WHO/CDS/EPR/2007.4

Scientific working group on life science research and global health security

Report of the First Meeting

Geneva, Switzerland
16–18 October 2006

EPIDEMIC AND PANDEMIC
ALERT AND RESPONSE

World Health Organization

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Contents

Foreword

This meeting report is part of the "Life science research and development and global health security" project. The project is aimed at raising awareness among WHO Member States about the potential implications of life science research and development (R&D) for global health security. It underlines the importance of carrying out life science R&D for improving the health of all people, as well as the potential risks linked with life science R&D. As part of this project, a scientific working group met in Geneva, 16–18 October 2006. This report is a summary of this group's deliberations.

The overall objectives of the October meeting were to review — from a public health perspective — the risks and opportunities of life science research for global health security and to provide input on the project's activities and plans, including regional activities. Regional activities are aimed at raising awareness of these issues and at gathering feedback on the scientific working group's recommendations. Feedback on this report will also be gathered by way of a questionnaire that will be posted on the Internet during the first half of 2007. The present recommendations made by the participants may be revised in order to reflect the feedback received.

Recognizing that these issues are complex and challenging for public health, the scientific working group stressed the need for a global response that is sustained and comprehensive. The report also emphasizes the pivotal role of WHO as a facilitator in engaging all interested parties in this process. Education, training and awareness raising, together with capacity building (in ethics, clinical practice, laboratory work and research), preparedness, risk assessment methodologies and research oversight guidelines are the priorities identified by the scientific working group and for which action is now needed.

The project, which is contributing to the implementation of the World Health Assembly resolution WHA55.16 of 18 May 2002, is the follow-up of an exploratory phase that was concluded in 2005 with the publication of a working paper (*1*). The project is being implemented by the department of Epidemic and Pandemic Alert and Response (EPR) in close collaboration with three other departments: Research Policy and Cooperation (RPC); Research and Training Tropical Diseases (TDR/PRD); and Ethics, Trade, Human Rights and Health Law (ETH).

I. Introduction

The public health implications of both the positive and potentially negative consequences of life science research are profound. The tremendous advances in biology, biotechnology, genomics, proteomics, synthetic biology and bioinformatics in recent years are almost certain to lead to improved health and well-being through, for example, new diagnostics, treatments and vaccines to fight infectious diseases. Unfortunately, the possibility that a laboratory accident may lead to a major outbreak or that such advances may be deliberately misused to do harm on an unprecedented scale cannot be ignored. In other words, the knowledge and technologies that result from life science research used for legitimate research and technology development may also be appropriated for illegitimate intentions and applications. This is sometimes referred to as the "dual-use" dilemma.

Finding and maintaining the right mix of policies that will enable the benefits of life science research to be maximized while minimizing the risks requires efforts on the part of both the life science and the security communities. Among life scientists there are concerns that the focus on deliberate outbreaks is hindering further developments in the life sciences. In some cases, security measures have led to policies that have affected scientists carrying out legitimate and much needed research on certain biological agents (e.g. security clearance, travel restrictions, difficulty obtaining research grants or long delays in exchanging biological materials and equipment). At the same time, within the security community there are concerns that many scientists are unaware of the potential for accidental or intentional harm from their research and of their roles and responsibilities in helping to mitigate those risks. In recent years, research with potentially dangerous consequences has occurred in laboratories in a number of countries. This research has generated controversy not only in government circles but also within the public at large.

The scientific working group convened by WHO (hereinafter "the Group") met to discuss the implications of life science research for global health security (see annex 1 for the agenda of the meeting and annex 2 for the list of participants). The Group took life science research as relating to all life forms — human beings and animals as well as plants — and as embracing numerous fields of study, including biology and parts of chemistry. Likewise, global health security was taken to mean minimizing the "risks and dangers to health arising from global interactions among peoples and states. The global health security concept also sends the message that a nation's health security is intertwined with the rest of the world through the processes of globalization." (*2*).

The Group started from the premise that finding and maintaining the right mix of policies is a complex and dynamic process that calls for a multifaceted solution, international coordination and sustained engagement. Equally important is to view the problem from a public health perspective, albeit with appropriate recognition of the importance of national and human security. There are several reasons that call for a public health perspective. First, public health is concerned with protecting and promoting the health of communities and therefore must give due consideration to both the benefits and the possible risks of life science research for public health. Second, it recognizes the possibility of harm to public health if rules and regulations to prevent the potential misuse of life science research are so stringent that they stall advances in the life sciences or so weak that such research may foster dangerous results. Third, communication, cooperation and openness, which are central to a public health perspective, are needed to uphold public trust in the research endeavour and to provide evidence-based advice to policy-makers.

Fourth, the strong sense of social responsibility that underlies public health research can be readily extended to include the responsibility to minimize, through responsible conduct of research, the risks of deliberate outbreaks or inadvertent consequences. And fifth, such a perspective takes into account the vastly different health needs and experiences of WHO Member States, as well as the mandate of WHO.

II. Recommendations

As Professor Peter Folb, who chaired the meeting, summarized in his closing remarks, the Group identified five priority areas for which action is now needed:

1. Education and training for life science students and researchers, and ultimately even for high school students, journalists and the public;
2. Preparedness for a possible major outbreak of disease resulting from the intentional or inadvertent misuse of biological agents by preparing for natural disease events;
3. Development of risk assessment methodologies;
4. Engagement of all stakeholders in the life science community, and development with and through them of guidelines for oversight; and,
5. Thoroughgoing capacity building at country level, including ethics, clinical practice, laboratories and research.

Reflecting a shared sense of urgency, the group recommended that WHO should establish a standing scientific advisory group[1] charged with advising the Director-General and supported within the Secretariat by the relevant departments. The scientific advisory group would meet on a regular basis to develop principles and guidelines for assessing the risks of life science research and to evaluate policies. It would also seek expert advice and commission research, as and when required. Sub-groups would be set up for each of the five priority areas, which are briefly elaborated on in the following section.

Why WHO should lead the way

Participants agreed that WHO should collaborate with the Food and Agricultural Organization of the United Nations (FAO) and the World Organization for Animal Health (OIE), and lead, in line with its public health mandate, global efforts and help maintain effective policies that will maximize the benefits of public health research while minimizing the risks. It must be done in collaboration with the scientific community, policy-makers, security experts, industry and civil society, and the developing world must be well represented. In addition, when appropriate and feasible, it should build on existing documents, standards and guidelines and highlight the added value of the expected deliverables.

[1] During the revision of the meeting report, it was suggested to name the group "scientific and ethics advisory group" so as to underline the role of ethics in the work of the group.

The Group believes that WHO is ideally positioned — technically, operationally, and politically — to take on such a role primarily because:

- decisions on how best to reduce the risk of accidental and deliberate misuse of life science research should not be taken by individual governments in isolation;
- assessing the public health impact and effectiveness of any proposed control mechanism from a global health perspective is essential;
- WHO is already a recognized authority in relation to laboratory biosafety and to infectious diseases; the revised International Health Regulations, IHR(2005), will further increase its roles and responsibilities in epidemic and pandemic surveillance and response, prevention and preparedness;
- WHO has the mandate and the capacity to help achieve global harmonization and to build a network, and network of networks; and
- WHO has the moral authority to undertake this work.

The Group also underlined that the response from WHO and other bodies must be backed by adequate and sustained funding. The possible consequences of inaction or inadequate action include:

- worsening of the "biological divide" or the "10-90 gap" (of the US$70 billion spent every year on health research only 10% is used for the health problems of 90% of the world's people) (*3, 4*);
- ineffective oversight and overly restrictive rules and regulations being imposed on life science research, to the detriment of global health security;
- unilateral action taken by countries in counterproductive ways and an increase in bilateral agreements between countries;
- increased risk of emergence of new pathogens or modification of existing pathogens with potentially dangerous consequences for public health and national economies;
- increased actual or perceived risk of incidents and releases (accidental and deliberate) with harmful consequences for public heath and national economies, which might trigger policy-makers to advocate for over restrictive, non evidence-based, rules or regulations; and
- loss of public trust in science and threats to funding for life science research.

The first step is to secure political support from the Member States for the Secretariat to implement these recommendations by raising the issue at the level of the Executive Board and subsequently securing inclusion of this topic at the World Health Assembly.

III. Five priority areas

Raising awareness through education and training

The accidental or potential deliberate misuse of life science research cannot be averted with a technical or political solution alone. For this reason, it is essential to include ethics and human behaviour considerations in the approach taken and to raise awareness about the potential misuse of the life sciences. This would be done through education and training. In developing a strategy, methods and content, the scientific advisory group should build on already established norms, assess existing programmes and explore how to include international partners, transnational programmes and people with experience in applying training programmes in the ethical, legal and social implications of the life sciences. Coordination at regional and national levels is vital and their input is essential.

The ultimate goal here is for everyone to be better informed about the issues surrounding the accidental and potential deliberate misuse of life science research and to build a culture of responsibility and transparency within the life science community. It was suggested that life science students in all countries, as early as the first year of university, learn about international agreements such as the Biological Weapons Convention (BWC), which bans the misuse of biology, and about a scientist's ethical and moral obligations as an individual, to the profession and to society. In addition, mandatory training for all professionals working in the life sciences (in academia, for governments, and in the private sector) would reinforce these messages and encourage them to think about the risks of their work and how to avoid unintended consequences. Appropriate awareness raising programmes also need to be developed for editors, journalists, policy-makers, industry and the public.

Preparing for an intentional release

The World Health Assembly resolution WHA55.16 of 18 May 2002 (see annex 3) states: "(…) one of the most effective methods of preparing for deliberately caused disease is to strengthen public health surveillance and response activities for naturally or accidentally occurring diseases." The resolution urges Member States "to treat any deliberate use, including local, of biological and chemical agents (…) to cause harm also as a global public health threat, and to respond to such a threat in other countries by sharing expertise, supplies and resources in order rapidly to contain the event and mitigate its effects".

The Group felt that this approach to preparedness was necessary but not sufficient and so it drew attention to the need to address the special issues pertaining to a possible deliberate outbreak. A deliberately caused public health emergency of international concern would fundamentally transform the context in which public health services are delivered because the measures that would need to be taken to ensure people's safety and security would involve both public health and security officials. This would pose a challenge as each group has different roles and responsibilities as well as different mandates. It is imperative, therefore, to clarify the role of WHO in events that may be caused by deliberate releases. Difficult decisions would have to be taken — how would they be made, who would be responsible for making them, and through which channels and by whom would information be communicated. Governments, the public, health-care professionals, police forces and intelligence agencies need to be properly informed about how such an emergency would be managed. Because of the spectrum of actors involved in a response to a deliberate outbreak, preparedness will depend on proper procedures and on training them in joint operations and communications exercises. More dialogue and openness on these issues are urgently required.

Developing risk assessment methodologies

According to WHO, "biorisk" is the possibility or chance that a particular adverse biological event,[1] likely to affect health, may occur. From a public health perspective, this broad definition encompasses the full spectrum of biological risks to global health security. This includes new infectious diseases (e.g. avian influenza and Severe Acute Respiratory Syndrome (SARS)), modified strains of long-established diseases (e.g. multi- and extensively drug resistant tuberculosis), unintended consequences of research, laboratory accidents, lack of awareness, negligence, and deliberate use (bioterrorism and biological/chemical warfare). The term "biorisk reduction" is defined as the reduction of the risk of diseases, whatever their origin or source.

Risk assessment methodologies need to be developed before a consensus can be reached on how to minimize and manage biological risks effectively at global, regional and country levels. A full assessment of all forms of biological risks is important for both relevance and balance in priority setting and with regard to funding.

Developing guidelines for research oversight

Another important task for the scientific advisory group would be to develop guidelines for life science research oversight. This includes peer-review processes, risk-benefit assessment methodologies (including ethical, legal and social implications), guidelines for their application, education, training, awareness raising, etc. It was emphasized that the objective of research oversight is to ensure that research is undertaken safely and securely, and maintains public trust. It is not intended to inhibit research initiatives.

The objective would be for WHO to publish a shared set of practical guidelines for research oversight that have been developed and agreed on by key stakeholders and international partners, including broad participation from developing countries. Member States would be encouraged to translate these guidelines, as appropriate, within their national context. These guidelines may also evolve into an international standard (e.g. ISO) in 5–10 years' time and into national legislation. In the longer term, a more formal international mechanism for oversight may be an outcome of this process.

In developing the guidelines for oversight, WHO should collaborate with other intergovernmental organizations, professional societies, security experts and industry. Likewise Member States at regional and national levels need to be involved in gathering all relevant input. Fostering communication among all countries is crucial in order to build mutual understanding, trust and transparency. The development of these guidelines should also build upon the existing WHO guidelines for laboratory biosafety and biosecurity.

Building capacity in all areas of life science research

The first four priority areas highlight the main components of a global harmonized approach to biorisk management — awareness raising, preparedness, risk assessment and oversight. But principles, guidelines, programmes and mechanisms are only useful to the extent that they are acted on and implemented. To improve the likelihood of uptake at country level the Group recommended linking this harmonized approach to real public health problems and to the needs

[1] The word "biological" is being used not exclusively to indicate involvement of "biological agents", but in the wider sense of an event impacting on life. It could involve disease-causing agents such as toxins or other toxic agents or, more generally, inanimate pathogens that are not commonly thought of as "biological" agents.

of a given community. In developing countries, for instance, the possible misuse of life science or the threat of a deliberate outbreak may have little direct relevance, but chances are that the capacity needed for fighting naturally occurring infectious diseases are considerable and may include ethics, clinical practice, laboratories and research.

The coming into force of the revised International Health Regulations, IHR(2005), is a powerful opportunity to use capacity building for biorisk management and for enhancing international cooperation. Complying with IHR will require a comprehensive approach to building and strengthening capacity that spans prevention, preparedness, surveillance (detection, identification, diagnosis), and response to biological incidents (natural outbreaks of infectious diseases as well as accidental or deliberate releases).

One suggested approach is to link development assistance and capacity building to the national implementation of the biorisk reduction strategy of WHO. It aims to raise the standards of laboratories by addressing both biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion or intentional release) along with responsible life science research. The Group's other recommendations related to capacity building and include supporting the development of accounting systems for biological agents and international exchange programmes of specimens for diagnostic and research purposes; strengthening networks and South-South relationships among life science researchers; and fostering the development of magnet centres to keep health-care workers — who will be a vital part of responsiveness during outbreaks of infectious disease (natural, accidental or deliberate) — within the country.

IV. Summaries from the presentations of the five working papers

The secretariat commissioned working papers from five members of the group covering different aspects of life science research and global health security. These papers are summarized below.[1]

Science, security and health

In her working paper, Dr Caitríona McLeish first explores the concepts of health and security and then uses historical examples from nuclear physics and chemistry to underline the links between scientific research and security issues. Scientific activities, including the development of technologies, have the potential to be used to address national security issues in several different ways. They can be used to enhance national security by strengthening capabilities for defence, to afford protection against an adversary's means of attack, and to strengthen capabilities for offence. There are also ambivalent links in which a new technology could serve both offensive and defensive or protective purposes and thereby detract from national security.

The historical record provides evidence of both formal and informal linkages between science and security and between scientists and security. The formal links include scientists directly commissioned by the security community and scientists performing research as a result of other contractual arrangements (e.g. basic research in promising areas of science). Informal links

[1] The papers were first reviewed by the secretariat and modified by the authors. These papers were then circulated among the scientific working group participants for discussion.

include the use of research and/or technologies developed for other purposes but which are "spun on".

Dr McLeish emphasizes that the historical examples represent legitimate, unique and, for their time, unprecedented alliances — chemists and physicists were called on to apply their skills in the face of a threat. The examples demonstrate that the socio-political context of the day and the bringing together of sociological goals of two communities are the deciding factors in shaping the relationship between science and security and the application of science for those ends. Dr McLeish argues that a similar alliance will be needed to prevent the exploitation of life sciences for malevolent purposes and for the application of life sciences within the human security framework.

Public health, biological security and ethics

Dr Samia Hurst presented the working paper that had been written by Professor Margaret Somerville, who was unable to attend the meeting. In conjunction with other measures, ethics can contribute to the protection of people, the reduction of serious harm, and the deterrence of bioterrorism and biowarfare. The global nature of the challenge and the need for an international dialogue to help define the boundaries that science must respect makes it clear that WHO has an important role to play.

One part of the solution is for the international scientific community to ensure that all persons and institutions associated with or involved in science or medicine are aware of their ethical obligations to prevent the misuse of science. The process of undertaking an ethical analysis is called "doing ethics". An important part of doing ethics is engaging in "ethics talk" with all the people who should be involved in making a certain ethical decision. The role of ethicists is to show people that they might have an ethical problem and to help them understand as fully as possible the nature of the decisions they have to make. This is important because ethical analysis does not start out from a neutral position, rather the arguments put forward are built on one of four basic presumptions: "No", you must not do that; "Yes", you must or may do that; "No, unless…", no, you must not do that unless certain conditions are fulfilled that justify your action; "Yes, but….", yes, you may do that but not if certain conditions are present. Science almost always takes the latter approach — anything which is not prohibited, either expressly or by necessary implication, is permitted.

While there are deeply conflicting opinions within the life science community on whether or not there should be restrictions on the search for new knowledge, the need to place limits in certain instances on the application of that knowledge is broadly accepted. And there is widespread agreement that all research in the life sciences must be conducted in a safe and ethical manner. Professor Somerville's paper argues that a code of ethics for life sciences is needed in order to foster on-going "ethics talks" and to counter bioterrorism. According to Professor Somerville, the drafting of such a code must start with three basic presumptions: openness and transparency of scientific information, justification of exceptions to the general rule of freedom to publish, and support and protection for whistleblowers.

The role of research for public health

In his working paper, Professor Zulfiqar Bhutta argues that capacity development is the priority for ensuring the proper use of life science research and minimizing its misuse. Professor Bhutta highlights the links between health and development and the essential role health research plays in improving public health. The principal goals of public health are to: i) determine the underlying factors and determinants of health and social inequalities and reduce them through

effective policies and ii) sustain good health within populations by assuring long-term changes in the social and natural environments.

Professor Bhutta notes that a perception prevails that public health research is more resource intensive than managing diseases. Countries and especially developing countries should be encouraged to undertake research that is relevant to their health needs. The problems are due to a lack of investment in health systems and health systems research, migration, inappropriate priority setting mechanisms, limited capacity for public health research, and limited demand for public health research. WHO can help by developing frameworks, guidance and tools, but each country has to work out the implementation details for itself.

Professor Bhutta offers four suggestions, listed below, about how to increase public trust and engagement in health research, which he sees as the way to get politicians and civil society on board and to encourage new approaches to solving the health problems of developing countries.

- To ensure that developing countries benefit from the fruits of biomedical research;
- To strengthen national health research systems, which WHO defines as "the people, institutions and activities whose primary purpose is to generate high quality knowledge that can be used to promote, restore and/or maintain the health status of populations";
- To improve the health of health systems;
- To foster international cooperation in health research among researchers, policy-makers, advocacy groups and funding institutions in developing and developed nations.

Life science research and applications and their duality

According to Dr David Franz, when technologies exist that may be used for good or harm, intent becomes the most important factor in the misuse equation. The agents and tools used to make biological weapons are and always will be available in nature or legitimate laboratories, legal, and important to our well-being. Furthermore, the biotechnological revolution of the 21st century along with the increased emphasis on biodefence research after the events of 2001 may increase the likelihood of accidental or unintentional development or release of a harmful biological agent. Dr Franz therefore underlines the need to consider the risk of accidental, serendipitous or intentional release.

Dr Franz also emphasizes that different levels of risk can be assigned across the biorisk spectrum: naturally occurring chronic metabolic and endemic infectious disease will continue to occur; emerging diseases will certainly arise; the misuse of "dual-use" technologies may occur; and the risks of bioterrorism or biowarfare are unknown. Dr Franz believes that the process of working together internationally across the spectrum of biological challenges will both reduce the impact of already present naturally occurring disease and reduce the likelihood of intentional misuse of biology.

Dr Franz presented arguments for and against several possible solutions including regulation, attribution and retribution, and codes of conduct. He concluded that any solution must be multifaceted, it must be international, and it must be built on a foundation of education and awareness raising.

Measures/initiatives to manage life science research and their impact for research and public health

In her working paper, Professor Kathryn Nixdorff, who was also the meetings' rapporteur, calls for a multi-faceted approach on governance measures. The weakness of the BWC is that it has no treaty organization and it does not contain adequate measures for verifying compliance. National legislation and regulations concerning biological security are important but their impact is limited because there is no international harmonization. Professor Nixdorff highlighted five additional control measures: adopting a research oversight system; adding provisions to the biological and chemical weapons conventions that would allow States to prosecute offenders as individuals, regardless of their nationality; harmonizing the various provisions in the biological and chemical weapons conventions regarding the definition of crimes, the rights of the accused, dispute resolution and judicial assistance; developing a convention focussed on preventive measures that would better secure pathogens that might be used by terrorists; and taking a "bottoms up" approach to biological security that seeks to objectively understand and communicate the benefits and risks of life science research.

According to Professor Nixdorff, professional societies have a positive role to play in governance as seen in the implementation of the Chemical Weapons Convention (CWC). Professional societies of biologists would benefit from having an overarching organization like the International Union of Pure and Applied Chemistry (IUPAC). Individual scientists also have responsibilities. Codes of conduct for life scientists could be effective if they are designed to promote awareness of the complex "dual-use" dilemma and to encourage thought on risk assessments and consideration of alternative approaches during the research process. Governments can encourage universities to offer courses on these subjects in their curricula.

Professor Nixdorff underlined that the registration and licensing of all facilities and their scientists working with agents of biological weapons relevance would be another potentially beneficial biological security measure. Life scientists should be able to demonstrate awareness of the content of the BWC and their obligations as a scientist. Risk assessment models have been developed that could be taught, learned and modified to suit specific needs, subjects or activities. The potential problems are that registration may discourage scientists from working in certain areas and that the cost of implementing the new measures may be prohibitively high.

V. Chair's concluding remarks

Professor Peter Folb summarized the main points discussed by the scientific working group as follows:

Health was considered in our deliberations in its broadest sense — human, animals and plants. We have paid special attention to the needs and vulnerabilities of developing countries, and to capacity development and strengthening in those countries. The capacity referred to is not only that of life scientists; it includes laboratory standards, policies and how they are made, and public health response to emergencies. It will not do for WHO, or other bodies, to respond half-heartedly or in a manner that is not sustained. Indeed, that would be worse than doing nothing at all. The Group identified the need for the global community to respond to these challenges in a manner that is sustained and comprehensive, with continual review, while recognizing the complexity and interlinked relationships of the issues.

WHO has a pivotal role in the process. WHO has access to expertise, indeed, to the world's best and most willing; it would ensure transparency, and it could serve as a central clearing house or facilitate that. In doing so, WHO would need to work with all interested parties — industry, defence and security establishments included — in a spirit of openness and mutual trust that would ensure their full cooperation. Sustained and adequate funding would be a *sine qua non* for any such WHO initiative; there is no doubt that such funding can be secured for this vital international public health initiative. All this is the more important when one considers the speed of change in the biosciences and the potential that exists of a catastrophe. Chernobyl was a "wake-up" call for the nuclear industry. We should not wait for the biological equivalent before preparing a global response. The meeting calls upon the WHO to assume leadership in this initiative. The organization would have special claim to moral authority for global health in doing so.

Admittedly, the issues are complex and the challenge considerable. It would include clinical, scientific and research components. Policy in this field is troubled and there are many conflicting and vested interests. Education and ethics, together with capacity building, lie at the heart of the approach that would be necessary. Yet there are precedents for WHO taking on, and succeeding with, such multifaceted and complex issues. One thinks, for example, of the Global Training Network of the Vaccines and Biologicals Department, of the Expert Committee on Biological Standards and the Global Advisory Committee on Vaccine Safety of the same department, and of the Diarrhoeal Diseases Control Programme in the 1980s and 1990s. The public, their governments and politicians have great faith in WHO, and rightly so. We need to call on that for this purpose and to do whatever is possible to ensure that the Organization in this aspect of public health continues to earn it. WHO should consider establishing a standing scientific advisory group charged with advising the Director-General on the public health implications of the possible use and misuse of biological and toxic materials. The scientific advisory group, supported within the Secretariat by the relevant departments, would consider ethics, life science, technology and policies. It would seek expert advice on a regular basis and commission research as and when required. Bioethics, laboratory standards, and the vital needs of the developing world would receive the scientific advisory group's closest attention. It would advise on and integrate information derived from surveillance and monitoring. It would attend to capacity development. The scientific advisory group would build on what has already been achieved in the field. The efforts of other professional societies would be included by the

scientific advisory group. Its work would be closely aligned to the IHR. Education and training, including ethics, would be among the highest priorities of the scientific advisory group. It would facilitate and encourage the establishment of laboratory networks, and its work would encompass the full spectrum of biorisks. It would need to be served by an excellent secretariat. The scientific advisory group would encourage multinational agreements and discourage bilateral arrangements.

The Group at this meeting decided to request WHO to give the most careful and urgent attention to the results of its deliberations.

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2. Fidler DP. Caught between paradise and power: public health, pathogenic threats, and the axis of illness. *McGeorge Law Review*, 2004, 35: 45–104.
3. *World Report on Knowledge for Better Health. Strengthening Health Systems*. Geneva, World Health Organization, 2004.
4. *The 10/90 report on health research, 2003–2004*. Geneva, Global Forum for Health Research, 2004.

Annex 1 – Agenda

Day 1 - Monday, 16 October

14:00 – 15:30	**Session 1 Introduction**	
14:00 – 14:05	Welcome	Dr Cathy Roth, Team Coordinator EPR/BDP
14:10 – 14:20	Opening Remarks by ETH, RPC and TDR	Dr Andreas Reis, ETH, and Dr Ayoade Oduola, TDR
14:20 – 14:40	Appointments of the Chairman and Rapporteur Adoption of agenda Introduction of participants	
14:40 – 15:00	Project overview	Dr Ottorino Cosivi, EPR/BDP
15:00 – 15:30	Questions and answers	
15:30 – 16:00	**Coffee break**	
16:00 – 18:00	**Session 2 : Working papers**	
16:00 – 16:20	Objectives of the meeting, introduction to working papers	Dr Emmanuelle Tuerlings EPR/BDP
16:20 – 16:40	Questions and answers	
16:40 – 17:05	Working paper on science and security	Dr Caitríona McLeish
17:05 – 17:50	Discussion	
17:50 – 18:00	Wrap-up session	Rapporteur

Day 2 - Tuesday, 17 October

09:00 – 12:30	**Session 3: Working papers**	
09:00 – 09:25	Working paper on ethics	Prof Margaret Somerville (presented by Dr Samia Hurst)
09:25 – 10:30	Discussion	Chairman
10:30 – 11:00	**Coffee break**	
11:00 – 11:25	Working paper on health research	Prof Zulfiqar Bhutta
11:25 – 12:30	Discussion	Chairman
12:30 – 14:00	**Lunch break**	
14:00 – 17:55	**Session 4: Working papers (continued)**	
14:00 – 14:25	Working paper on life science research and duality	Dr David R Franz
14:25 – 15:30	Discussion	Chairman
15:30 – 16:00	**Coffee break**	
16:00 – 16:25	Working paper on governance measures	Prof Kathryn Nixdorff
16:25 – 17:30	Discussion	Chairman
15:30 – 17:45	Wrap-up session	Chairman/Rapporteur

Day 3 - Wednesday, 18 October

09:00 – 12:30	**Session 5: Group discussions**	
09:00 – 09:20	Introduction to group discussions	Dr Ottorino Cosivi, EPR/BDP
09:20 – 10:30	*One group was asked to discuss the scenario: "In an ideal world, what would you like to see happening in 2, 5 and 10 years from now in order to address the challenge and opportunities of life science research? Do not focus only on WHO, provide recommendations that should help your working group to reach your "ideal world" scenario, and consider the consequences if the recommended actions are not undertaken.* *The second group was asked to discuss the scenario: "What specific activities WHO should undertake in the next 2 and 5 years from now in order to address the challenges and opportunities of life science research?" Provide recommendations and consider the opportunities and risks for WHO and Member States if the recommended actions are not undertaken.*	
10:30 – 11:00	**Coffee break**	
11:00 – 12:30	Group discussion (continued)	
12:30 – 14:00	**Lunch break**	
14:00 – 16:00	**Session 6: Group reports**	
14:00 – 14:30	Presentation and discussion of the group reports	
15:30 – 16:00	**Coffee break**	
16:00 – 17:00	**Session 7: Conclusions and recommendations**	
16:00 – 16:15	Wrap-up session	Chairman

Annex 2 – List of participants

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Annex 3

FIFTY-FIFTH WORLD HEALTH ASSEMBLY **WHA55.16**

Agenda item 13.15 18 May 2002

Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health

The Fifty-fifth World Health Assembly,

Underlining that the World Health Organization focuses on the possible public health consequences of an incident involving biological and chemical agents and radionuclear material, regardless of whether it is characterized as a natural occurrence, accidental release or a deliberate act;

Having reviewed the report on the deliberate use of biological and chemical agents to cause harm: public health response;[1]

Seriously concerned about threats against civilian populations, including those caused by natural occurrence or accidental release of biological or chemical agents or radionuclear material as well as their deliberate use to cause illness and death in target populations;

Noting that such agents can be disseminated through a range of mechanisms, including the food- and water-supply chains, thereby threatening the integrity of public health systems;

Acknowledging that natural occurrence or accidental release of biological, chemical agents and radionuclear material could have serious global public health implications and jeopardise the public health achievements of the past decades;

Acknowledging also that the local release of biological, chemical and radionuclear material designed to cause harm could have serious global public health implications and jeopardize the public health achievements of the past decades;

Recalling resolution WHA54.14 on global health security: epidemic alert and response, which stresses the need for all Member States to work together, with WHO and with other technical partners, in addressing health emergencies of international concern, and resolution WHA45.32 on the International Programme on Chemical Safety, which emphasized the need to establish or strengthen national and local capacities to respond to chemical incidents;

[1] Document A55/20

WHA55.16

Recognizing that one of the most effective methods of preparing for deliberately caused disease is to strengthen public health surveillance and response activities for naturally or accidentally occurring diseases,

1. URGES Member States:

(1) to ensure they have in place national disease-surveillance plans which are complementary to regional and global disease-surveillance mechanisms, and to collaborate in the rapid analysis and sharing of surveillance data of international humanitarian concern;

(2) to collaborate and provide mutual support in order to enhance national capacity in field epidemiology, laboratory diagnoses, toxicology and case management;

(3) to treat any deliberate use, including local, of biological and chemical agents and radionuclear attack to cause harm also as a global public health threat, and to respond to such a threat in other countries by sharing expertise, supplies and resources in order rapidly to contain the event and mitigate its effects;

2. REQUESTS the Director-General:

(1) to continue, in consultation with relevant intergovernmental agencies and other international organizations, to strengthen global surveillance of infectious diseases, water quality, and food safety, and related activities such as revision of the International Health Regulations and development of WHO's food safety strategy, by coordinating information gathering on potential health risks and disease outbreaks, data verification, analysis and dissemination, by providing support to laboratory networks, and by making a strong contribution to any international humanitarian response, as required;

(2) to provide tools and support for Member States, particularly developing countries, in strengthening their national health systems, notably with regard to emergency preparedness and response plans, including disease surveillance and toxicology, risk communication, and psychosocial consequences of emergencies;

(3) to continue to issue international guidance and technical information on recommended public health measures to deal with the deliberate use of biological and chemical agents to cause harm, and to make this information available on WHO's web site;

(4) to examine the possible development of new tools, within the mandate of WHO, including modelling of possible scenarios of natural occurrence, accidental release or deliberate use of biological, chemical agents and radionuclear material that affect health, and collective mechanisms concerning the global public health response to contain or mitigate the effects of natural occurrence, accidental release or deliberate use of biological, chemical agents and radionuclear material that affect health.

Ninth plenary meeting, 18 May 2002
A55/VR/9

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