# SUMMARY

## Background

In September 2011, Dutch virologist Ron Fouchier announced that, based on his group's research findings, the H5N1 (bird flu) virus has the potential to gain airborne transmissibility between mammals. He also identified the biological mutations that the virus must undergo to do so. The US National Science Advisory Board for Biosecurity (NSABB) advised against publishing the full version of the paper. Any data or information that could be used to deliberately develop or spread a mutant H5N1 virus should be left out, it said. The NSABB's advice sparked off heated debate among scientists, politicians and the media. The Dutch government required Fouchier to obtain an export licence before sending the papers out for publication, citing a European Union regulation that puts limits on the export of dual-use technology – in other words, technology that can be used for both scientific and military purposes. After Fouchier was granted the licence, the publication appeared in *Science* (June 2012). Fouchier's employer, Erasmus Medical Centre in Rotterdam, had filed an appeal against the Government's decision to require an export licence, but the competent court rejected that appeal in 2013.

## Request for advice

The H5N1 controversy led the Dutch State Secretary for Education, Culture and Science to ask the Royal Netherlands Academy of Arts and Sciences to advise on how to deal with dual-use research in the life sciences. specifically, the State Secretary wanted to know:

- *how dual-use research should be assessed,*
- *who should assess dual-use research?*

The Academy Board appointed a Biosecurity Committee and charged it with investigating and answering these questions.

## Security, risk and uncertainty

There is a difference between security (protection against intentional threats) and safety (protection against accident, human failure or threats of nature). The concepts of risk and uncertainty play an important role in security. The Committee agrees with the Scientific Council for Government Policy (WRR) that in issues involving security, the point is to weigh opportunities and threats. That is what it has done with the threats, risks and uncertainties associated with the misuse of biological agents.

## Biosecurity and dual-use research

Biosecurity focuses on preventing the misuse of life sciences research. It is an issue that not only concerns scientists, laboratory technicians and administrators, but also security specialists, politicians, public servants in various ministries and – last but not least – the media. The Biosecurity Committee believes that any definition of dual use involving biological agents should consider both on the technological and biological aspects and on the social and political context. It therefore proposes the following description:
In the context of biosecurity, dual-use research is research

1. that, based on current information, utilises or can reasonably be expected to lead to knowledge, products or technologies that can be misused, and
2. that involves an identifiable threat and a significant risk of misuse, and
3. that can have serious consequences for society (health, safety, agriculture, plants, animals, the environment or property).

## How should dual-use research be assessed?

In line with this definition, the Committee has developed an assessment framework that allows for both biological considerations (the biological agent itself and the nature of the relevant research) and contextual considerations (the social and political context in which the research is being conducted). Researchers should refer – if necessary, repeatedly – to both sets of considerations in the various stages of a research project.

The first question to be considered is *whether* a research project is dual use in nature. The second question is whether this should have consequences. This gives rise to further questions, for example: What constitutes a threat? What sort of threat is it? Who decides? Is the threat serious enough to designate the relevant technology or study (or publication) as dual-use research in accordance with the Committee's definition?

The considerations that apply in the case of research funding or the execution of research may differ from those applying in the case of publication. A threat analysis is therefore relevant when weighing the dual-use aspects of research and of publication.

## Who should assess dual-use research?

In the Committee's opinion, the public should be able to trust researchers and others who engage in knowledge acquisition to assess whether their results can be misused for criminal or terrorist purposes. The responsibility for making that assessment lies mainly with researchers and other parties in the knowledge chain. That is why all such parties must have the opportunity to request specific advice on potential bio-security aspects of their research proposal or research results.

The ability to advise on research with potential dual-use aspects requires knowledge and expertise in multiple areas (the science involved, laboratory security, and national and international threat analyses). The Committee investigated whether any existing arrangements and institutions can serve as an example or act as advisory bodies in potential cases of dual-use research.

In the Committee's view, none of the existing committees or institutions are sufficiently equipped for this task. The Committee therefore proposes establishing a separate Advisory Committee: the **Biosecurity Advisory Committee for Research in the Life Sciences.**

The Committee suggests that the Ministry of Health, Welfare and Sport should install the Advisory Committee and act as coordinator. It also proposes the Advisory Committee should be under the authority of the Health Council. The Committee concludes its advisory report by making a number of proposals for the composition of the Advisory Committee and the duties with which it should be charged.