

「バイオテクノロジー産業の今後に関するアジア地域ワークショップ」  
フォローアップ会合の開催

日 時：2004年6月15日（火）15:00～16:00  
場 所：日本国際問題研究所 軍縮・不拡散促進センター 大会議室  
講演者：テイラー-ISS-US 所長  
目 的：生命科学（life science）及びバイオ技術の悪用を防止するための基本綱領の策定とその運営組織の設立を目的とする3か年計画の説明会。

1. 概要

本年4月、軍縮不拡散問題及びバイオ問題に関する著名な政策シンクタンクである ISS-US 及び The Chemical and Biological Arms Control Institute (CBACI)（以下、共催者）の共催により、生命科学（life science）及びバイオ技術の悪用を防止するための基本綱領の策定とその運営のための組織の設立を目的とする3か年計画の一環として、「バイオテクノロジー産業の今後に関するアジア地域ワークショップ」が開催された。

右3か年計画は、生命倫理及びバイオ技術の開発と安全保障との密接な関連性と、右悪用のリスクを低下させる取り組みを求める政府及び産業界の期待を受けて策定されたものであり、共催者は日本を含む約90カ国の関連団体及び企業に参加を呼びかけている。

今次フォローアップ会合は、テイラー-ISS-US 所長より、本邦における本件説明会の開催の可能性につき打診があったことを受けて開催されるものであり、日本の関連団体へのアウトリーチを目的として、テイラー-ISS-US により右3か年計画の説明が行われるものである。

2. 主要議題

(1) 「基本綱領」合意に向けた3か年計画の概要説明

テイラー-ISS-US と CBACI の企画する以下の計画について説明及び質疑応答が行われる。

(イ) 「基本綱領 (The Charter)」合意に向けた3か年計画

運搬及び廃棄が容易な生物剤とその関連技術は、インサイダーによる持ち出しが核・化学分野以上に容易であるため、特に生命科学及びバイオ技術の悪用防止のためには、生物剤を扱う現場での対応が不可欠。この観点から、共催者は、生命科学、バイオ技術関連産業及び研究者を対象として、以下の3点を実現するための3か年計画を2003年に立ち上げた。 → 米国の民間ベース  
— 関連企業及び研究機関等を対象とする「行動規範 (code of conduct)」への合意。

— 右規範に合意する企業及び研究機関を会員とする民間ベースの組織 (International Council for the life science industries) の設立。

— 上記2点を構成要素とする「基本綱領 (the Charter)」への合意。

(ロ) 「行動規範」の内容は、国家及び国際規則、人の管理、情報管理、施設の安全及び保安措置、研究の管理 (governance of research) が構成要素となる。また、運営組織は、行動規範の遵守を誓約する企業及び研究機関等による会員制とする民間組織とし、その組織の会員であることが社会的信頼に繋がるような組織の在り方を目指す。今次ワークショップでは行動規範及び運営組織の在り方について意見交換を行いたい。

(ハ) 作業計画

◇初年度 (2003 年) は計画実現性の調査にあてられた。主要産業の関係者からなる Senior

Advisory Panel (8名) が右作業を支援している。

◇2年目となる本年は、3つの地域ワークショップ(アジア、欧州及び北米)を開催して、基本綱領の内容や組織の在り方について議論を深めつつ、参加者の拡大を呼びかけることとしている。今次ワークショップはそのアジア地域ワークショップに該当する。欧州地域ワークショップはロンドンにて7月20日から22日、北米ワークショップ地域はワシントンDCにて12月8日から10日に開催される。

◇2005年には、「基本綱領」のドラフトを策定作業を終了し、その合意に向けた会議を開催し、右運営組織を設立する。

## (2) 「基本綱領」のドラフトについて

アジア地域セミナーにおいて配布された「基本綱領」のドラフトの説明及び質疑応答。なお、IISS-US 側は、ドラフトはまだ素案の段階であり、引き続き参加者からのコメント及びアイデアを求めたいとしている。

(イ) 「行動規範」(別紙)の概要説明

(ロ) 組織運営の在り方

予算措置については、主な収入源は毎年1回開催される総会の参加費を徴収することにより賄う。会費の導入も検討の余地有り。独立性を守るため、企業からの献金は受け付けないが、人道支援団体からの献金は仰ぎたいと考えている。

組織の活動内容の詳細は、「基本綱領」採択後に立ち上げられる事務局及びワーキング・グループで議論されることになるが、例えばバイオセキュリティ・ガイドライン作り等が可能なのではない。但し、あくまで私的セクターであるため、査察のような「行動規範」遵守の検証措置の導入は考えていない。

(丁)

<< CPDNPとは >> 軍縮・不拡散促進センター

# アクセス

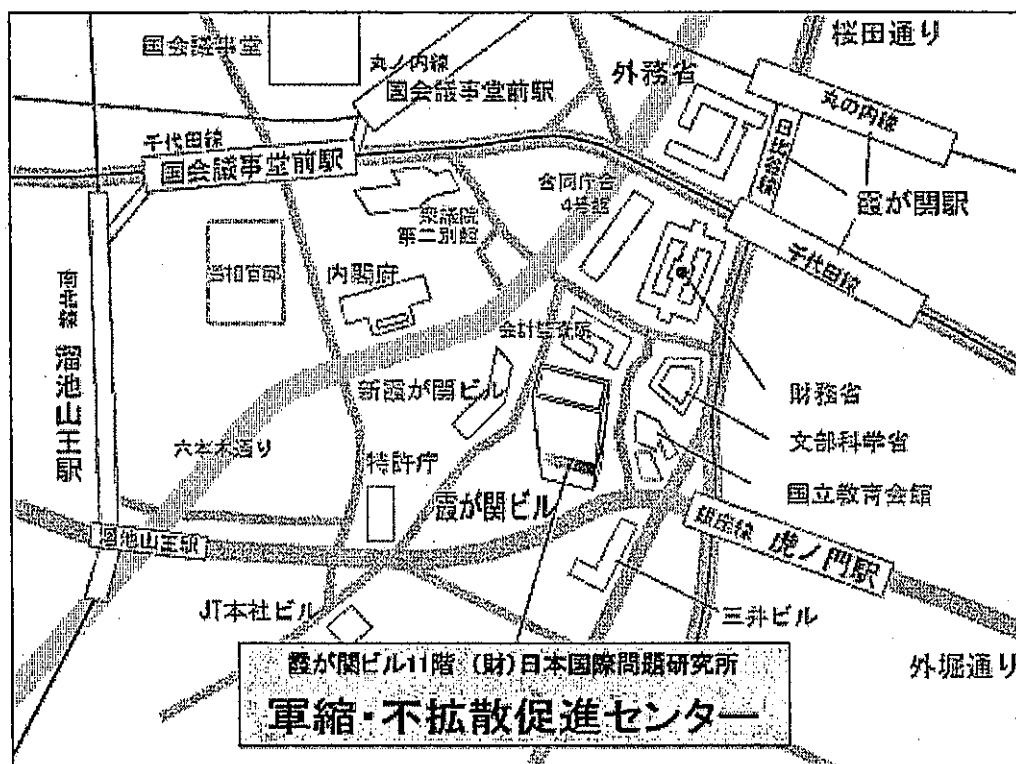


当センターへのお問い合わせ他、ご意見・ご要望は下記までご連絡ください。

財団法人 日本国際問題研究所 軍縮・不拡散促進センター  
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当センターまでの地図



**【最寄り駅】**

営団銀座線	虎ノ門駅	5番出口	徒歩3分
営団千代田線	霞ヶ関駅	A13番出口	徒歩5分
営団日比谷線	霞ヶ関駅	A13番出口	徒歩5分
営団丸の内線	霞ヶ関駅	A4番出口	徒歩8分

>> [組織概要](#)

>> [スタッフ紹介](#)

◇English◇[トップ](#)◇

April 28, 2004

Dear Colleague:

Thank you for participating in the 2004 Asian Regional Meeting on "The Future of the Biotechnology Industry: Safeguarding the Opportunities and Managing the Risks." Your contributions were of great value for the further development of our efforts.

On behalf of the Chemical and Biological Arms Control Institute (CBACI) and the International Institute for Strategic Studies-US (IISS-US), we are also pleased to invite you to the European Regional Meeting on July 20-22 in London. In London, we will be discussing issues similar to those covered during this meeting. The July workshop is designed to target critical stakeholders in Europe. The meeting would benefit, however, from the views and experience of participants from other parts of the world, especially Asia.

We look forward to continued dialogue with you on this initiative. Contributions from stakeholders such as yourself are critical to shaping the project and the global organisation's creation. If you have any ideas that you would like to share with us in the future, please do not hesitate to contact us.

With kind regards,

Michael Moodie  
President  
Chemical and Biological  
Arms Control Institute

Terence Taylor  
President  
The International Institute  
for Strategic Studies-US



**The International Institute for Strategic Studies**, founded in 1958, is the world's most prestigious private, not-for-profit membership organization for the study of military strategy, arms control, regional security, and conflict resolution. The IISS, with offices in London, Singapore and Washington DC, is the primary source of accurate, objective information on international strategic issues for politicians and diplomats, foreign-affairs analysts, international business, economists, the military, defense commentators, journalists, academics and the informed public. The US office focuses on studies in relation to the intersection of science, technology and politics and its impact on international security policy.

The IISS publishes the authoritative annual *The Military Balance*, an inventory of the world's armed forces; *Strategic Survey*, an annual retrospective of the year's political and military trends; the *Adelphi Paper* monograph series, in-depth analysis of general strategic issues; *Survival*, a quarterly international relations journal; *Strategic Comments*, containing short briefings on breaking strategic issues, which is widely syndicated in the international press, and *Strategic Pointers*, shorter 750-word assessments carried on its web site.

For more information, please see our website: [www.iiss.org](http://www.iiss.org)

**The Chemical and Biological Arms Control Institute** is a private, nonprofit, nonpartisan policy research organization established in 1993 to address the challenges to global security and stability in the early 21<sup>st</sup> century, with a special, but not exclusive focus on the elimination of chemical and biological weapons. It fosters this goal through an innovative program of research, analysis, technical support, training, and education. CBACI's objective is to promote a strategic approach to contemporary national security challenges that fosters the translation of ideas into action.

The Institute emphasizes not only issues of immediate national concern but also problems that reflect the dynamics of a new global environment, take shape from the complex interaction of security, science, and technology, and present demanding decision making challenges to national and international leaders.

The Institute's research program is designed to alert leaders in government, industry, the media, and the scientific community to problems before they become crises, to challenge conventional wisdom in light of new realities, and to promote the integration of diverse perspectives into decision options that effectively balance competing interests. CBACI stresses, therefore, studies and analyses whose hallmarks are their anticipatory nature, action orientation, integrative approach, policy focus, and political realism.

For more information, please see our website: [www.cbaci.org](http://www.cbaci.org)



The Chemical and Biological Arms Control Institute (CBACI)  
The International Institute for Strategic Studies - US (IISS - US)

**The Future of the Biotechnology Industry:  
Safeguarding the Opportunities and Managing the Risks**

**Project Overview**

Extraordinary advances in biotechnology over the past decade have brought enormous benefits to medicine, public health, the food industry, and agriculture. At the same time, the risks to public safety and security from the misuse of this technology have increased. More efficient and damaging weapons can be developed today than heretofore by government-sponsored weapons programs and possibly terrorist groups. In addition, as biotechnology diffuses worldwide, chances increase for industrial accidents through misunderstanding and inadvertent misuse of new technology.

Governments are struggling with the need for national and international regulation of the life sciences industry in the face of such issues. However, the speed of developments within the life sciences sector appears to be outpacing national and international attempts at legal and regulatory action. Private industry and non-governmental institutions define the leading edge of these burgeoning industries. Any international effort to deal with biological threats to public safety and security that does not engage private industry directly will be seriously lacking in effectiveness and ultimately unsuccessful.

The Chemical and Biological Arms Control Institute (CBACI) and the International Institute for Strategic Studies-US (IISS-US) are conducting a joint, multi-year project designed to promote the sustained, active, and positive engagement of the global biotechnology industry on issues of public safety and security related to the life sciences, with special attention to issues of biological weapons and bioterrorism. More specifically, the project is intended to promote the creation of a global organization of biotechnology companies, large pharmaceutical firms, and other entities to focus industry engagement on such issues. The objective would be to establish a self-sustaining enterprise that provides a mechanism for private industry to contribute to improved quality of life and to enhanced international standards of public safety and security on a global scale through responsible, ethical, and sound business and scientific practices. An equally important second goal is to facilitate the development of effective partnerships between the life sciences industry, government, international organizations, the scientific community, and other critical constituencies on these vital issues of common concern.

The life sciences industry must become more involved in the safety and security agenda for several reasons.

First, industry has much to offer. The life sciences industry stands at the cutting edge of the application of rapidly advancing sciences. That is its business. Exploiting that position for the purpose of reducing the risks from the misuse of the life sciences is just as beneficial to the nation and its people as using it to deal with health challenges, agricultural improvements, or other areas in which biotechnology is now applied.

Second, the public and policy makers expect such a contribution. New medicines, new diagnostics, new sensors, and other innovative tools to deal with the novel challenges of biological weapons and bioterrorism can only come from industry. Governments recognize that they are not up-to-date on the latest developments that might provide technological breakthroughs to the problems they confront in dealing with the biological challenge. They can only come from industry.

Third, it is very much in industry's interest to become more engaged on issues of safety and security. Pfizer Chairman Hank McKinnell has said, "If we are seen as part of the problem, we'll be dealt with as a problem." If further deliberate misuse of the life sciences occurs (anywhere in the world) and the industry has not engaged, it will be seen as part of the problem. The result will be actions by governments, which are notoriously blunt and heavy-handed in responding to political crises, that are ill-considered and onerous to industry. Further regulation and restrictive measures will dampen business prospects and injure an industry that can ill-afford setbacks.

The best way for the life science industry to safeguard the remarkable opportunities before it is to demonstrate – to publics and policy makers – that it is aware of and is proactively taking steps to manage the risks associated with the misuse of the life sciences. The proposed global industry entity is an excellent means for doing so.

**Project Progress**

The first year of the project focused on evaluating the feasibility of the proposed organization and the "blueprint" for carrying its creation forward. Regional workshops in Washington DC, Singapore, and London were a key component of this process. While the workshops were designed for executives from the life sciences industry, an effort was made to include other constituents from the scientific community, academia, government, and the traditional security community. The workshops covered themes such as the governance structure and membership of the proposed entity. In addition to convening regional workshops, the CBACI and IISS-US project team met with CEOs and other executives from life sciences firms on a one-on-one basis. Workshop reports are available by request.

As expected, the project team received a variety of feedback, but the need for industry to acknowledge and to address proactively the security issues relating to the advances in the life sciences was strongly and consistently advanced. The proposed entity would be a viable forum for industry to do so. Of particular note, industry representatives did not want the entity to be composed solely of industry personnel. They believed this would jeopardize the accountability

and objectivity that would be necessary in the proposed entity. What is needed is for the new entity to serve the key role in creating new dynamics within industry itself and between industry and government, the scientific community, and the public. To that end, industry representatives proposed that former senior government policy makers and representatives of other key stakeholders, such as university professors and presidents of non-profit laboratories, should be part of the governance structure and their institutions eligible for membership.

The project team also established a Senior Advisory Panel of key industry officials to help guide the project. Panel members will aid the project team in galvanizing the global industry on safety and security issues and to foster enthusiasm for the project. A list of Senior Advisory Panel members is attached.

The CBACI and IISS-US project team have also expanded their global engagement by partnering with regional biotechnology trade organizations, economic development organizations, individual companies, and other policy research organizations. Partners have included the Australian Biotechnology Industry Organization (AusBiotech), the University of Maryland Biotechnology Institute, and the OxfordshireBioscience Network.

As the project enters its second year, the current activities of the project focus on:

- Fostering additional awareness throughout industry worldwide;
- Continuing engagement of the CEOs and other related constituents who have already expressed support for the project; and
- Expanding the Senior Advisory Panel to provide an on-going mechanism for the expression of industry leadership and to engender support for the project.

While all of these activities are ongoing, the project team is focusing its Year Two efforts in particular on drafting and refining the proposed entity's charter. This charter for the new entity represents the mechanism for translating the concept of the project into concrete terms. The charter is intended to express the core philosophy of the new entity, articulate the commitments and principles to which its members will pledge, and aid private firms in managing the critical safety and security issues they face as they participate in a cooperative forum with other stakeholders. Another concern is making sure the charter reflects the relationship between biotech firms, pharmaceutical firms, and other key constituents, such as universities, governments, and trade organizations while maintaining the industry's interest.

The charter for the new organization addresses the critical risks this entity will help manage. Issues that will be considered include:

- Risk Assessment
- National/International Rules and Regulations
- Safe And Secure Operation Of Facilities
- Personnel Issues
- Laboratory Standards
- Information Handling
- Business Conduct



- 16
- Bioethics
  - Governance Of Research

Key components of the charter will also include governance structure and member eligibility.

### Upcoming Meetings

Throughout 2004 the CBACI and IISS-US project team will continue its global engagement through one-on-one meetings and partnering with regional organizations. Another key element of the 2004 work plan is three regional conferences focused on Asia, Europe, and North America. The goal of the regional conferences is primarily to present and discuss the draft charter to ensure that the proposed entity is shaped by regional industry perspectives. The Asia conference is scheduled for April 26-28 in Singapore. This meeting will be followed by the Europe conference on July 20-22 and the North America conference on December 8-10.

Year Three of the project will begin in the autumn of 2004. The focus of the effort in this period will be twofold. First, the project team will continue to build support for the proposed entity, culminating in a "Commitment Conference" in 2005 at which companies and others will pledge their support for the principles and commitments embodied in the charter of the new organization and begin to plan its creation and operation. Second, building on the Commitment Conference, the project team will engage in the process of "standing up" the new organization. This process will entail not only the necessary administrative and logistical steps, but also the development of the organization's initial work plan. This plan will identify the critical issues deemed to be of highest priority to the members and specify the best mechanisms – e.g., working groups, task forces, forums, workshops, etc. – to address those issues of priority concern.

Please direct any questions or comments regarding the project to Jennifer Runyon:  
CBACI & IISS-US, 1747 Pennsylvania Avenue, NW, 7<sup>th</sup> Floor, Washington, DC 20006, USA  
[jrunyon@cbaci.org](mailto:jrunyon@cbaci.org) or (202) 296-3550, ext. 113



### Senior Advisory Panel

Bob Erwin  
Chairman of the Board  
Large Scale Biology Corporation  
Vacaville, California

George Poste, PhD  
Chief Executive Officer  
Health Technology Networks  
Gilbertsville, Pennsylvania

Paul Fischer, PhD  
Chief Executive Officer  
GenVec, Inc  
Gaithersburg, Maryland

Una Ryan, PhD  
Chief Executive Officer  
AVANT Immunotherapeutics  
Needham, Massachusetts

William Haseltine, PhD  
Chairman of the Board and  
Chief Executive Officer  
Human Genome Sciences  
Rockville, Maryland

Gurinder Shahi, BMMS, PhD  
Chairman & Chief Executive Officer  
BioEnterprise Asia  
Singapore

Professor Charles R. Penn, PhD  
Business Division, Director  
of Research and Development  
Health Protection Agency  
Salisbury, United Kingdom

Rainer Wessel, PhD  
President & Chief Executive Officer  
GANYMED Pharmaceuticals AG  
Mainz, Germany



## CHARTER

### INTERNATIONAL COUNCIL FOR THE LIFE SCIENCES INDUSTRIES

#### *PREAMBLE*

Extraordinary advances in biotechnology have brought enormous benefits to medicine, public health, the food industry, and agriculture. At the same time, the risks to public safety and security from the misuse of this technology have increased. Certain states and non-state groups, if it suits their objectives, could develop and acquire more efficient and damaging biological weapons. In addition, as biotechnology diffuses worldwide, chances increase for industrial accidents through misunderstanding and inadvertent misuse of new technology. Added to this there is mounting public concern worldwide about the advances in the life sciences from an ethical and moral perspective. In order for the enormous humanitarian and economic benefits arising from the advances in the life sciences to be realized it is essential that all these concerns are explicitly recognised.

The international community and national governments are faced with a demand for national and international regulation of the life sciences industry. However, the speed of the developments is outpacing national and international attempts at effective legal and regulatory action. Private industry and non-governmental institutions are at the leading edge of these advances and dissemination of the scientific developments and their technological applications. The private sector and academia need to contribute directly to the international effort to deal with biological threats to public safety and security in order that effective legal and regulatory regimes can be implemented without unnecessary costs and other burdens. It is important that industry becomes accepted as responsible actors that promote both the interest of public safety and security, and public understanding of the issues, risks, and benefits of life sciences research and development.

In the light of public and governmental concerns there is a widespread recognition in the private sector of the life sciences that they have a unique capacity to meet their collective responsibility to conduct research and business operations to the highest possible standards. To achieve this objective leaders from business and academia around the world have agreed to the creation of an international entity called the International Council for the Life Sciences Industries, specifically designed to contribute, in a proactive way, to the management of the risks involved and thereby help safeguard the future development of the life sciences and the associated industries.

## **THE CHARTER**

An International Council for the Life Sciences Industries (hereinafter referred to as the Council) is hereby established that will:

- Create a self-sustaining global enterprise for industry and the academic community to contribute to improved quality of life and enhanced public safety and security;
- Promote the engagement of the life sciences industries worldwide on issues of public safety and security; and
- Facilitate effective partnerships between the private life sciences industries, government, academia and other critical constituencies.

### **Mission**

The mission of the Council is to promote public health, safety and security by:

- Safeguarding opportunities offered by advances in the life sciences and their application by the life sciences industries; and
- Enhancing the management of risks arising from the development and dissemination of such science and technology.

### **Principles**

To accomplish this mission the Council will facilitate essential and timely contributions to national and international policy development through being:

- **Action-oriented:**  
To proactively engage industry, governments and the public to enable accurate communication and understanding of the risks and benefits arising from the advances in the life sciences.
- **Independent:**  
While the Council will be independent of governments, and represent its interests through its governance structure, it will cooperate closely with national governments and international inter-governmental organizations.
- **Global:**  
The diffusion of the life sciences is not confined by borders and as such the Council will engage the biotechnology industry globally through promoting the widest possible membership.

### **Membership**

Membership of the Council is open to corporate and academic entities that have a direct interest in guiding the appropriate use of the life sciences and biotechnology.

**CHARTER COMMITMENTS**

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

***International and National Laws and Regulations***

Observe, promote and help develop effective national and international laws and regulations in relation to the life sciences.

***Personnel***

Exercise the highest standards in the recruitment, training and management of personnel with access to information, materials and technology that could directly affect public safety and security if misused or not operated safely and appropriately.

***Information***

Ensure the security of information by observing the relevant international and national laws and regulations in the handling of sensitive information that could have a negative impact on public safety and security; and also to contribute to developing, in cooperation with governments and the academic community as appropriate, effective and responsible procedures for the release of potentially sensitive 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 in the interest of public and environmental safety; and to contribute to the development of effective international and national laws and regulations in this regard.

***Governance of Research and Development Activities***

Take full account of security, safety and ethical concerns 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.

## *GOVERNANCE*

The governing authority is an initial convening conference (CC) and subsequent Annual General Meetings (AGMs). Members are entitled to send one representative with voting rights to the CC and to the AGMs. The CC will approve the Charter of the Council. The AGMs will approve any subsequent amendments to the charter. The CC will appoint the first President of the Council whose term should last for at least two AGMs. Subsequent appointments of Presidents will be made by the AGMs for terms of at least two years.

The CC will appoint an Executive Committee composed of no more than [twenty] members to manage the Council's affairs. The Executive Committee will be composed of individuals that reflect as broad a range of members' interests as possible. These members, who will be internationally recognized as leaders in their fields as well as being aware of the far-reaching policy and security implications of the life sciences, will reflect expertise in the following areas:

- Industry – An understanding of the interests of all sectors of the life sciences and what impact this may have on security.
- Relevant science and technology – An understanding of the security implications of the life sciences and related areas.
- Public Policy – An understanding of the public policy implications in relation to safety and security from advances and developments within the private industry.
- Risk assessment - An ability to accurately gauge the possible impact of developments in the life sciences and biotechnology in the context of challenges from naturally occurring disease and the possible use of biological agents by government or non-government entities.

Members of the Executive Committee should serve for at least [three] years and for no more than [two] terms consecutively, unless the AGM agrees otherwise. The AGM will approve appointments of its members based on the recommendations of the Executive Committee.

The Council and the Executive Committee will be served by a small permanent Secretariat. The Secretariat will be headed by a Chief Executive Officer appointed by the Executive Committee. The Secretariat will be composed of international staff with properly recognised expertise in the life sciences, public policy and private industry. The number of staff and specific responsibilities will be determined by the Executive Committee and subject to approval by the Council as a whole.

### **Mechanisms**

In addition to the AGMs other mechanisms will be set up on the advice of the Executive Committee to deliberate over issues pertinent to safeguarding the public and the industry as determined by members at the AGMs such as multi-stake holder working groups, forums, and projects, information exchange, and educational activities.

# バイオテクノロジー産業の今後に関するアジア地域ワークショップ

## (IISS-US 及び CBACI 主催) フォローアップセミナー

日 時: 2004年6月15日(火) 15:00 ~ 16:00

場 所: 日本国際問題研究所 軍縮・不拡散促進センター 大会議室

### 参加申込用紙/Application Form

必要事項をご記入の上、6月11日(金)までにFAX(03 - 5501 - 8220)にてご返送ください。(日本語及び英文の両方の表記にてご記載願います。)

本セミナーへの参加を希望します。

フリガナ		
お名前 Name	姓/Family	名/Given Name
ご所属団体・部署名 Organization		
役職名 Title		
ご連絡先 Address		
電話		
ファックス/Fax		
E-mail		

・使用言語 英語

・ 会場(軍縮・不拡散促進センター)へのアクセス

住所: 東京都千代田区霞が関3 - 2 - 5 (霞ヶ関ビル11階)

地図: HP (<http://www.ijnet.or.jp/JIIA-CPDNP/>) 御参照

\* セミナーの内容につきご質問がある場合は、外務省生物・化学兵器禁止条約室(03-5501-8222、担

当 <sup>こうたけ</sup>神武)までご連絡願います。