

OECD INTERNATIONAL FUTURES PROGRAMME (IFP)

“Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources” Frascati, Italy Sept 17-19, 2004

Chairman’s Summary

In September 2004, 55 participants selected from government, academia, industry, public research organisations, scientific societies, the science publishing field gathered in Frascati, Italy for three days to discuss the promotion of responsible stewardship in the biosciences and means of avoiding the potential abuse of research and resources. The meeting was convened by the International Futures Program of the OECD.

The role of responsible stewardship in helping to achieve a balance between scientific freedom and security concerns was one of the themes raised at a meeting of OECD Science Ministers in Paris in January this year. The OECD Frascati meeting developed this issue further by bringing together a broad range of participants in their personal capacity to address balancing the needs of science with those of security.

Rapid advances in the biological sciences offer significant benefits to mankind while posing new challenges to the scientific and security communities. Whereas biological research has greatly contributed to the improvement of human health, the same methods and materials, technologies, and knowledge bases can also be used to produce potentially dangerous agents and toxins for harmful use. Nevertheless, excellence in scientific research depends on open interactions among researchers, including the exchange of scientific data and methodologies and open access to biological resources.

Whilst this central conundrum is being discussed in other fora, the unique value of the Frascati meeting was to bring together a broad cross-section of international representatives from the three major communities – government, industry and academia – directly affected by the debate about balancing access and security.

The meeting was divided into four sessions. Following brief introductory remarks from the session Chair, participants engaged actively in a discussion of the issues addressed by that session. The final session drew together in conclusion the key discussion points that had emerged from the previous sessions.

Session I – Exploring the Balance of Risks – Openness and Precaution

Discussion in Session I centered on the ways in which the biosciences have changed in the last decade and the extent to which there have been developments in the biosciences that might lay such research open to abuse – particularly in view of the escalation of security concerns in recent years.

Defining the risks associated with the dual-use nature of bioscience was universally acknowledged as conceptually difficult and difficult to quantify. The availability of known, dangerous pathogens has always been evident, but in an age of genomics, proteomics, genetic

engineering and mass informatics resources the risk profile has become more difficult to define. Restricting access to biological material and/or information is one solution, but this creates new challenges in the form of possible impediments to the future advancement of science.

That biotechnology *per se* does not present a risk was acknowledged, but that it presents a new potential for misuse of bioscience is evident. Distinction was made between access to known, harmful pathogens and access to other biological material, techniques and information –many of which emerge from biotechnology - that have the potential to be used for harm.

The value of having broad representation from the key communities was clear in discussions characterizing the multi-faceted threat drawn from different perspectives across the communities (threat to public health, to plant and to animal life and hence agriculture, to food security, to economic stability etc.)

Discussions acknowledged that not only technical advances, but societal and geopolitical changes have influenced how science is conducted; the global reach of the scientific community transcends national boundaries, and wider availability has greatly diminished controls over the use of technology.

In reconciling an open research environment with the threat of misuse of bioscience research a number of key needs were identified. The need to establish a common international understanding of key terminology was emphasized; participants reported diverse interpretations of and uses of the terms ‘biosafety’ and ‘biosecurity’. It was noted during the meeting that in some languages, there is a single word that encompasses both concepts (e.g. French, Italian, German or Russian). Discussions also highlighted the need for increased awareness among researchers of both biosafety and biosecurity. In the context of encouraging responsible stewardship and fostering a security-conscious culture among scientists, the need for raising awareness-raising was stressed. Discussions raised the need for codes of practice, for accreditation of facilities and for registration of personnel. The need for a balanced approach was deemed essential in assuring public and political confidence that the risks are being correctly addressed.

The support and cooperation of the science community was confirmed as being integral to the process of describing a way forward.

Session II - A Review of Legal, Administrative and Regulatory Approaches

This session reviewed existing frameworks for governance of bioscience research. Participants discussed whether these sufficiently minimize the risk of misuse, in light of the threats identified in Session I.

Existing frameworks operate at three levels:

International

International cooperation is well established on restricting/denying access to materials (BWC, WHO, OECD Biological Resource Centres Network, European Commission) and on surveillance

and response to disease outbreaks (WHO, OIE, FAO). The need to strengthen all of these existing international efforts, and to ensure that they are mutually complementary, was highlighted. Raising awareness of biosecurity issues in the scientific communities was also seen as an important goal in any future action.

National

All OECD countries have systems in-place to address biosafety. The systems employed by many countries also indirectly address biosecurity. A small number of countries (notably US, UK, France) have legislation that specifically addresses biosecurity. Countries employ a variety of legal mechanism to prevent the export of material that could threaten biosecurity. Many developing countries lack legislation in this area entirely.

Self-Regulation

The history of successful self-regulation within the science community was discussed. The science community voluntarily conforms to codes of conduct on issues such as research ethics and professional conduct. Self-regulation has worked well in these and other areas. Initiatives are underway to apply a self-regulatory approach in the context of balancing scientific freedom and biosecurity. The augmentation of existing regulatory frameworks with self-regulation is the approach most likely to succeed, although the practicability of specific recent initiatives is not yet established. There were, however, questions as to how effective a purely self-regulatory approach could be.

Emerging from this discussion, a clear demand was articulated for an information resource that would provide ready access to details of legislation in force throughout OECD countries and beyond.

Session III - Roles of the Academic and Industrial Scientific Communities

This session considered the contribution of the individual components of the scientific community, and the extent to which they can assure responsible conduct through voluntary arrangements. Participants reported on initiatives underway to develop, or to encourage the development of codes-of-conduct. The Inter-Academy Panel ¹, representing over 80 scientific societies, is currently in the process of negotiating a code of conduct for scientists. A Royal Society paper² published earlier this year on the individual and collective roles that scientists can play in strengthening international agreements, presented as one of its key recommendations that ‘there should be a clear objective of moving towards an international consensus on adopting appropriate codes of good practice, particularly in relation to their role in combating the diversion of science advances into activities that pose a threat to global security and peace.

¹ The Inter Academy Panel effort is being led by Professor Edoardo Vesentini of the Accademia dei Lincei, Italy.

² <http://www.royalsoc.ac.uk/templates/press/showpresspage.cfm?file=554.txt>

Participants debated the need for a code of conduct specific to the life sciences rather than a code addressing scientists in all fields. An inclusive process of negotiating and agreeing a code of conduct was deemed to be essential to the success of any such code. The external imposition of a set of rules/guidelines was considered less workable in practice.

The role of journal editors in ensuring the non-dissemination of scientific information that could increase the threat is of prime importance. The policies of editors and the practices to which many prominent journals adhere were discussed. Participants raised the issue of internet publishing and the increasing ease with which such information may be accessed. Problems could also arise from informal exchanges among scientists concerning sensitive information, data or techniques in internet forums and chat rooms.

Session IV Options and Next Steps

Session IV addressed whether new efforts in governance and oversight are required and identified some possible next steps.

Current legal structures need to be better understood by all concerned. The impact of existing systems – whether specifically focused or not – on delivering the twin goals of protecting science and the public in an age of terrorism need to be further evaluated. Equally, some consolidation of existing self-scrutiny efforts need to be considered. For example, there is no clear view yet on whether a single coordinated approach or multiple approaches (via government, academic institutions and industry) might best achieve the desired balancing of openness and security. Clarity is needed on how international efforts on access (e.g. the OECD Biological Resource Centers initiative, scientific association guidelines, legal and policy instruments at the national level) best compliment one another; it is equally vital to ensure that these initiatives deliver results quickly.

An evolutionary process of education, self-scrutiny and security awareness is on-going among life scientists. Responsibility and stewardship are increasingly coming to the forefront, complementing and informing statutory approaches. It is a process that provides the opportunity to cross communities and to create a culture of cooperation. A need is emerging for a more transparent and better informed debate to consolidate existing activities, including through the provision of a more comprehensive and nuanced information resources. Bringing together the different communities was identified as an important step forward, perhaps through a dedicated forum.

A series of questions therefore emerged:

What process or processes are required to shepherd the evolution of a package of measures designed to increase responsibility and stewardship?

If a dedicated forum is needed, how might this best be constituted and what might be the limits of its operation? Some areas (open access, internet publishing) have scarcely been touched upon.

How might the strengths and opportunities provided by existing structures and initiatives be maintained and built upon?

What steps are necessary to ensure that efforts enjoy the support and confidence of life scientists and the broader community?

Some Concluding thoughts ...

The Frascati meeting explored ways to ensure public health and safety by managing the risks of possible terrorist action while preserving life sciences R&D freedoms that provide society with enormous benefits.

There is a demonstrated need to further define appropriate actions necessary to capture and to synthesize the information being generated in the numerous on-going dialogues between the life sciences and the security communities at the international level. Although these discussions serve to develop increasing awareness of the underlying issues and to promote responsibility among scientists, it is clear that **there is scope for new efforts to address the entire range of the problem.**

Two prospects for further specific action emerged from the meeting:

1 – to help to provide the framework for developing the appropriate oversight responses to biosecurity concerns - including codes of conduct - among the academic, government and industry scientific communities;

2 – to help to devise criteria and the subsequent processes to operationalize such actions at the national and international levels.

Codes of conduct and oversight criteria for biosciences research may require the development and implementation of different mechanisms at different points in the process; these range from the first steps of devising initial concepts, through fundamental research and on through the final publication of results. Securing the physical security of resources is needed in some stages of research, while other types of oversight mechanisms are needed to advise on the dissemination of research results.

It is important to look carefully at the complete process of biological sciences research before devising and implementing new generic policy tools. It is equally important to understand the legal as well as policy constraints under which each system must operate, especially in the international context.

Some first steps forward...

A first concrete step would be to inventory all of the efforts in OECD and non-OECD countries where governments, associations or industry groupings are discussing or formulating different approaches to biosecurity. This inventory should include policy as well as legal approaches. The overview would detail specific tools being used to address problems.

A small working party should be formed to review and to assess the inventory and to provide guidance on further work. In particular, the group could focus on measures that have been implemented, looking at what has worked, and under what conditions. These first efforts would provide the basis for a "gap analysis" of current biosecurity efforts, particularly at the international level.

On a second point, there is ample scope to facilitate further action at the international level in the area of the development of scientific codes of conduct. While several codes are currently being developed at different levels- within industry, at the scientific association level and at the level of the Inter Academy Panel, and even within some governments - these are being done independently and are in different time-frames , addressing different constituencies.

But many countries have not begun to reflect on this issue, either within the government or within the scientific communities. The working party could act as a clearing house for information on the different efforts on codes of conduct; the working party could also provide the impetus and stimulus for exchanging experience and converging towards mutually compatible efforts based upon agreed minimum standards, thus raising international awareness of the special problems involved with biosecurity research oversight.

Codes need to be monitored if they are to be effective. Voluntary measures to monitor codes within several national scientific communities are being developed, and there has been progress in this area in the past three years. But much needs to be done. New oversight mechanisms at the national and international levels need to be developed, and these should demonstrate convergence of purpose and coverage from the outset. By starting from common concerns and a concerted effort to design realistic policy tool kits, stakeholders can work together to develop effective, timely and compatible tools. As the codes and the tools are used, lessons learned can be gathered to help address concerns, and to encourage broader participation once the codes show their worth.

To facilitate these two types of action, a small scale, bi-annual working group could be organized by the OECD's International Future's Program to gather key players in the different stakeholder communities.

The general mandate of this working group would be 1) to identify and to document common concerns in the various stakeholder communities regarding the oversight of biosciences research at its different stages; 2) to develop a common vocabulary concerning the new security issues facing society particularly in relation to biosciences research; 3) to help broker and to integrate the concerns of the constituent stakeholder communities into the development of codes of conduct and the mechanisms to ensure their operability; 4) to facilitate the convergence of minimum standards for codes of conduct among the science communities in academia, government and industry; 5) to help develop criteria and to phase relevant processes to render codes, and other oversight tools, operational, particularly in an international context.

These meetings would be informal and would be organized around specific issues. Participation would vary according to the focus of the debate. The ongoing work of OECD Committees dealing with the biosciences would be an important element of this work.

Michael Osborne
Chair