made to ensure coordination and collaboration on an international basis between the

communities concerned with biosafety and those interested in preventing the deliberate misuse of the life sciences. This will enable nations to address the full spectrum of biological risks and to ensure the best use of resources.

Thus, new partnerships and fresh ideas are essential for addressing biological risks on a global basis. Although governments and multilateral treaties will continue to be necessary and important, there is a need for leadership from the private and academic sectors of the life sciences in order to identify and manage biological risks, whatever their origin. Furthermore, a private organization is needed to generate an effective transnational network of organizations from the different sectors of the life-sciences community concerned with biological risks. To fulfil this role, the ICLS was created as a non-governmental membership organization on the basis of a charter that focuses on critical areas of concern for organizations and government agencies operating in the life sciences (see sidebar). Its aims include, in particular, international and national laws and regulations; personnel and information policies; safe and secure operation of research facilities; governance of research and development activities; and risk evaluation and mitigation.

... to realize the full humanitarian and economic benefits from the advances in the life sciences, it is essential that ... risks are properly identified, understood and effectively managed

A key element in enhancing global biological safety and security is the promotion of best standards and practices in the conduct of research and development activities and in the operations of life-science facilities and laboratories. The ICLS thus provides a much-needed forum to engage organizations and individuals from the governmental, academic and private industry sectors of the international life-sciences community. ICLS members and the ICLS

Senior Advisory Panel—a group of international scientific, technical and policy experts that guide the ICLS—provide input on the organization's activities.

The ICLS has already identified several international biosafety and biosecurity issues and is acting in areas where it believes there is a good prospect of producing tangible results. It is now forming an International Advisory Committee, consisting of its Senior Advisory Panel and outside advisors, to build on the World Health Organization's biosafety and biosecurity guidelines for containment facilities. An equally important task is to develop a biological safety and security training programme for scientists, business executives and policy-makers. Another key issue is a global biological risk assessment, to be presented in 2007. This assessment, on the basis of the advances in the life sciences and the implications for public health, safety and security, will be carried out annually to contribute to the ICLS plan of action for the following year. The results will be published and made available to governments and others responsible for biological safety and security.

The ICLS began as a collaborative project between two research institutes: the International Institute for Strategic Studies—US (IISS—US; Washington, DC, USA) and the former Chemical and Biological Arms Control Institute (CBACI; Washington, DC, USA). The project, which initially explored safeguarding future

advances in the life sciences and managing risks from the perspectives of the biotechnology and pharmaceutical industries, eventually expanded to include all sectors of the life sciences. The IISS global network, which includes world leaders, business executives, academics and policy-makers, proved to be an excellent resource in engaging the global community on biological risks.

From 2002 to 2005, IISS—US and CBACI staff met with hundreds of representatives from academia, government, industry, non-governmental organizations and intergovernmental organizations to discuss safety and security topics related to the life sciences and the roles of each sector in dealing with these issues. The ICLS Charter was developed from these interactions.

... there is a need for leadership from the private and academic sectors of the life sciences to identify and manage biological risks, whatever their origin

Six international conferences, held between 2003 and 2005, attracted a variety of participants from biotechnology and pharmaceutical companies, non-profit laboratories, universities, scientific journals, professional societies, venture capital firms and governments. Participants outlined critical risks and the need for international standards. In addition, these conferences further refined the ICLS Charter, which was made public in April 2005 at a life-sciences conference in Lyon, France. Eventually, the ICLS was incorporated as an independent non-profit organization in the District of Columbia, USA, on 23 December 2005.

Soon after its launch, the ICLS conducted a seminar for experts from academic, governmental and the private industrial sectors of the G8 countries and Sweden on 'Enhancing Biological Safety and Security—A Global Agenda'. As Russia holds the G8 presidency in 2006, and will host the summit meeting in St Petersburg in July, the seminar was held at the

I.M. Sechenov Moscow Medical Academy. In addition to the Medical Academy, the Center for New Medical Technologies (NP TEMPO; Moscow, Russia)—a non-commercial partnership of 17 Russian life-science institutes—and the Moscow-based International Science and Technology Centre (ISTC) supported the meeting. This seminar will lead to work particularly in the area of training in biosafety and biosecurity. The ICLS plans to develop an international advisory committee of qualified experts to gather in October 2006 to initiate an International Biosafety and Biosecurity System that will assess training standards and curricula, on request, at life-science organizations to ensure that they measure up to the best international standards and practices.

A second key area of interest that arose from the discussions of the international group was the urgent need to develop a common methodological approach to the assessment and explanation of the full spectrum of biological risks. This would be a

At present, a lack of understanding of the differing priorities can hinder international cooperation in enhancing biological safety and security

major contribution to enabling dialogue between life-science communities in various risk environments around the world. At present, a lack of understanding of the differing priorities can hinder international cooperation in enhancing biological safety and security. The ICLS plans to set up an international multidisciplinary working group to develop a practical methodology.

Now firmly established, the ICLS is committed to help safeguard future advances by becoming the authoritative, private global source for identifying and managing biological risks. Membership of the organization will become a seal of approval for best practices and standards in scientific research, collaboration and commerce. In addition, the ICLS is creating a

network of non-governmental organizations, law firms, trade associations, professional societies, universities, private companies, government agencies and intergovernmental organizations that address these important issues. It is vital that the life-science community joins these efforts so as to connect with society at large and keep the confidence of legislators and the public.

Terence Taylor is Director of the International Council for the Life Sciences, Washington, DC, USA (www.icscharter.org).
E-mail: taylor@icscharter.org

doi:10.1038/sj.embor.7400725