

A Code of Conduct for Biosecurity

Report by the Biosecurity Working Group

Royal Netherlands Academy of Arts and Sciences
Amsterdam, August 2007

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1. Introduction and background

The Dutch Ministry of Education, Culture and Science asked the Royal Netherlands Academy of Arts and Sciences (KNAW) to provide it with advice and input for a national Biosecurity Code of Conduct for scientists, as required by the Biological and Toxin Weapons Convention (BTWC), which was ratified in 1972. The request arose in part from the KNAW's active contribution to the Statement on Biosecurity issued by the InterAcademy Panel (IAP) in 2005. The KNAW is the IAP's 'lead academy' for activities relating to biosecurity.

The KNAW agreed to the ministry's request and carried out a study into the possibilities and conditions for a code of conduct on Biosecurity. That project was supervised by a working group made up of Professor L. van Vloten-Doting (chairman), Professor S.S. Blume, Professor P. Crous and Professor A. van der Eb. The project was carried out by J.J.G. van der Bruggen, who was seconded for this purpose from the Rathenau Institute.

If a code of conduct is to have the intended effect, it must reflect the experience and practice of the relevant actors. It was therefore decided to establish a focus group whose members would make comments and suggestions based on their practical experience as researchers and policymakers. The members of the focus group will also be able to help in the promotion and dissemination of the final product in research institutions and laboratories. A list of the members of the focus group is included in an appendix.

The first step of the project was to conduct a survey of measures already taken by central governments, fellow academies and research institutions in other countries, including the USA and the UK. The information was gathered by studying relevant literature, holding discussions with personal contacts and attending conferences in Edinburgh, Berlin and Washington DC.

A further survey was made of current legislation and existing codes of conduct for biotechnology and microbiology with relevance for biosecurity.

The findings of these surveys were used to identify how the adoption of a code of conduct can help to ensure that biosecurity issues are effectively addressed in scientific research. This led to the formulation of the contours of a code of conduct on biosecurity. The first draft of this code of conduct was submitted to the working group and the biosecurity focus group at the end of January 2007.

A workshop was then organised in March. Most of the participants were researchers and other professionals working in laboratories. The discussion was lively and yielded a number of useful suggestions for practical improvements in the code of conduct.

Following these discussions, a new draft was presented to the focus group and the working group at the end of April. The version presented here is that draft, with a few final corrections and additions. This document was adopted by the Board of Management of the KNAW on 29 May 2007. The Biosecurity Code of Conduct is accompanied by an explanatory memorandum and a background review which were also submitted to the working group and the focus group for comment.

The presentation of the code of conduct completes this phase of the biosecurity project. The KNAW is currently holding talks with the Ministry of Education, Culture and Science on a follow-up project. During this second phase the KNAW will organise debates, workshops and other activities to publicise the code of conduct and promote awareness of the topic of biosecurity. This process is essential for promoting adherence to the code of conduct by scientists.

2. Biosecurity Code of Conduct

2.1 Introduction

Research in the life sciences generates knowledge and understanding that make a significant contribution to global health and welfare. However, the same knowledge and understanding can also be misused to develop biological and toxin weapons. A large number of countries took an important step towards ending the development, production, stockpiling and acquisition of biological and toxin weapons by signing and ratifying the 1972 Biological and Toxin Weapons Convention (BTWC). However, this has not eliminated the risk of misuse of biosciences research. Some states have still not signed the convention, while there is also the risk that terrorists will use biological agents and toxins (bioterrorism).

Scientists and other professionals engaged in biological, biomedical, biotechnological and other life sciences research are bound by the codes of ethics of their professions and their responsibilities as scientists. Their actions are also governed by legislation and by numerous codes of practice. Many of these rules and regulations greatly reduce the risk that research in the life sciences can be misused to develop biological or toxin weapons.

Nevertheless, it is important to continue highlighting the potential for misuse (dual use) of life science research. This was recently reaffirmed in the final declaration issued at the end of the sixth BTWC review conference (November-December 2006), which also referred to the importance of raising awareness of the issue, for example by adopting codes of conduct. At the request of the Ministry of Education, Culture and Science, the Royal Netherlands Academy of Arts and Sciences (KNAW) has assumed the task of formulating a Biosecurity Code of Conduct for the Netherlands.

2.2 Implementation and compliance with the code of conduct

The rules laid down in the Biosecurity Code of Conduct call for implementation and compliance at different levels. These levels correspond with the various target groups identified in the code. Calls for awareness, accountability and oversight are targeted mainly at individuals: researchers, laboratory workers, managers and others. Other provisions apply to research institutions or financing or monitoring agencies.

Because the provisions of the code of conduct apply at different levels and to different types of organisation, it is the responsibility of the organisations themselves to tailor the practical implementation of the code of conduct to the needs of their institution. In practice, many of the rules in the code of conduct will already be implemented by virtue of existing rules and guidelines based on biosafety policy or occupational health and safety legislation. However, additional rules and provisions will sometimes be necessary.

2.3 Supervision and oversight

The organisations and institutions will be able to monitor compliance with these additional rules and instructions themselves. The organisations and institutions will

have to appoint compliance officers with responsibility for this supervision. There is therefore no need for a central supervisory body. However, in the interests of oversight and coordination it would be useful to create a National Biosecurity Centre.¹

The centre's activities would include:

- monitoring relevant developments in the field of biosecurity;
- coordinating the publication of information and educational materials, including maintaining a website with up-to-date information;
- organising conferences;
- maintaining contacts with relevant actors in the government and civil society;
- consulting experts who can provide advice on whether the results of potential dual use life science research should be published;
- performing regular evaluations of awareness of and compliance with the Biosecurity Code of Conduct.

¹ The government could, for example, delegate this task to the KNAW.

Code of conduct on biosecurity

BASIC PRINCIPLES

The aim of this code of conduct is to prevent life sciences research or its application from directly or indirectly contributing to the development, production or stockpiling of biological weapons, as described in the Biological and Toxin Weapons Convention (BTWC), or to any other misuse of biological agents and toxins.

TARGET GROUP

The Biosecurity Code of Conduct is intended for:

1. professionals engaged in the performance of biological, biomedical, biotechnological and other life sciences research;
2. organisations, institutions and companies that conduct life sciences research;
3. organisations, institutions and companies that provide education and training in life sciences;
4. organisations and institutions that issue permits for life sciences research or which subsidise, facilitate and monitor or evaluate that research;
5. scientific organisations, professional associations and organisations of employers and employees in the field of life sciences;
6. organisations, institutions and companies where relevant biological materials or toxins are managed, stored, stockpiled or shipped;
7. authors, editors and publishers of life sciences publications and administrators of websites dedicated to life sciences.

Rules of conduct

RAISING AWARENESS

- ✓ Devote specific attention in the education and further training of professionals in the life sciences to the risks of misuse of biological, biomedical, biotechnological and other life sciences research and the constraints imposed by the BTWC and other regulations in that context.
- ✓ Devote regular attention to the theme of biosecurity in professional journals and on websites.

RESEARCH AND PUBLICATION POLICY

- ✓ Screen for possible dual-use aspects during the application and assessment procedure and during the execution of research projects.
- ✓ Weigh the anticipated results against the risks of the research if possible dual-use aspects are identified.
- ✓ Reduce the risk that the publication of the results of potential dual-use life sciences research in scientific publications will unintentionally contribute to misuse of that knowledge.

ACCOUNTABILITY AND OVERSIGHT

- ✓ Report any finding or suspicion of misuse of dual-use technology directly to the competent persons or commissions.
- ✓ Take whistleblowers seriously and ensure that they do not suffer any adverse effects from their actions.

INTERNAL AND EXTERNAL COMMUNICATION

- ✓ Provide (additional) security for internal and external e-mails, post, telephone calls and data storage concerning information about potential dual-use research or potential dual-use materials.

ACCESSIBILITY

- ✓ Carry out (additional) screening with attention to biosecurity aspects of staff and visitors to institutions and companies where potential dual-use life sciences research is performed or potential dual-use biological materials are stored.

SHIPMENT AND TRANSPORT

- ✓ Carry out (additional) screening with attention to biosecurity aspects of transporters and recipients of potential dual-use biological materials, in consultation with the competent authorities and other parties.

3. Explanatory notes to the text of the code of conduct

Grateful use was made of the comments of numerous stakeholders and experts in developing the Biosecurity Code of Conduct. Existing codes were also studied. These codes provided useful illustrations of the ‘unique’ style and sometimes specific vocabulary used in codes. It became clear that the code of conduct should not lay down specific procedures. These can be found in the existing rules and regulations or, where there are none, a company or organisation can develop its own specific guidelines for putting the code of conduct into practice.

The rules in the code of conduct are briefly explained below.

Raising awareness

- ✓ **Devote specific attention in the education and further training of professionals in the life sciences to the risks of misuse of biological, biomedical, biotechnological and other life sciences research and the constraints imposed by the BTWC and other regulations in that context.**
- ✓ **Devote regular attention to the theme of biosecurity in professional journals and on websites.**

Creating and promoting awareness are the most important reasons for adopting a code of conduct. This subject therefore comes first. The first section is addressed mainly to trainers and managers in the scientific community and the business community who must incorporate biosecurity as a regular and permanent component of training, not only in the initial phase of a scientist’s education but also in further training and on other occasions.

Professional journals and websites of professional associations should also devote attention to the subject of biosecurity, for example by writing about current developments, publishing interviews with experts and – especially on websites – devoting a special page to relevant information on the subject.

A great many people working in the life sciences regularly consult these sources for up-to-date information about developments in their profession or perhaps to look for jobs or courses they can follow. Their attention can then be drawn to the possible risks of potential dual-use applications.

Research and publication policy

- ✓ **Screen for possible dual-use aspects during the application and assessment procedure and during the execution of research projects.**
- ✓ **Weigh the anticipated results against the risks of the research if possible dual-use aspects are identified.**
- ✓ **Reduce the risk that the publication of the results of potential dual-use life sciences research in scientific publications will unintentionally contribute to misuse of that knowledge.**

The first thing that has to be said is that these rules of conduct are not intended to impede (new) research or scientific publications. The point of departure is to allow

scientific research and the inseparably linked publication of research results to proceed unimpaired.

However, it is legitimate to demand that every individual or institution with direct or indirect responsibility for initiating, financing or conducting research in the life sciences should consider the potential dual-use character of the research as one of the criteria in deciding whether to conduct that research. Biosecurity should be explicitly included in the check list of issues to be considered in application and assessment forms for life sciences research. In the vast majority of cases, this aspect will not affect the final decision, either because the risk is extremely small or because the benefits of the research outweigh the risks, although in the latter case adequate security measures must be taken throughout the course of the research. Only in those cases where the risks of a study are demonstrably greater than the expected benefits does the code of conduct advise against performing the relevant research.

The rules governing the publication of research results follow from the rules for the performance of research. Here too, publication is the rule and non-publication the rare exception. This is apparent from the experience in the United States, for example, where the screening of thousands of articles for dual-use aspects has raised questions in only five or six cases and up to now has never led to a decision not to publish the article. Even if the results of research clearly have a dual-use character, it does not mean that the results should not be published. They can be published in such a way that they do not produce ready-made instructions for individuals who may wish to misuse them.

Publishers, editors and reviewers may be asked to consider the possible dual-use nature of the information when assessing articles. In those exceptional cases where doubts arise about whether or not to publish an article, the final decision could be taken by a specially appointed committee of experts.

Finally, once an article has been published, information contained in it that was not initially regarded as risky may in time prove to have a dual-use character, for example because of new scientific developments. This is an almost inevitable fact of life.

Accountability and oversight

- ✓ **Report any finding or suspicion of misuse of dual-use technology directly to the competent persons or commissions.**
- ✓ **Take whistleblowers seriously and ensure that they do not suffer any adverse effects from their actions.**

Calling for accountability and oversight is not intended to create a culture of mistrust in a company or scientific institution. It is always important to assume that colleagues and visitors are acting in good faith. But history – particularly in the Netherlands – has shown that abuses can occur. A well-known example is the action of the Pakistani nuclear physicist Khan who took the ‘recipe’ for the atomic bomb from the Dutch company Urenco, where he worked for many years. Behaviour or actions that are out of the ordinary should therefore be reported to a specially designated officer

in a company or laboratory. Any such reports should of course be dealt with in confidence and prudently, especially if the warning concerns an individual.

On the other hand, it is important to ensure that whistleblowers do not suffer reprisals for their intervention. For example, their privacy must be guaranteed even if their tips prove unfounded, although in that case the ombudsman can investigate whether the whistleblower had ulterior motives for providing the tip.

Internal and external communication

- ✓ **Provide (additional) security for internal and external e-mails, post, telephone calls and data storage concerning information about potential dual-use research or potential dual-use materials.**

Nowadays a lot of internal and external communication is conducted electronically. This brings with it the risk that e-mails can be intercepted, websites can be hacked, USB sticks can be lost, etc. Institutions must therefore ensure that anyone who transmits information or saves data about potential dual-use research or potential dual-use materials employs additional security for their communication, for example by using separate e-mail circuits, encoding or encrypting the information, protecting USB sticks with security mechanisms, etc.

It goes without saying that appropriate security measures must also be taken when information is sent using the traditional means of communication such as post, telephone or fax or when employees take documents home from work.

Primary responsibility for implementing the additional security in these areas rests with the ICT managers, although they will require the assistance of the individuals responsible for the information itself in identifying potential risks.

Accessibility

- ✓ **Carry out (additional) screening with attention to biosecurity aspects of staff and visitors to institutions and companies where potential dual-use life sciences research is performed or potential dual-use biological materials are stored.**

Shipment and transport

- ✓ **Carry out (additional) screening with attention to biosecurity aspects of transporters and recipients of potential dual-use biological materials, in consultation with the competent authorities and other parties.**

Various laws and regulations concerning biosafety already contain numerous rules and guidelines governing access to laboratories and research institutions. These rules will generally be adequate to guarantee safety in the context of biosecurity. However, it is important for laboratories and research institutions to investigate whether additional security measures may be needed, both with respect to materials and in terms of screening procedures for employees and visitors.

Quasi-public institutions such as universities, institutions of higher professional education and hospitals in particular should investigate whether potential

dual-use materials are adequately safeguarded in areas to which the public does not have access.

Many regulations are already in place governing the transport of biological materials from the perspective of biosafety. In the context of biosecurity, attention should focus on the transporters and recipients of dual-use agents. In consultation with the competent authorities, organisations can investigate whether additional screening requirements can or should be imposed on the transporters and their staff in relation to biosecurity. The forwarding party must satisfy itself that the recipients of dual-use agents will only use the materials they receive for scientific purposes. If any doubt exists, further enquiries may lead to the decision not to send the relevant materials.

The responsible security officials should receive any additional training and information they need to recognise risks related to biosecurity.

4. Background to a Biosecurity Code of Conduct

The anthrax letters, September 2001

Shortly after 11 September 2001 the United States received another scare, this time caused by the so-called anthrax letters. These letters arrived in two waves. The first set was sent from Trenton, New Jersey to newspapers and media in New York and Boca Raton (Florida) on 18 September 2001. Only two of these letters were found but the outbreak of anthrax infections led to the conclusion that there were others. On 9 October two more letters were sent, again from Trenton, addressed to two Democratic senators at the Capitol in Washington DC. The material in these two letters was stronger than the substance in the first set. The letters contained approximately one gram of almost pure anthrax spores. According to researchers, the anthrax was 'weaponised', although this was later denied. More than 22 people were infected, 11 of them with a life-threatening variant. Five people ultimately died. The anthrax letters created a worldwide panic and prompted additional security measures in the handling of post. On several occasions these measures led to the suspicion of new attacks, usually because some inevitable 'jokers' sent envelopes containing a different type of white powder.

4.1 Background and prior history

The decision to draft a code of conduct on biosecurity was taken in response to the widespread recognition of the increased threat of the production and use of biological weapons. The above examples are an illustration of this. The risk of bioterrorism is regarded as more serious than the threat that biological and toxin weapons² will be used by governments. The efforts to develop a code of conduct are also related to the Biological and Toxin Weapons Convention (BTWC), which the Netherlands has ratified (see Appendix 1). During the fifth review conference in 2002 and at interim expert meetings of the States Parties to the BTWC, there were calls for the adoption of codes of conduct. This call was repeated at the sixth review conference of the BTWC in the autumn of 2006. 'The Conference encourages States Parties to take necessary measures to promote awareness amongst relevant professionals of the need to report activities conducted within their territory or under their jurisdiction or under their control that could constitute a violation of the Convention or related national criminal law. In this context, the Conference recognises the importance of codes of conduct and self-regulatory mechanisms in raising awareness, and calls upon States Parties to support and encourage their development, promulgation and adoption' (point 15 (of Article IV) in the Final Document Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production

² The term toxin is usually used to describe a potent, complex organic compound of biological origin. There are mineral, vegetable, bacterial and animal toxins.

and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction).

The warnings from the BTWC were picked up by the academic world, including the InterAcademy Panel (IAP), a body that includes representatives of academies of sciences from around the world. Consequently, 68 academies of science signed the IAP's 'Statement on Biosecurity'. This statement was issued in 2005 and sets out the principles that should be taken into account when formulating a code of conduct on biosecurity (see Appendix 2).

At the request of the Ministry of Education, Culture and Science, the Royal Netherlands Academy of Arts and Sciences (KNAW) has drawn up a Biosecurity Code of Conduct for the Netherlands.

4.2

Biological weapons

What do we mean by biological and toxicological weapons? There are many different definitions and descriptions. An explanatory memorandum to the BTWC describes these weapons as follows³:

'Biological weapons are devices which disseminate disease-causing organisms or poisons to kill or harm humans, animals or plants. They generally comprise two parts – an agent and a delivery device. In addition to their military use as strategic weapons or on a battlefield, they can be used for assassinations (having a political effect), can cause social disruption (for example, through enforced quarantine), kill or remove from the food-chain livestock or agricultural produce (thereby causing economic losses), or create environmental problems.

Almost any disease-causing organism (such as bacteria, viruses, fungi, prions or rickettsiae) or toxin (poisons derived from animals, plants or microorganisms, or similar substances synthetically produced) can be used in biological weapons. Historical efforts to produce biological weapons have included: aflatoxin; anthrax; botulinum toxin; foot-and-mouth disease; glanders; plague; Q fever; rice blast; ricin; Rocky Mountain spotted fever; smallpox; and tularaemia. The agents can be enhanced from their natural state to make them more suitable for use as weapons.

Delivery devices can also take any number of different forms. Some more closely resemble weapons than others. Past programmes have constructed missiles, bombs, hand grenades and rockets. A number of programmes also constructed spray-tanks to be fitted to aircraft, cars, trucks, and boats. Efforts have also been documented to develop delivery devices for use in assassination or sabotage missions, including a variety of sprays, brushes, and injection systems as well as contaminated food and clothes.

As well as concerns that these weapons could be developed or used by states, modern technology is making it increasingly likely they could be acquired by private organisations, groups of people or even individuals. The use of these weapons by such non-state actors is known as bioterrorism. Biological weapons have been used in politically-motivated or criminal acts on a number of occasions during the 20th century.'

3 [http://www.unog.ch/80256EE600585943/\(httpPages\)/29B727532FEcBE96C12571860035A6DB?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/29B727532FEcBE96C12571860035A6DB?OpenDocument)

Dual use

As the extract quoted above explicitly states, there are many different disease-causing organisms that can be used in biological weapons. On the other hand, many of these organisms are extremely important for research and development in the domains of medicine, biology and agriculture. These organisms can therefore be used for two purposes. The term used by the international community for these types of organism is ‘dual use’.

‘Dual use’ is one of the key terms employed in discussions of the risks of misuse of biological agents. One general description of the term is given by the American National Science Advisory Board for Biosecurity (NSABB). Its description is as follows: ‘Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment or material.’

Elsewhere, the NSABB argues that special attention is required for knowledge, products or technologies that:

- enhance the harmful consequences of a biological agent or toxin;
- disrupt immunity or the effectiveness of an immunisation without clinical and/or agricultural justification;
- confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies;
- increase the stability, transmissibility or the ability to disseminate a biological agent or a toxin;
- alter the ‘host range’ or ‘tropism’ of a biological agent or toxin;
- enhance the susceptibility of a host population; and/or
- generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

This list of features does not necessarily lead to definitive conclusions for research policy in practice, as is apparent from a number of other considerations mentioned by members of the NSABB. For example, NSABB member Anne Vidaver remarked that ‘dual use concerns pertain to misapplication of technologies yielded by the research, not the conduct of the research itself’. Consequently, identifying research as ‘dual use’ does not necessarily mean that the research should not be conducted or that the results should not be published. Interestingly, the NSABB adds the words ‘of concern’ to the term dual-use research. This implies that not all dual-use research is a cause for concern. Concerns arise if the results of the research can be directly misapplied (immediacy) and when such misuse would have major consequences (scope), which does not have to mean a large number of victims but can also refer to large-scale social disruption.

However, even these two criteria do not immediately produce clarity. The aim of terrorists in particular does indeed seem to be to strike immediately and on a large scale. But is that always the case? The anthrax attacks in the US (2001) ultimately caused ‘only’ five fatalities, but the panic they caused was enormous!

So there are thousands of biological agents that can potentially be misused. But documents, treaties and reports – such as the text quoted above – often refer to specific agents that are particularly susceptible to misuse. A detailed list can be found in the article *CBRNE – Biological Warfare Agents*.⁴ Many states, including the US, have their own lists.⁵ The Health Council in the Netherlands has a far shorter list⁶: variola major virus (smallpox); *Bacillus anthracis* (anthrax); *Yersinia pestis* (the plague); *Clostridium botulinum* toxin (botulism); *Francisella tularensis* (tularemia); and the influenza virus. Moreover, there is growing need to take account of genetic modification of existing pathogens.

The Ministry of Economic Affairs has also published a Manual on Strategic Goods, which contains a list of dual use micro-organisms and toxins. Other initiatives have been taken at international level. One of the best known is the Australia Group, an informal arrangement in which 39 states (including the Netherlands) and the European Commission currently cooperate in efforts to minimise the risk that exports or transshipments from the countries concerned will (unintentionally) contribute to chemical or biological weapon proliferation. The participating states do this by exchanging information about suspicious shipments and by compiling lists of potentially suspect materials and agents.⁷

4.4

Threat analysis

How great is the threat that biological weapons will actually be used? Historically speaking, until the beginning of the 20th century the use of biological weapons took three forms: 1) the poisoning of food or water with infectious agents; 2) the use of micro-organisms or toxic substances in weapon systems; 3) the spread of infected substances and materials.

For example, Emperor Frederik I (Barbarossa) threw corpses into sources of drinking water and American Indians were given sheets or clothing used by smallpox patients.

The methods adopted during World War I were more refined. Relatively little use was actually made of biological weapons, although there is evidence that the Germans spread bubonic plague in St. Petersburg. In 1925, 108 countries signed the Geneva Protocol prohibiting the use of biological weapons. However, some countries, including the US and the Soviet Union, continued with production and research. Japan carried out experiments on Chinese prisoners during the World War II. Great Britain, Canada and the United States conducted experiments with anthrax on the Scottish island of Gruinard. The island was only ‘cleared’ in the 1990s. The experiments continued after the war, sometimes with fatal consequences. It is generally assumed that a mistake during an experiment with anthrax in Sverdlovsk in Russia caused more than 70 deaths in April 1979.

This accident occurred after the signing of the Biological and Toxin Weapons

4 <http://www.emedicine.com/emerg/topic853.htm>

5 <http://www.cdc.gov/od/sap/docs/salist.pdf>;

6 Health Council. *Verdediging tegen bioterrorisme. [Defence against Bioterrorism]* The Hague: Health Council, 2001; publication no. 2001/16

7 See: http://www.australiagroup.net/en/control_list/bio_agents.htm

Convention (BTWC) in 1972. This convention prohibits the development and production of biological weapons. Consequently, almost every country has disabled or destroyed its stockpile of weapons, although 17 countries are still suspected of possessing or producing biological weapons.

But the greatest threat is now thought to come from the use of biological weapons by terrorists. These fears increased after 9/11 and after letters containing anthrax were posted in the US a short time later.

The General Intelligence and Security Service (AIVD) and the National Coordinator for Anti-Terrorism (NCTB) are constantly carrying out analyses of the actual threat of a terrorist attack, including the risk that biological weapons might be used. It is reasonably safe to assume that even now there is no really serious threat of such weapons being used. One reason for this is that few people possess the biological and medical knowledge required to produce disease-causing agents. Fantastical reports that any schoolchild can simply download instructions for producing biological weapons from the internet are greatly exaggerated. And in this day and age, clothes and blankets infected with chickenpox are not widely available. Nevertheless, however small the threat, the risk is so great that it must not be underestimated or trivialised. This warning applies above all to the scientific community.

4.5 Life sciences and biological weapons

Given the revolutionary developments in the field, public interest in the life sciences is greater than ever before. Many people expect the breakthroughs that have been achieved in recent years to make a major contribution to solving health, food and environmental problems. And progress is being made all the time. Research in the fields of genomics and proteomics is still in its infancy. There has also been a lot of attention recently for the emergence of synthetic biology. Synthetic biology can be defined as the design and replication of biological components, devices and systems (DNA) and the redesign of existing, natural biological systems (for example a virus or bacteria) for specific purposes, such as the development of medicines.

There is also a potential downside to many of these developments. They can be misused to produce biological weapons or to carry out bioterrorist attacks.

Since cutting-edge knowledge is needed to produce biological weapons, it is particularly important that scientists who possess this expertise are aware of the potential risks associated with the application or misuse of their knowledge. Recent research, by Brian Rappert⁸ among others, has shown that relatively few scientists are aware of those risks. It is therefore vital to raise awareness among scientists. This is also one of the conclusions from *Biotechnology Research in an Age of Terrorism*, a report written by a committee of the American National Research Council chaired by the biologist Gerald Fink (MIT).⁹ This authoritative

8 Rappert, B. (2003). Expertise, Responsibility and the Regulation of Research in the UK. Presented at Foreign and Commonwealth Office seminar entitled 'Managing the Threats from Biological Weapons: Science, Society, and Secrecy', 28 July.

9 Committee on Research, Standards and Practices to prevent the Destructive Application of Biotechnology (2004), *Biotechnology Research in an Age of Terrorism*. National Research Council, Washington DC.

report prompted the US government to establish the National Science Advisory Board for Biosecurity (NSABB).

Researchers, laboratory workers and other employees of large research laboratories have traditionally displayed a great deal of vigilance and alertness, since even without the danger of (efforts to) misuse the findings, there are numerous risks attached to biological and genetic research, such as infection and the spread of potentially harmful agents in the natural environment, etc. Many laws and regulations have been promulgated at national and international level to address these risks. Most of these rules have been translated into practical guidelines in research institutions, companies and laboratories. The following section discusses these laws and regulations.

It is also important to note that various agencies are increasingly alert to the possibility of disease-causing agents being dispersed intentionally. In the Netherlands, for example, the National Coordinator for Infectious Disease Control (LCI) has revised numerous protocols to ensure that additional attention is devoted to the aspect of biosecurity¹⁰ in compliance with one of the recommendations made by a committee of the Health Council in 2001 (before 11 September!).¹¹

4.6

Existing legislation

Numerous laws and regulations have been drawn up in the last few decades at both national and international level to guarantee the safety and health of employees, visitors to and people living close to biological research laboratories and research institutions. The attention to health and safety has intensified further in recent years following the emergence of new epidemics such as SARS and avian influenza (bird flu). Many of the instructions and rules designed to promote biosafety are also relevant to efforts to combat the misuse of bioscientific research for terrorism.

The legislation can be broken down into general legislation, which also applies to other industries, and legislation specifically targeted at scientific institutions. General legislation includes occupational health and safety laws and environmental legislation, legislation governing the transport of hazardous substances (ADR) and the Building Decree. These laws and regulations generally include separate chapters on specific substances or activities, for example the transport of hazardous substances.

There are also regulations that relate specifically to research and which can cover various different aspects. For example, the website of the Platform of Biological Safety Officers (BVF) contains a section with rules on how to handle biological agents.¹² To give another example, Appendix 3 contains a list of laws and regulations pertaining to genetic modification. The table below lists some examples of laws and regulations together with the body that promulgated them and their scope.

10 See website LCI: <http://www.infectieziekten.info/index.php3>

11 'Existing LCI protocols (LCI: National Coordinator for Infectious Disease Prevention) for some priority agents should be expanded with an appendix on possible bioterrorist applications', in: Health Council, op.cit. 2001.

12 <http://www.bvfplatform.nl/wetregelgeving/voorschriften.html>

Table 1: Examples of laws and regulations

	General	Biosciences	Biosecurity
Global and International	Stockholm Convention on Persistent Organic Pollutants Kyoto protocol	Convention on biological diversity/Cartagena protocol	Biological and Toxin Weapons Convention (BTWC) Guidelines For Transfers of Sensitive Chemical or Biological Items (Australia Group)
European	ADR Convention (transport)	Protection of workers exposed to biological agents at work	
National	Working Conditions Act Building Regulations Environmental legislation Dangerous Substances Act	Decree on Genetically Modified Organisms	List of Strategic Goods
Regional/local	Environmental permit		
Company, organisation, sector	Organisation's Safety, Health and Environment rules.	Measures for working safely with cells and tissue cultures (BVF Platform) Practical guidelines for the shipment and transport of biological materials intended for human or animal diagnosis (Netherlands Association for Microbiology)	

What stands out is that there are few if any agreements and rules specifically addressing the issue of biosecurity, particularly at institutional level. There is a growing realisation among biosafety officials that biosecurity could become an increasingly important aspect of their duties. Nevertheless, measures have been and still are being taken in that area. For example, many establishments have tightened up the rules on access, which were already in place under the biosafety procedures, in the context of biosecurity. Additional measures have also been taken in the areas of transport and exports.

4.7 What is a code of conduct?

Many organisations have adopted codes of conduct for various aspects of their activities in recent years. A code is a set of principles and instructions that are binding on members of a particular group in a profession or industry. Codes should not be confused with guidelines (which are less binding) and contracts or treaties (which are more binding).¹³

¹³ Pearson, Graham S., and Dando, Malcolm R. *Towards a life sciences code: countering the threats from biological weapons*. Bradford Briefing Papers, University of Bradford Department of Peace Studies, UK. 2004.

A further distinction can be made according to the agency that drafts the code. Some codes are formulated by government bodies. For example, the Municipalities Act provides that the local councils must adopt a code of conduct for their members, the aldermen and the mayor. Institutions and companies also draw up codes laying down how their employees should act. Philips, for instance, has a General Code of Conduct setting out the company's ethical standards for conducting business. The code of conduct lays down the basic principles to be followed in all of Philips's business activities.¹⁴ Then of course there are codes drawn up by and for specific professional groups. More and more professions have adopted professional codes in recent decades. The medical world has traditionally observed the 'Hippocratic Oath', but other professions have also adopted general professional codes. One example is the code of the Netherlands Institute for Biology.¹⁵ Finally, there are also codes that are drawn up 'externally' for specific groups of individuals or organisations. One example is the *Code of Ethics for Persons and Institutions Engaged in the Life Sciences* drafted by the influential Pugwash movement.¹⁶

Finally, codes can also be categorised according to their content and their target group. The three categories are codes of ethics, codes of conduct and codes of practice.¹⁷ A code of ethics describes in more general terms the personal and professional standards and ideals that practitioners should uphold; a code of conduct lays down guidelines for appropriate behaviour; and a code of practice describes how individuals should act in specific situations. The latter category is the most specific.

The table below, courtesy of Brian Rappert, fleshes out this typology.

Table 2: Types of code

Type	Name	Main Aims
<i>Aspirational codes</i>	Code of ethics	Alert; set realistic or idealistic standards
<i>Educational/ Advisory codes</i>	Code of conduct	Provide guidelines, raise awareness & debate; foster moral agents
<i>Enforceable codes</i>	Code of practice	Prescribe or proscribe certain acts

The table below presents a number of existing codes of the various types and categories that could serve as possible examples for a code of conduct for biosciences and biosecurity.

14 <http://www.philips.nl/About/company/local/corporategovernance/Index.html>

15 <http://www.nibi.nl/>

16 <http://www.pugwash.org/reports/cbw/cbwlist.htm>

17 Brian Rappert, *Towards a life sciences code: countering the threats from biological weapons. Strengthening the Biological Weapons Convention*, Briefing paper 13, Second Series. Department of Peace Studies, University of Bradford. Available online: www.brad.ac.uk/acad/sbtwc/BP_13_2ndseries.pdf

Table 3: Examples of codes

	Code of Ethics	Code of Conduct	Code of Practice
Government code	Rigour, Respect and Responsibility: a universal ethical code for scientists (UK government)	Code of scientific ethics for the United States Department of Agriculture	Code of conduct for prudent forest management
Institutional code	EuropaBio's core ethical values (EuropaBio)	Philips's general code of conduct Code of conduct of the pharmaceutical industry	Code of conduct for pharmaceutical advertising
Professional code	Dutch medical oath (KNMG)	Rules of conduct for doctors (KNMG)	Guideline on online doctor-patient contact (KNMG)
External code		INES Appeal to engineers and scientists	

4.8 **Why a code of conduct on biosecurity?**

A code of conduct can make good people better, but probably has negligible impact on intentionally malicious behaviour (NSABB).

If this is true – and there is little reason to doubt that it is – the question is why there should be a code of conduct on biosecurity. What is its added value alongside existing codes and existing legislation at different levels? And will a code of conduct provide this added value or would new or amended legislation be more appropriate?

In a formal sense, the why is fairly easy to answer. By formulating a code of conduct the academic world in the Netherlands is meeting the wishes of national and international authorities: the States Parties to the BTWC and the Dutch government. It is also in line with the statement of the IAP, to which the KNAW made a major contribution.

But this formal argument is inadequate. According to a survey of the academies of science that endorsed the IAP statement, only three countries, Albania, France and the Netherlands, have started drafting a national code of conduct on biosecurity. That is not to say that no steps have been taken in the other countries, but merely that they have not yet decided to develop a code of conduct. What is happening in many places is that debates about biosecurity are being conducted in the academic world. For example, Dando and Rappert have been organising workshops in various countries.¹⁸ These have helped to raise awareness of the possible risks of the misuse of biological knowledge.

¹⁸ Brian Rappert, Marie Chevrier and Malcolm Dando, *In-depth Implementation of the BTWC: Education and Outreach*. University of Bradford 2006.

The KNAW is of the opinion that drawing up a code of conduct on biosecurity is not a goal in itself. There is no point in having a document that simply disappears into a desk drawer or a filing cabinet. Raising awareness is the most important objective of a code of conduct on biosecurity, which is why the code of conduct presented here was developed in dialogue with practitioners and with stakeholders from the world of science, the business community and government. After all, the content of the code of conduct must reflect relevant scientific, social and political developments and, equally importantly, the day-to-day practice of individuals and organisations working in the field.

The process of drafting the code of conduct has already helped to raise awareness. It has prompted regular debates and encouraged various organisations and professional associations to discuss the subject. The added value of the code of conduct will have to be seen in practice. Here too, actions speak louder than words. There must be a change of attitude and behaviour. There will have to be regular evaluation of questions such as: How is the code being implemented? How effectively is it being disseminated and communicated? Is the code being complied with?

The code of conduct on biosecurity will be publicised by organising debates and meetings in relevant laboratories and research institutes of universities and companies and through publications in trade journals.

Appendices

**1. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (1972)
(Entry into force: 26 March 1975)**

The States Parties to this Convention,
Determined to act with a view to achieving effective progress toward general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and convinced that the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures, will facilitate the achievement of general and complete disarmament under strict and effective control,

Recognizing the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925, and conscious also of the contribution which the said Protocol has already made and continues to make, to mitigating the horrors of war,

Reaffirming their adherence to the principles and objectives of that Protocol and calling upon all States to comply strictly with them,

Recalling that the General Assembly of the United Nations has repeatedly condemned all actions contrary to the principles and objectives of the Geneva Protocol of June 17, 1925,

Desiring to contribute to the strengthening of confidence between peoples and the general improvement of the international atmosphere,

Desiring also to contribute to the realization of the purposes and principles of the Charter of the United Nations,

Convinced of the importance and urgency of eliminating from the arsenals of States, through effective measures, such dangerous weapons of mass destruction as those using chemical or bacteriological (biological) agents,

Recognizing that an agreement on the prohibition of bacteriological (biological) and toxin weapons represents a first possible step towards the achievement of agreement on effective measures also for the prohibition of the development, production and stockpiling of chemical weapons, and determined to continue negotiations to that end,

Determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

Convinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk,

Have agreed as follows:

Article I

Each State Party to this Convention undertakes never in any circumstance to develop, produce, stockpile or otherwise acquire or retain:

1. Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

2. Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

Article II

Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, which are in its possession or under its jurisdiction or control. In implementing the provisions of this article all necessary safety precautions shall be observed to protect populations and the environment.

Article III

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

Article IV

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Article V

The States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and cooperation pursuant to this article may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.

Article VI

1. Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.
2. Each State Party to this Convention undertakes to cooperate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council. The Security Council shall inform the States Parties to the Convention of the results of the investigation.

Article VII

Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.

Article VIII

Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any State under the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925.

Article IX

Each State Party to this Convention affirms the recognized objective of effective prohibition of chemical weapons and, to this end, undertakes to continue negotiations in good faith with a view to reaching early agreement on effective measures for the prohibition of their development, production and stockpiling and for their destruction, and on appropriate measures concerning equipment and means of delivery specifically designed for the production or use of chemical agents for weapons purposes.

Article X

1. The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes.
2. This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

Article XI

Any State Party may propose amendments to this Convention. Amendments shall enter into force for each State Party accepting the amendments upon their acceptance by a majority of the States Parties to the Convention and thereafter for each remaining State Party on the date of acceptance by it.

Article XII

Five years after the entry into force of this Convention, or earlier if it is requested by a majority of the Parties to the Convention by submitting a proposal to this effect to the Depositary Governments, a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.

Article XIII

1. This Convention shall be of unlimited duration.
2. Each State Party to this Convention shall in exercising its natural sovereignty have the right to withdraw from the Convention if it decides that extraordinary events, related to the subject matter of the Convention, have jeopardized the supreme interests of its country. It shall give notice of such withdrawal to all other States Parties to the Convention and to the United Nations Security Council three months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

Article XIV

1. This Convention shall be open to all States for signature. Any State which does not sign the Convention before its entry into force in accordance with paragraph (3) of this Article may accede to it at any time.
2. This Convention shall be subject to ratification by signatory States. Instruments of ratification and instruments of accession shall be deposited with the Governments of the United States of America, the United Kingdom of Great Britain and Northern Ireland and the Union of Soviet Socialist Republics, which are hereby designated the Depositary Governments.
3. This Convention shall enter into force after the deposit of instruments of ratification by twenty-two Governments, including the Governments designated as Depositaries of the Convention.
4. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Convention, it shall enter into force on the date of the deposit of their instrument of ratification or accession.
5. The Depositary Governments shall promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or of accession and the date of the entry into force of this Convention, and of the receipt of other notices.
6. This Convention shall be registered by the Depositary Governments pursuant to Article 102 of the Charter of the United Nations.

Article XV

This Convention, the English, Russian, French, Spanish and Chinese texts of which are equally authentic, shall be deposited in the archives of the Depositary Governments. Duly certified copies of the Convention shall be transmitted by the Depositary Governments of the signatory and acceding States.

In evidence whereof the undersigned, duly authorised, have signed this Convention.

Done in three copies at London, Moscow and Washington on the 10th of April 1972.

2. IAP Statement on Biosecurity

*Knowledge without conscience
is simply the ruin of the soul.*
F. Rabelais, 1532¹⁹

In recent decades scientific research has created new and unexpected knowledge and technologies that give unprecedented opportunities to improve human and animal health and the conditions of the environment. But some science and technology can be used for destructive purposes as well as for constructive purposes. Scientists have a special responsibility when it comes to problems of ‘dual use’ and the misuse of science and technology.

The 1972 Biological and Toxin Weapons Convention reinforced the international norm prohibiting biological weapons, stating in its provisions that ‘*each state party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic or other peaceful purposes.*’ Nevertheless, the threat from biological weapons is again a live issue. This document presents principles to guide individual scientists and local scientific communities who may wish to define a code of conduct for their own use.

These principles represent fundamental issues that should be taken into account when formulating codes of conduct. They are not intended to be a comprehensive list of considerations. These principles have been endorsed by the national Academies of science, working through the InterAcademy Panel, whose names appear below.

- 1. Awareness.** Scientists have the obligation *to do no harm*. They should always take into consideration the reasonably foreseeable consequences of their own activities. They should therefore:
 - always bear in mind the potential consequences – possibly harmful – of their research and recognize that individual good conscience does not justify ignoring the possible misuse of their scientific endeavour;
 - refuse to undertake research that has only harmful consequences for humankind.
- 2. Safety and Security.** Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or by common practice.²⁰
- 3. Education and Information.** Scientists should be aware of, disseminate and teach the national and international law and regulations, as well as policies and principles aimed at preventing the misuse of biological research.

¹⁹ ‘Science sans conscience nest que ruïne de l’âme.’

²⁰ Such as the WHO Biosafety Manual, Second Edition (Revised).

- 4. Accountability.** Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or international customary law should raise their concerns with appropriate people, authorities and agencies.
- 5. Oversight.** Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation.

These principles have been endorsed by the following national academies of science, working through the Inter Academy Panel:

Albanian Academy of Sciences
National Academy of Exact, Physical and Natural Sciences, Argentina
The National Academy of Sciences of Armenia
Australian Academy of Science
Austrian Academy of Sciences
Bangladesh Academy of Sciences
National Academy of Sciences of Belarus
The Royal Academies for Science and the Arts of Belgium
Academy of Sciences and Arts of Bosnia and Herzegovina
Brazilian Academy of Sciences
Bulgarian Academy of Sciences
Cameroon Academy of Sciences
The Royal Society of Canada
Chinese Academy of Sciences
Academia Sinica, China Taiwan
Colombian Academy of Exact, Physical and Natural Sciences
Croatian Academy of Arts and Sciences
Cuban Academy of Sciences
Academy of Sciences of the Czech Republic
Royal Danish Academy of Sciences and Letters
Academy of Scientific Research and Technology, Egypt
Estonian Academy of Sciences
The Delegation of the Finnish Academies of Science and Letters
Académie des Sciences, France
Union of German Academies of Sciences and Humanities
Academy of Athens, Greece
Hungarian Academy of Sciences
Indian National Science Academy
Indonesian Academy of Sciences
Royal Irish Academy
Israel Academy of Sciences and Humanities
Accademia Nazionale dei Lincei, Italy
Science Council of Japan
African Academy of Sciences
Kenya National Academy of Sciences

The National Academy of Sciences, The Republic of Korea
National Academy of Sciences of the Kyrgyz Republic
Latvian Academy of Sciences
Lithuanian Academy of Sciences
Macedonian Academy of Sciences and Arts
Akademi Sains Malaysia
Academia Mexicana de Ciencias
Academy of the Kingdom of Morocco
The Royal Netherlands Academy of Arts and Sciences
Academy Council of the Royal Society of New Zealand
Nigerian Academy of Sciences
Pakistan Academy of Sciences
Palestine Academy for Science and Technology
Academia Nacional de Ciencias del Peru
National Academy of Science and Technology, Philippines
Polska Akademia Nauk, Poland
Russian Academy of Sciences
Académie des Sciences et Techniques du Sénégal
Serbian Academy of Sciences and Arts
Singapore National Academy of Sciences
Slovak Academy of Sciences
Slovenian Academy of Sciences and Arts
Academy of Science of South Africa
Royal Academy of Exact, Physical and Natural Sciences of Spain
Royal Swedish Academy of Sciences
Council of the Swiss Scientific Academies
Turkish Academy of Sciences
The Uganda National Academy of Sciences
The Royal Society, UK
US National Academy of Sciences
Academia de Ciencias Físicas, Matemáticas y Naturales de Venezuela
Zimbabwe Academy of Sciences
TWAS, the Academy of Sciences for the Developing World

3. Laws and rules on genetic modification

National

Anyone working with genetically modified organisms in the Netherlands must possess a permit. These permits are issued by the Ministry of Housing, Spatial Planning and the Environment.

Decree on Genetically Modified Organisms (GMO Decree)²¹

A permit is required under the GMO Decree for activities involving GMOS within establishments such as laboratories ('contained use'). The establishment must also have a permit under the Environmental Management Act. There is a central European procedure governing activities involving GMOS outside establishments ('introduction into the environment'). This procedure is described in Directive 2001/18/EC. The GMO Decree provides that a permit is required if the GMOS are only introduced into the environment for research purposes and are not brought onto the market.

Ministerial Regulation on Genetically Modified Organisms (GMO Regulation)²²

The GMO Regulation is linked to the GMO Decree and contains more detailed rules, general safety prescriptions and rules for specific types of facility and for working with GMOS. The GMO Regulation applies primarily to the contained use of GMOS.

Environmental Management Act²³ and the Establishments and Permits Decree

The Environmental Management Act and the Establishments and Permits Decree provide that an institution must have a permit for the contained use of GMOS. The Environmental Management Act permit lays down the requirements that a facility must comply with. These permits are generally issued by the municipality or province in which the establishment is located.

Other national legislation governing GMOs

Other permits are also needed for some activities involving the use of GMOS.

In addition to an environmental permit, institutions require a permit under the Decree on biotechnology with animals²⁴ for genetic modification of animals. The competent authority is the Ministry of Agriculture, Nature Management and Food Quality. The Act on Animal Testing²⁵ also provides that the animal experiments committee (DEC) must give its permission. The Ministry of Health, Welfare and Sport is the competent authority.

21 <http://www.wetten.nl/besluit%20genetisch%20gemodificeerde%20organismen%20wet%20milieugevaarlijke%20stoffen>

22 <http://www.wetten.nl/regeling%20genetisch%20gemodificeerde%20organismen>

23 <http://www.wetten.nl/wet%20milieubeheer>

24 <http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Besluit%20biotechnologie%20bij%20dieren>

25 <http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Wet%20op%20de%20dierproeven>

The Central Committee on Research involving Human Subjects²⁶ (CCMO) must also give its permission for research on people, for example in the case of gene therapy.

Naturally, in addition to the regulations listed above, institutions must comply with all the other rules that also apply for activities not involving genetically modified organisms (e.g. the Pesticides Act, Commodities Act, the Working Conditions Act, the Decree on Immunological Pharmaceutical Products, etc.).

European

The legislation governing biotechnology is based primarily on European directives and regulations. The difference between a directive and a regulation is that a regulation has direct application in every European Member State. A directive must first be transposed into the national legislation of the member states and the member state can adopt its own form and methods of implementation.

Directive 98/81/EC²⁷

This directive lays down the framework for tests with GMOs in laboratories (contained use). This directive is implemented in Dutch legislation through the GMO Decree, the GMO Regulation and the Environmental Management Act.

Directive 2001/18/EC²⁸

This directive lays down the framework for the deliberate introduction into the environment of genetically modified organisms. The directive was implemented in Dutch legislation on 12 May 2004.

Regulation (EC) no. 1829/2003²⁹

This regulation relates to genetically modified food and animal feed.

Regulation (EC) no. 1830/2003³⁰

This regulation relates to the traceability and labelling of genetically modified organisms and the traceability of food and animal feed produced with genetically modified organisms.

Global

Convention on biological diversity³¹

The objective of the convention is the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources. The value of biological diversity is seen not only from a human perspective but also from the perspective of the unique intrinsic value of nature.

26 <http://www.ccmo.nl/>

27 http://europa.eu.int/eur-lex/pri/nl/oj/dat/1998/l_330/l_33019981205n100130031.pdf

28 http://europa.eu.int/eur-lex/pri/nl/oj/dat/2001/l_106/l_10620010417n100010038.pdf

29 http://europa.eu.int/eur-lex/pri/nl/oj/dat/2003/l_268/l_26820031018n100010023.pdf

30 http://europa.eu.int/eur-lex/pri/nl/oj/dat/2003/l_268/l_26820031018n100240028.pdf

31 <http://www.biodiv.org/convention/articles.asp?lg=0>

The Convention obliges the parties to the convention to develop national strategies for concrete activities.

Cartagena Protocol (Biosafety Protocol)³²

The Cartagena Protocol is also known as the Biosafety Protocol (BSP). It is a supplementary protocol implementing the UN Convention on biological diversity (see above). The objective of the protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biodiversity. It contains primarily rules on the cross-border movement of GMOs.

The protocol prescribes that in the case of cross-border movements of living GMOs that are intended to be introduced into the environment (for field trials, for example), the exporter must notify the country of import in advance of the proposed movement and must wait for approval from the country of import. The protocol also established a clearing house (the BioSafety Clearing House, BCH) for the exchange of information about cross-border movements of GMOs which are intended to be used as food or animal feed or directly for processing in products. Ninety countries have so far ratified the protocol.

Aarhus convention³³

The Aarhus Convention regulates access to environmental information, public participation in decision-making and access to justice in environmental matters. The convention includes a provision on GMOs (section 11 of Article 6). This clause states that countries must allow, within the framework of their national legislation, to the extent feasible and appropriate, public participation in decisions on whether to allow the deliberate release of GMOs into the environment. The Netherlands complies with this section, since the General Administrative Law Act, which provides for public participation in political decision-making, applies to decisions to permit the introduction of GMOs into the environment.

32 <http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>

33 <http://unece.org/env/pp/gmo.htm>

4. **Biosecurity Working Group**

Chairman:

Prof. L. van Vloten-Doting

Ministry of Agriculture, Nature Management and Food Quality and Groene Kennis
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Professor of Science and Technology Studies, University of Amsterdam

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Director of Fungal Biodiversity Centre (CBS-KNAW) and Professor of Evolutionary
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Emeritus Professor of Molecular Biology, University of Leiden

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Netherlands Biotechnology Association (NIABA)

Prof. G.M.A. van Beynum

KNAW's Committee for Biochemistry and Biophysics

H. Bout

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