INFLUENZA VIRUS RESEARCH AND EU EXPORT REGULATIONS: PUBLICATION, PROLIFERATION, AND PANDEMIC RISKS

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ABSTRACT

An influenza pandemic would be a global health emergency, and laboratory-based research on influenza viruses is an important component of worldwide efforts to prevent and prepare for this. There are concerns, however, that publishing the findings of such research might sometimes increase the risk of a pandemic caused by a laboratory accident or the deliberate release of a deadly virus. This article addresses the challenge of governing scientific information sharing, with regard to public health benefits and risks, from an export-control perspective. The discussion focuses on research findings produced in 2011 by a team of influenza virologists in the Netherlands, and on the Dutch Government's unprecedented decision to regard the intended publication of these findings as being subject to European Union regulations on the export of 'dual-use' items. I argue that, when a government is uncertain about whether the benefits of publishing particular research findings in a scientific journal outweigh the risks, a process of selectively disseminating those findings should be available as an alternative to official censorship.

KEYWORDS: Bioterrorism, Dual-use dilemma, European Union, Export controls, Pandemic influenza, Research

I. INTRODUCTION

Pandemic influenza is a public health risk of global concern. A variety of pharmaceutical and non-pharmaceutical measures can be used to mitigate that risk. However, the effectiveness of those measures, now and into the future, is in large measure dependent upon a strong scientific understanding of the changing properties and behaviour of influenza viruses. For this reason, laboratory-based influenza research, to the extent

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that it contributes to better treatments and disease-control methods, is important to all people everywhere. At the same time, such research can itself sometimes present risks to public health or national security. In the course of experimentation, a deadly virus might accidentally escape from a laboratory and spark contagion, or a laboratory worker might decide to use the virus in a biological attack. Just as there are benefits and risks associated with the conduct of laboratory-based influenza research, so too the written findings of such research have the potential to be put to good or bad uses. This expansion of the 'dual-use' problem in pathogen research is largely due to advances in genetic engineering and gene synthesis technologies. Increasingly, gaining access to a virus with particular genetic properties is enabled by the sharing of a technique for producing it in a laboratory rather than by the shipping of physical specimens between scientists. From a security perspective, a shift from tangible to intangible technology transfer presents a challenge to export-control regimes aimed at preventing the international proliferation of 'weapons of mass destruction' (including biological weapons). And yet, from a public health perspective, the swift and extensive sharing of new discoveries about influenza viruses potentially improves global preparedness for a pandemic.

This article focuses on the dilemma a government potentially faces when it attempts to prevent biological attacks by regulating the international transfer (export) of certain research findings. Of central concern is the publication in scientific journals of experimental techniques for producing an influenza virus that is more dangerous (e.g. more transmissible or more virulent) to human health. On the one hand, it might be argued that the mass communication of information on exactly how a virus can be made more dangerous could further enable the use of that information for a harmful purpose. On the other hand, making such findings available to lots of other scientists could raise awareness and assist in the development of new and improved measures for preventing, containing, and treating influenza. The conundrum for policymakers is: what kind of regulation is necessary to reduce the risk of this intangible technology being harmfully misused, and what kind of regulation is likely to thwart the spread of knowledge applicable to health protection purposes? When it comes to the securing of populations against infectious disease risks—be they naturally occurring or deliberately caused—the required approach seems to be both to restrict *and* to facilitate the dissemination of certain research findings.

In 2012, the Dutch Government took the unprecedented decision to characterise research findings, produced by a team of virologists in the Netherlands, as technology that was subject to European Union (EU) regulations on the export of dual-use items.¹ It was the first instance anywhere in Europe of an export permit being required before a manuscript could be submitted to an international journal (*Science*) for publication. The virologists, led by Ron Fouchier of the Erasmus Medical Centre (EMC) in Rotterdam, intended to publish an account of how they produced an H5N1 avian influenza virus that was airborne transmissible between ferrets. Because a ferret's respiratory system is similar to a human's, this new virus was presumptively

1 Council Regulation (EC) 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering, and transit of dual-use items [2009] OJ L134; Martin Enserink, 'Will Dutch Allow "Export" of Controversial Flu Study?' (2012) 336 *Science* 285.

able also to spread easily between humans in a pandemic. Although an export permit was eventually granted and publication went ahead,² Fouchier questioned whether the EU regulations were applicable in the first place, raising the issue in two Dutch court cases (in 2013 and 2015). However, the broader public debate that ensued was about whether the Dutch Government did the right thing when it ultimately allowed the publication of these research findings, and more generally it was about how to govern transfers of intangible dual-use technology.

To address these issues, the discussion here begins by exploring the tension between the governance imperatives of restrictiveness and permissiveness when it comes to the sharing of dual-use biotechnology. The article then considers legal and ethical questions surrounding Fouchier's intended publication of his team's H5N1 findings: was it lawful for the Dutch Government to require Fouchier to apply for an export permit, and was it morally right to grant one? Assuming that EU export control law was applicable, the problem in this case was that, despite deep uncertainty about the benefits and risks of publication, only two governance options were available: censorship (refusal of an export permit) or full publication. In the final section of the article, a third option is suggested: granting a permit for targeted export (PTE). When a government is uncertain about whether the benefits of publishing particular research findings in a scientific journal outweigh the risks, it should be able to authorise the selective dissemination of those findings. Such dissemination could be arranged so as to address security as well as public health concerns, although it would probably be less beneficial than publication to the careers of individual academic scientists.

II. DUAL-USE BIOTECHNOLOGY, EXPORT CONTROLS, AND RESEARCH PUBLICATIONS

Biotechnology, along with virtually all other technologies, has the potential to be used for beneficial and malign purposes. In practice, dual-use potential rarely poses a governance challenge because the benefit of the widespread application of most technology usually far outweighs the risk of harmful misuse. Occasionally, however, a particular technology can present a dual-use *dilemma* because the preponderance of benefits over risks (or vice versa) associated with its application is not obvious. In such circumstances, the challenge is to govern access to and use of a particular technology in a way that is likely to achieve more good than harm. Here, 'good' includes both actual benefits and avoided harms, and 'harm' includes both actual harm and foregone benefits. When it comes to certain kinds of research on pathogenic microorganisms, the benefit to be gained is a better understanding of how to protect human health against infectious diseases. The countervailing risk is that the production of such knowledge might result in the accidental release from a laboratory of a disease-causing microorganism or its use in a biological attack.

Dual-use biotechnology today includes gene modification and synthesis techniques that make it possible to produce pathogenic microorganisms with particular genetic

2 Martin Enserink, 'Dutch Government OK's Publication of H5N1 Study,' *Science* (27 April 2012) <<http://news.sciencemag.org/2012/04/dutch-government-oks-publication-h5n1-study>> accessed 31 August 2016; Sander Herfst and others, 'Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets' (2012) 336 *Science* 1534.

properties in a laboratory setting. One use of such technology is to investigate the potential for a microorganism's genome to mutate naturally and so present a new kind of infectious disease risk. By anticipating that risk, the findings of research into the nature and behaviour of a genetically mutated microorganism can then inform the preparation of clinical and public health responses on a just-in-case basis. A scientist might, for example, set out to produce a bacterium resistant to a certain class of antibiotics to determine whether it could ever become resistant to that class through natural evolutionary processes. Such information would be relevant to recommendations on how best to administer the antibiotic and it could help guide the medical management of infectious disease cases. Alternatively, laboratory work of this kind might make that bacterium more useful for biological attack purposes precisely because it has been rendered capable of defeating human immune systems and pharmaceutical defences.

In 2004, a report by the US National Research Council on *Biotechnology Research in an Age of Terrorism* identified seven kinds of experiments as most likely to have biological weapons potential: (i) demonstrating how to render a vaccine ineffective; (ii) conferring resistance to therapeutically useful antibiotics; (iii) enhancing the virulence of a pathogen or rendering a non-pathogen virulent; (iv) increasing the transmissibility of a pathogen; (v) altering the host range of a pathogen; (vi) enabling the evasion of diagnosis and/or detection by established methods; and (vii) enabling the weaponisation of a biological agent.³ More recently, the US Department of Health and Human Services has referred to a similar list of experiment categories using the term 'dual use research of concern', defined as:

life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.⁴

From a governance perspective, when contemplating the benefits and risks of research on influenza viruses and other microorganisms, an important threshold question is whether it should be conducted at all. For present purposes, however, the key issue is whether, how and to whom the findings of research already conducted should then be communicated. To the extent that sharing those findings with other scientists would be beneficial to public health, there is a technology transfer imperative. But if there are risks associated with such sharing, there might also be a non-proliferation imperative to prevent this.

A useful starting point for thinking about the tension between restrictive and permissive approaches to dual-use biotechnology transfers is the 1972 Biological Weapons Convention (BWC). Article I of the BWC binds Member States never to

3 National Research Council, *Biotechnology Research in an Age of Terrorism* (National Academy of Sciences 2004) 5.

4 'United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern' US Department of Health and Human Services (March 2012) <<http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>> accessed 31 August 2016.

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, protective or other peaceful purposes'. Article IV requires states to give effect to this rule through their domestic law. However, it can sometimes be difficult in practice to discern reliably the *lack* of a peaceful justification given the importance of biomedical research to human health and the scale of the scientific enterprise directed towards understanding pathogenic microorganisms. The task of preventing the use of microorganisms in biological attacks is also made difficult, from a legal standpoint, by two provisions of the BWC between which there is clear tension. On the one hand, Article III of the Convention requires Member States 'not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce' the manufacture or acquisition of any '[biological] agents' for biological weapons purposes. On the other hand, Article X requires states to 'facilitate . . . the fullest possible exchange' of technology and to 'cooperate in contributing . . . to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes'.⁵

The language of Article X ('peaceful purposes') is such that the provision is subject to interpretations of intent, and it has long been a sign of international distrust that many developed countries are afraid to share certain kinds of biotechnology with some developing countries for fear that it will not be used peacefully. Article III of the BWC was reinforced in 2004 by United Nations (UN) Security Council Resolution 1540 which requires all states to 'take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials'. To this end, states must establish, develop, review, and maintain 'effective national export and trans-shipment controls over such items . . .'.⁶ Subsequently, many developed countries have continued to favour export controls (with more emphasis on the need to reduce proliferation risks) over the facilitating of biotechnology transfers. Since 1984, a group of states known as the Australia Group (AG) has cooperated to restrict exports of biological (and chemical) technology with a view to preventing the use thereof in weaponised form. The AG maintains lists that define dual-use biological agents and biological equipment, with participating states informally committed to ensure these items are subject to national export controls, and each state assesses export licence applications in accordance with an agreed set of guidelines.⁷ With respect to biotechnology, the list of controlled equipment includes, for example, fermenters, aerosol inhalation chambers, and spraying systems. In

5 'Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction' *United Nations Office at Geneva* (10 April 1972) <[http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/C4048678A93B6934C1257188004848D0/\\$file/BWC-text-English.pdf](http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/C4048678A93B6934C1257188004848D0/$file/BWC-text-English.pdf)>.

6 United Nations Security Council, Resolution 1540 (2004) para 3 <<http://www.un.org/en/sc/1540/>>.

7 'Guidelines for Transfers of Sensitive Chemical or Biological Items' *Australia Group* (June 2012) <<http://www.australiagroup.net/en/guidelines.html>>.

addition, in the category 'related technology', AG controls are intended to cover the 'transfer of technology (technical data) by any means, including electronic media, fax or telephone' and 'transfer of technology in the form of technical assistance'.⁸

The decision to control 'the intangible transfer of information and knowledge' was made at an AG meeting in 2002,⁹ and several participating states have since implemented enforceable legislation. For example, since 2009 and throughout the EU, Council Regulation 428/2009 has provided a common legal basis for the 28 EU Member States individually to control exports of dual-use technology to non-EU states. For the purposes of the Regulation, 'dual-use items' means 'items, including software and technology, which can be used for both civil and military purposes', and 'export' is defined to include 'transmission of software or technology by electronic media, including by fax, telephone, electronic mail or any other electronic means to a destination outside the European Community' (Article 2). If an item of dual-use technology is listed in Annex 1 of the Regulation, the government of an EU state must require the export of that item to be officially authorised (Article 3). In Annex I, 'technology' means specific information, taking the form of 'technical data' or 'technical assistance', necessary for the development, production, or use of goods, and a general exception to technology transfer controls is made for 'basic scientific research' and information 'in the public domain'.¹⁰

In 2012, Regulation 428/2009 was for the first time applied to the intended transmission (for publication purposes) of written research findings; specifically, the findings of particular research on the transmissibility of H5N1 influenza virus that had been conducted in the Netherlands. Although this was an unprecedented application of export control law to this form of intangible technology transfer, it was not the first time that the risks of publishing the findings of virus research had generated public concern. Over the preceding decade, a small number of cases had generated concern about the possible harmful application of published research methods. The controversies surrounding these cases in turn gradually intensified the political pressure on the editors of scientific journals to refrain from publishing (on security grounds) or else perhaps see governments one day take the decision out of their hands. One such controversy arose from an article that appeared in *Science* in 2002, less than a year after the anthrax envelope attacks in the USA. The article was authored by some US scientists who, sponsored by the US Defense Department, had spent 3 years chemically synthesising the polio virus using sequences of genetic material purchased via the Internet. The assembled material was then used to create live polio virus that paralysed and killed mice, thus showing that eradicating a virus in the wild might not mean it is gone forever.¹¹ More broadly, the findings demonstrated how gene synthesis technology could obviate the need to source pathogens from natural reservoirs or from other laboratories. Criticisms of the journal's decision to publish ranged from

8 'Control List of Dual-use Biological Equipment and Related Technology and Software' *Australia Group* (January 2014) <http://www.australiagroup.net/en/dual_biological.html>.

9 'New Measures to Fight the Spread of Chemical and Biological Weapons' *Australia Group* (June 2002) <http://www.australiagroup.net/en/agm_june2002.html>.

10 reg 428/2009 (n 1).

11 Jeronimo Cello, Aniko V Paul and Eckard Wimmer, 'Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template' (2002) 297 *Science* 1016.

claims that the research findings were scientifically uninteresting to claims that the information could be maliciously and harmfully misused by its reader. One US Congressman even tabled a congressional resolution accusing *Science* of publishing 'a blueprint that could conceivably enable terrorists to inexpensively create human pathogens'.¹² But the journal's editor at the time, Donald Kennedy, defended his decision by arguing: 'Sticking one's head in the sand and hoping that unpleasant realities will go away has never been a fruitful approach to science or public policy'. He conceded, though, that 'there should continue to be serious conversations about the relationship between scientific research, publication, and security'.¹³

In 2005, journal editors again came under political pressure in respect of two sets of written findings from research on the H1N1 virus that caused the devastating Spanish Flu of 1918–19. One of the papers was eventually published in *Nature*,¹⁴ and the other in *Science*,¹⁵ but on this occasion, the US Government (which had funded the research) first referred the papers to the newly formed National Science Advisory Board for Biosecurity (NSABB) for advice on whether the benefit to be derived from publishing this information outweighed the risk of harmful misuse. In combination, the findings revealed the genetic traits that made this influenza virus (which killed around 50 million people worldwide) so deadly. The promise of sharing such information was that it could assist in further gene synthesis experiments aimed at better understanding the nature of influenza viruses and developing new vaccines or treatments. However, the intended publication of this information also gave rise to concerns that would-be bioterrorists could use it to reconstruct the Spanish Flu virus for the purpose of attacking a target population with no natural immunity. For example, an opinion article in the *New York Times* described the published genome of this virus as 'essentially the design of a weapon of mass destruction'.¹⁶ Members of the NSABB agreed that publication should proceed anyway, and *Science*'s Donald Kennedy explained that the risk of doing so was far outweighed by the benefit that it 'could help prevent another global flu pandemic'.¹⁷

Six years later, when another influenza research controversy (involving the H5N1 virus) began to unfold in the Netherlands, the situation was quite different. The editor of *Science* (a journal based in the USA) was less in control of whether the research findings should be published, because the Dutch Government decided that electronic transmission of the researchers' manuscript beyond the EU first required an export permit. As the next section will show, this decision raised legal and ethical questions to which the answers remain unclear: was this kind of research covered by Regulation

12 Jennifer Couzin, 'A Call for Restraint on Biological Data' (2002) 297 *Science* 749, 749.

13 Donald Kennedy, 'A Not-So-Cheap Stunt (Response)' (2002) 297 *Science* 769, 770.

14 Jeffery K Taubenberger and others, 'Characterization of the 1918 Influenza Virus Polymerase Genes' (2005) 437 *Nature* 889.

15 Terrence M Tumpey and others, 'Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus' (2005) 310 *Science* 77.

16 Ray Kurzweil and Bill Joy, 'Recipe for Destruction' (*New York Times*, New York, 17 October 2005) <<http://www.nytimes.com/2005/10/17/opinion/recipe-for-destruction.html>> accessed 31 August 2016.

17 Jocelyn Kaiser, 'Resurrected Influenza Virus Yields Secrets of Deadly 1918 Pandemic' (2005) 310 *Science* 28, 29.

428/2009? If so, should the researchers have been allowed to proceed towards publication?

III. A POTENTIAL PANDEMIC VIRUS IN A DUTCH LABORATORY

Since 2003, according to the World Health Organization (WHO), there have been 854 confirmed human cases of H5N1 avian influenza across 16 countries, including 450 deaths (a global average case fatality rate of around 53%).¹⁸ The continued circulation of H5N1 viruses in poultry, and occasional infections of humans, has enabled ongoing viral evolution, and a key question for scientists has been whether this could eventually lead to the emergence of a virus with pandemic potential. Such a virus would be able to spread through the air between humans via tiny droplets expelled during coughing and sneezing, and some influenza researchers have been interested to discover which genetic mutations might allow H5N1 to do this. Ron Fouchier at the EMC in Rotterdam, the Netherlands, was one of a number of scientists funded by the US National Institutes of Health (NIH) to conduct experiments to investigate how H5N1 might evolve to acquire the ability to spread from person to person.¹⁹ In September 2011, at the fourth conference of the European Scientific Working Group on Influenza held in Malta, Fouchier announced a breakthrough: using a combination of genetic engineering and serial infection of ferrets, he and his team had succeeded in causing the mutation of H5N1 into a form directly transmissible (through the air) between the animals.²⁰ A ferret's respiratory system closely resembles that of a human, and ferret-to-ferret transmission of influenza virus is generally assumed to demonstrate human-to-human transmissibility. Thus, it seemed, a new and presumably pandemic virus had emerged not through natural evolutionary processes but as a result of human experimentation at the molecular level of biology.

A written account of this discovery, including a step-by-step description of how it was achieved, was made ready for submission to *Science*.²¹ The journal's editorial board referred the manuscript to the NIH (which had funded the research), and in October 2011 the NIH in turn referred it to the NSABB to make recommendations regarding the responsible communication of Fouchier's findings. Two months later the Board recommended against publication unless certain methodological details were omitted. The recommendation was unanimous, and NSABB member David Franz explained: 'My concern is that we don't give amateurs – or terrorists – information that might let them do something that could

18 'Cumulative Number of Confirmed Human Cases of Avian Influenza A(H5N1) Reported to WHO' *World Health Organization* (19 July 2016) <http://www.who.int/influenza/human_animal_interface/H5N1_cumulative_table_archives/en/>.

19 Brendan Maher, 'The Biosecurity Oversight' (2012) 485 *Nature* 431, 432.

20 Michael Specter, 'The Trouble with Scientific Secrets' (The New Yorker, New York, 22 December 2011) <<http://www.newyorker.com/news/news-desk/the-trouble-with-scientific-secrets>> accessed 31 August 2016.

21 Around this time, a similar set of findings on the achievement of H5N1 transmissibility using a different technique was prepared for *Nature* by a team of researchers in the USA led by Yoshihiro Kawaoka of the University of Wisconsin–Madison. The intended publication of these findings is beyond the scope of the present article, because they originated outside the EU. See Masaki Imai and others, 'Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets' (2012) 486 *Nature* 420.

really cause a lot of harm.’²² In February 2012, however, participants in a meeting organised by the WHO recommended that the findings be published in full, on the grounds that ‘the results . . . provide an important contribution to public health surveillance of H5N1 viruses and to a better understanding of the properties of these viruses’.²³ The following month, after considering a revised manuscript received from the Dutch research team, the NSABB recommended that it should be published, although one-third of the Board’s members remained opposed to the publication of Fouchier’s findings.²⁴ Soon afterwards, with *Science* poised to publish, the Dutch Government made an extraordinary intervention on the basis that highly pathogenic avian influenza viruses of subtype H5 are listed in Annex I of EU Council Regulation 428/2009.²⁵ Under the terms of the Strategic Goods Decree, which implements the Regulation inside the Netherlands, the Ministry of Economic Affairs, Agriculture and Innovation announced in April 2012 that Fouchier was required to apply for and be granted a permit to export his dual-use technology beyond the EU.²⁶ A ministry spokeswoman explained that transferring technology without the required permit is ‘an infringement of export-control legislation under the Economic Offences Act’ for which the ‘maximum penalty, in case of premeditation or severe negligence, is six years’ imprisonment or a €78,000 fine’.²⁷

Prior to making a decision on whether to grant Fouchier an export permit, the Dutch Government convened a closed meeting in The Hague at which government officials discussed the risks and benefits of publication with an international group of scientists and security experts. After the meeting, Fouchier applied for a permit despite earlier claiming he did not need one,²⁸ and on 27 April 2012, the Dutch minister for agriculture and foreign trade announced his decision to allow the export.²⁹ The EMC nevertheless filed a formal objection to the requirement for an export permit in this case, and the government disallowed the objection in December 2012.³⁰ Thereafter, the matter of the applicability of Regulation 428/2009 to Fouchier’s H5N1 research findings was pursued in court.

A. Applicability of Regulation 428/2009

Was it lawful on this occasion for the Dutch Government to decide whether or not a scientific manuscript may be submitted for publication? Fouchier claimed that it was not required for him to obtain an export permit, because the information to be

22 Denise Grady and William J Broad, ‘Journals Asked To Cut Details of Flu Studies’ (New York Times, New York, 21 December 2011) A1.

23 ‘Technical Consultation on H5N1 Research Issues: Consensus Points’ *World Health Organization* (February 2012) <http://www.who.int/influenza/human_animal_interface/consensus_points/en/>.

24 ‘National Science Advisory Board for Biosecurity Findings and Recommendations, March 29-30, 2012’ *National Institutes of Health* <http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf>.

25 reg 428/2009 (n 1) Annex I, item 1C352a.2.b.2.

26 Enserink (n 1).

27 Declan Butler, ‘Mutant-flu Researcher Plans to Publish Even Without Permission’ (Nature, 17 April 2012) <<http://www.nature.com/news/mutant-flu-researcher-plans-to-publish-even-without-permission-1.10469>> accessed 31 August 2016.

28 *ibid*.

29 Enserink (n 2).

30 Royal Netherlands Academy of Arts and Sciences Biosecurity Committee, *Improving Biosecurity: Assessment of Dual-Use Research* (Royal Netherlands Academy of Arts and Sciences 2013) 12.

published fell within two exceptions to the authorization rule in Regulation 428/2009. With regard to items listed in Annex I, one exception is that which applies to technology that is 'in the public domain', and another applies to 'basic scientific research'.³¹ In a case brought before the District Court of Noord-Holland in Haarlem, Fouchier's lawyer argued that the methods used in the H5N1 mutation experiment had been described before and were well-known (in the public domain), and that the virologists at EMC had sought only to better understand mammalian transmissibility of an influenza strain (basic scientific research).³² On 20 September 2013, the District Court rejected both arguments.³³ In general, it considered that non-proliferation was a priority in the Regulation and that exemptions should therefore be interpreted narrowly. Regarding the first claimed exemption, the court found that Fouchier's study went beyond known methods, by selecting and detailing the genetic changes needed to produce mammal-transmissible H5N1 strains, and thus was not already in the public domain. The novelty of the research findings was also indicated by the willingness of *Science* to publish them.³⁴ The court found also that the research was not 'basic scientific research', defined in the Regulation as 'experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena . . . , not primarily directed towards a specific practical aim or objective'.³⁵ Instead, the court characterised the development of an airborne H5N1 virus as a practical goal, adding that it is not up to individual researchers to determine whether their research is basic.³⁶ Were the latter to occur, the court reasoned, it would compromise the obligation of *states* under UN Security Council Resolution 1540 to counter the proliferation of biological weapons.³⁷

When Fouchier appealed against this decision, the Dutch Court of Appeal in Amsterdam held (on 18 June 2015) that it did not need to decide whether his research was basic or applied and thus whether the international transfer of the H5N1 experiment data was subject to EU export regulations.³⁸ Rather, the court dismissed the appeal on procedural grounds alone. Fouchier had applied to the Dutch Government for an export permit, he had then received one, and so he did not incur damage for which a remedy was necessary. That is, he no longer had a legal interest in pursuing the case. Moreover, the Court of Appeal held that the government should not have taken Fouchier's complaint into consideration, and that the District Court

31 reg 428/2009 (n 1) Annex I, General Technology Note.

32 Martin Enserink, 'Flu Researcher Ron Fouchier Loses Legal Fight over H5N1 Studies' *Science* (25 September 2013) <<http://www.sciencemag.org/news/2013/09/flu-researcher-ron-fouchier-loses-legal-fight-over-h5n1-studies>>.

33 Netherlands: Rechtbank Noord-Holland, 2013 <<http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBNHO:2013:8527>>.

34 Declan Butler, 'Court Upholds Need for Export Permits for Risky Flu Research' (*Nature*, 26 September 2013) <<http://blogs.nature.com/news/2013/09/court-upholds-need-for-export-permits-for-risky-flu-research.html>>.

35 reg 428/2009 (n 1) 28, Annex I.

36 Enserink (n 32).

37 Butler (n 34).

38 Netherlands: Gerechtshof Amsterdam, 2015 <<http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:GHAMS:2015:2913&keyword=ECLI%3aNL%3aGHAMS%3a2015%3a2913>>.

should not have upheld the government's rejection of that complaint.³⁹ Effectively, then, the legal question of whether research findings like Fouchier's qualify as basic research remains open. Even so, a political precedent has been set for a government to assume that research of this kind is non-basic and therefore not exempt from the export authorisation requirement in Regulation 428/2009. An ethical question remains, though: should the Dutch Government have allowed Fouchier's findings to be submitted for publication?

B. Benefits and Risks of Publication

It is not clear exactly how the Dutch Government arrived at its decision to grant Fouchier a permit to transfer his intangible H5N1 technology to the editor of *Science*. Regulation 428/2009 provides that, in deciding whether or not to grant an export authorisation, EU states 'shall take into account all relevant considerations including: (a) the obligations and commitments they have each accepted as members of the relevant international non-proliferation regimes and export control arrangements, or by ratification of relevant international treaties; . . .'.⁴⁰ It is reasonable to assume, therefore, that the Dutch Government considered the requirements of the BWC, to which the Netherlands is a party; and UN Security Council Resolution 1540 which is binding on all states. Beyond that, taking into account 'all relevant considerations' appears to have involved assessing the perceived benefits and risks of allowing Fouchier's H5N1 findings to be published outside the EU. When export permission was announced on 27 April 2012, the Dutch ministry for agriculture and foreign trade issued a statement⁴¹:

Minister [Henk] Bleker has weighed all of the benefits and risks of publication of the avian influenza research, and has especially looked at the freedom of research and publication, health, and safety. He has also taken into consideration insights from national and international experts in the areas of security, health, and research; the positive advice of the U.S. National Science Advisory Board on Biosecurity to the U.S. government about publication of the research; and the U.S. government's decision to follow that advice.

What, then, were the benefits and risks that the Dutch Government might have considered before deciding to grant Fouchier an export permit? In March 2012, when a majority of NSABB members recommended the communication in full of Fouchier's data, methods, and conclusions, the benefit of publication was couched in the following terms:

New evidence has emerged that underscores the fact that understanding specific [viral] mutations may improve international surveillance and public health and safety. Global cooperation, critical for pandemic influenza preparedness efforts, is predicated upon the free sharing of information . . .⁴²

39 Martin Enserink, 'Dutch Appeals Court Dodges Decision on Hotly Debated H5N1 Papers' *Science* (16 July 2015) <<http://news.sciencemag.org/europe/2015/07/dutch-appeals-court-dodges-decision-hotly-debated-h5n1-papers>>.

40 reg 428/2009 (n 1) art 12.

41 Enserink (n 2).

42 See n 24.

Around this time, several of Fouchier's colleagues publicly emphasised the importance of information sharing for disease surveillance and vaccine-testing purposes,⁴³ and Fouchier himself had previously argued in a televised interview:

We have to be prepared for such viruses to emerge in the wild. If we would detect these viruses out in the field, then we could go out to outbreak areas and try to eradicate the virus and prevent a pandemic from happening. If that would fail, then we would still be in a good position to, ahead of that pandemic, evaluate our vaccines and anti-viral drugs and therefore gain months of time if a pandemic would hit and therefore we would be able to handle it better.⁴⁴

However, the public health benefit of publishing research findings on influenza virus mutation is diminished if, in practice, systemic problems deny the theoretical opportunity to 'prevent a pandemic from happening'. On the issue of translating scientific discovery into actual benefit, a minority of the NSABB members who met in March 2012 concluded that 'the current [disease] surveillance infrastructure is ill-equipped to detect the emergence of highly transmissible influenza viruses in real time prior to their dissemination in nature'.⁴⁵ NSABB chairman Paul Keim had earlier observed:

I'm not confident at all that we have the surveillance capability to spot an emerging virus in time to stop it. And even if we did spot it early on, I don't think we have sufficient vaccines. The vaccines aren't good enough, and the drugs are not good enough to stop this emerging and being a pandemic.⁴⁶

The message here seemed to be that the benefit of publication—to inform scientists worldwide of a discovery about H5N1 influenza virus—is dependent upon the degree to which the information can then be exploited in a timely fashion by public health practitioners. If the prospect of beneficial application of published findings is slim, it is harder to claim that any risk associated with publication is outweighed.

One such risk relates to laboratory biosafety. Even if it was sufficiently safe for Fouchier's team to conduct their H5N1 experiment inside the EMC in Rotterdam, the same work done (using a published methodology) in less well-managed laboratories elsewhere in the world might carry a greater risk of an unintentional release of the mutated virus. According to Marc Lipsitch and Alison Galvani, the likelihood of a scientist somewhere being infected accidentally, for example, approaches 20% over a

43 Ab Osterhaus, 'Why All Our Bird Flu Research Should Be Published' *The Guardian* (28 March 2012) <<https://www.theguardian.com/commentisfree/2012/mar/28/bird-flu-terrorism-security>> accessed 31 August 2016; Peter Palese and Taia T Wang, 'H5N1 Influenza Viruses: Facts, Not Fear' (2012) 109 *Proceedings of the National Academy of Sciences* 2211, 2211.

44 Andrew Fowler, 'Building the Perfect Bug' *Foreign Correspondent*, (ABC Television, Sydney, Australia, 13 March 2012) <<http://www.abc.net.au/foreign/content/2012/s3452543.htm>>.

45 See n 24.

46 Steve Connor, 'No Way of Stopping Leak of Deadly New Flu, Says Terror Chief' *The Independent* (London, 8 February 2012) <<http://www.independent.co.uk/news/science/no-way-of-stopping-leak-of-deadly-new-flu-says-terror-chief-6660997.html>>.

10-year period.⁴⁷ Fouchier has insisted that 'scientific research has never triggered a virus pandemic',⁴⁸ but accidental infections (such as with the SARS virus) have gone undetected before.⁴⁹ In addition, there is the risk of deliberate, harmful application of intangible technology. Thus, another probable consideration for the Dutch Government's risk assessors was whether scientists other than those working in Fouchier's laboratory really could achieve possession of his mutated H5N1 virus simply by following a published procedure for creating it. That is, to what extent (if at all) would publication increase the accessibility of this organism? In 2002, when Eckard Wimmer's team in the USA published their polio virus synthesis technique, this did not greatly increase accessibility to that organism. As one of Wimmer's colleagues, Aniko Paul, later explained: 'For terrorists, it would have made no sense to start putting this virus together because they already had an ample supply of poliovirus available. Polio is present in old medical samples that are stored in freezers, and it can still be bought from suppliers.'⁵⁰ By contrast, a human-to-human transmissible H5N1 virus was not known to exist anywhere prior to 2011 when one was created in Rotterdam, so information on how to do this appeared to be a critical determinant of access.

The view of a minority of NSABB members in March 2012 was that 'the revised Fouchier manuscript provides information that would enable the near-term misuse of the research in ways that would endanger public health or national security'.⁵¹ As one NSABB member, Michael Osterholm, had earlier put it: 'We don't want to give bad guys a road map on how to make bad bugs really bad.'⁵² Fouchier and two of his colleagues have dismissed this possibility, arguing that '[i]ndividuals with bad intentions do not need to read the details in our manuscript because the methods for creating similar viruses have already been published widely.'⁵³ The implication here is that publication of their H5N1 findings generated no additional risk. However, the problem with the 'it's already out there' argument is that the publication of a particular piece of writing is not simply an exercise in data dissemination; it also serves the purpose of assembling and packaging diffuse information for the reader. It can otherwise take much time and skill to bring together ideas and information from various sources and to craft them into an integrated, clearly explained message. Thus, publication of Fouchier's findings might have served qualitatively to increase accessibility to the

47 Marc Lipsitch and Alison P Galvani, 'Ethical Alternatives to Experiments with Novel Potential Pandemic Pathogens' (2014) 11(5) *PLoS Medicine* e1001646. doi:10.1371/journal.pmed.1001646.

48 Ian Sample, 'Virus Experiments Risk Unleashing Global Pandemic, Study Warns' *The Guardian* (London, 21 May 2014) <<http://www.theguardian.com/world/2014/may/20/virus-experiments-risk-global-pandemic>>.

49 David Murphy, 'Lab Bungle' *Far Eastern Economic Review* (6 May 2004) 18; Jim Yardley and Lawrence K Altman, 'China is Scrambling to Curb SARS Cases after a Death' (New York Times, New York, 24 April 2004) 4.

50 Michael J Selgelid and Lorna Weir, 'Reflections on the Synthetic Production of Poliovirus' (2010) 66(3) *Bulletin of the Atomic Scientists* 1, 6.

51 See n 24.

52 Martin Enserink, 'Scientists Brace for Media Storm around Controversial Flu Studies' *Science* (23 November 2011) <<http://www.sciencemag.org/news/2011/11/scientists-brace-media-storm-around-controversial-flu-studies>>.

53 Sander Herfst, Albert DME Osterhaus and Ron AM Fouchier, 'The Future of Research and Publication on Altered H5N1 Viruses' (2012) 205 *Journal of Infectious Diseases* 1628, 1630.

necessary mutation technology.⁵⁴ Nevertheless, in respect of any 'recipe', there remains the possibility that it will not be followed correctly or that a key 'ingredient' will unknowingly be left out. Regarding the problem of biological weapons proliferation, Sonia Ben Ouagrham-Gormley has found that 'such intangible factors as organizational makeup and management style greatly affect the use of acquired knowledge', and that these factors 'cannot be easily transferred among individuals or from one place to another'.⁵⁵ If this is true of proliferation (in the form of publication of methodologies) in the realm of pathogen research more generally, it is a reason perhaps to afford less weight to the risk of information being harmfully misused.

In any event, at the time the Dutch Government was attempting to weigh the benefits and risks of granting Fouchier an export permit, the inherent dangerousness of the mutated virus itself (extant in Fouchier's laboratory or reproduced elsewhere) remained uncertain. On the one hand, it is cause for concern that the global average case fatality rate for H5N1 is high (around 53%).⁵⁶ On the other hand, the WHO's figures reflect only confirmed cases of infection, and the proportion of deaths among all actual cases is probably much less.⁵⁷ The government might have noted also that, in Fouchier's experiment, '[n]one of the recipient ferrets died after airborne infection with the mutant A/H5N1 viruses',⁵⁸ and that this is consistent with the generally observed phenomenon that a virus's virulence decreases as its transmissibility increases. Moreover, there might have been some doubt about the pandemic potential of Fouchier's virus, given that virologists have disagreed on whether it would be as contagious and as pathogenic in humans as it is in ferrets.⁵⁹ If, then, the Dutch Government judged that the mutant virus was probably less dangerous than was first thought, it could have downgraded the risk associated with publishing information on how to create it. For the same reason, though, the government might also have assessed that there was a lesser degree of public health benefit to be gained from allowing publication to proceed, because any pandemic caused by the virus would probably not be a severe one.

C. The Problem of Risk–Benefit Uncertainty

Assuming that the Dutch Government proceeded towards a decision in this way—assessing and weighing the benefits and risks of publishing Fouchier's H5N1 research

54 See Michael T Osterholm and David A Relman, 'Creating a Mammalian-Transmissible A/H5N1 Influenza Virus: Social Contracts, Prudence, and Alternative Perspectives' (2012) 205 *Journal of Infectious Diseases* 1636, 1637.

55 Sonia Ben Ouagrham-Gormley, 'Barriers to Bioweapons: Intangible Obstacles to Proliferation' (2012) 36(4) *International Security* 80, 112–13. See also James Revill and Catherine Jefferson, 'Tacit Knowledge and the Biological Weapons Regime' (2014) 41 *Science and Public Policy* 597, 598.

56 'Cumulative number of confirmed human cases of avian influenza A(H5N1) reported to WHO' *World Health Organization* (19 July 2016) <http://www.who.int/influenza/human_animal_interface/H5N1_cumulative_table_archives/en/>.

57 Eric S Toner and Amesh A Adaljat, 'Is H5N1 Really Highly Lethal?' (2012) 10(2) *Biosecurity and Bioterrorism* 237, 238.

58 Herfst and others (n 2).

59 Sabrina Engel-Glatte, 'Dual-use Research and the H5N1 Bird Flu: Is Restricting Publication the Solution to Biosecurity Issues?' (2014) 41 *Science and Public Policy* 370, 373; Editorial, 'Avian Influenza and the Dual-use Research Debate' (March 2012) 12 *The Lancet Infectious Diseases* 167.

findings, and authorising export on the grounds that the benefits outweigh the risks—the problem remains that this process is not a strong basis for decision-making. Ideally, a government would indeed be able to conduct an integrated and exhaustive risk–benefit assessment of publication incorporating security, public health, and scientific perspectives. However, in the H5N1 case, there were two fundamental problems attempting to do this under conditions of uncertainty. First, there was a lack of empirical, undisputed data upon which a probabilistic assessment of benefits and risks could be based. Too little was known (or knowable) about the various claimed benefits and risks to allow measurement of the likelihood of their coming to pass and the consequences thereof. Assessing the risk of bioterrorism, for example, is difficult given that an intelligent adversary can adapt to the presence of successful countermeasures.⁶⁰ Secondly, there was no commensurability among the different values potentially affected or advanced by the publication or censorship of Fouchier's findings. It was not possible, for example, to balance concerns about public health benefits against concerns about national security risks in a precise, quantitative fashion.⁶¹ For these two reasons, judgments by the Dutch Government on the acceptability of risks and the desirability of benefits must have been based merely upon subjective assessments offered by numerous experts with different backgrounds, values, and opinions.⁶²

One alternative approach to making a decision in this case would have been to apply the precautionary principle. Originally conceived as a way to respond to the risk of irreversible environmental damage, this is a principle for 'making practical decisions under uncertainty when no reliable quantitative data is available'.⁶³ Because the prospect of such damage is the paramount consideration, other values (such as the financial interests of corporations) tend to be subordinated when decision makers invoke the precautionary principle.⁶⁴ There has been some support for adopting this approach also in respect of dual-use dilemmas arising in pathogen research. For example, Michael Imperiale has argued that, under conditions of uncertainty, 'the burden should be placed upon those who wish to engage in research and publish their results to make a convincing argument as to why the risks of disseminating those results are insignificant'.⁶⁵ In the H5N1 case, applying the precautionary principle would probably have disposed the Dutch Government more towards deciding to refuse Fouchier an export permit. However, it is important to note that the damage risked by publishing his findings is not, in contrast to some forms of environmental damage, irreversible. An influenza pandemic (whether caused naturally, accidentally, or deliberately) eventually ends, and its effects are able to be mitigated.

60 Frank Gottron and Dana A Shea, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress* (Congressional Research Service 2011) 7.

61 See Johannes Rath, 'Rules of Engagement' (2014) 15(11) EMBO Reports 1119, 1120.

62 See Nicole M Bouvier, 'The Science of Security Versus the Security of Science' (2012) 205 *Journal of Infectious Diseases* 1632, 1633.

63 Engel-Glatzer (n 59) 374.

64 Rath (n 61) 1121.

65 Michael J Imperiale, 'Dual-use Research after the Avian Influenza Controversy' *Bulletin of the Atomic Scientists* (11 July 2012) <<http://thebulletin.org/dual-use-research-after-avian-influenza-controversy>>. See also: Frida Kuhlau and others, 'A Precautionary Principle for Dual Use Research in the Life Sciences' (2011) 25(1) *Bioethics* 1; German Ethics Council, *Biosecurity – Freedom and Responsibility of Research* (German Ethics Council 2014) 177 <<http://www.ethikrat.org/files/opinion-biosecurity.pdf>>.

It seems excessively precautionous, then, to constantly emphasise risk avoidance in the governance of pathogen research and for a government to withhold authorisation to transfer a particular intangible technology because it might in some way pose a risk. Even in circumstances where benefits and risks are unquantified and the diverse values they affect are incommensurable, the achievement of *some* benefit remains important and indeed is what most influenza virus researchers probably have in mind when conducting laboratory experimentation. Hence, with regard to Fouchier's case and the issue of 'information security measures' generally, Johannes Rath has suggested that applying the proportionality principle is more appropriate for governance purposes.⁶⁶ This is a principle that requires, first, that a particular governance measure is to some extent effective in protecting society from the harmful misuse of information. And it requires also that the intended measure is the least intrusive way of achieving that beneficial effect.⁶⁷ Unfortunately, however, there is presently little scope for pursuing a proportional response under Regulation 428/2009. Rather, a national government within the EU is afforded only two choices when it comes to the intended publication of dual-use research findings that are covered by the Regulation: to refuse export authorisation (censorship) or to allow publication in full to proceed. This is highly unsatisfactory in circumstances where the merits of either choice are deeply contested; a government cannot be confident that full publication is not too risky or that censorship is not too heavy-handed. By contrast, having a third option available to deal with difficult cases (when the competing imperatives of non-proliferation and technology-transfer must both be addressed) would present an opportunity to apply the proportionality principle. Accordingly, the next section proposes a governance measure that involves restriction short of censorship and communication short of publication.

IV. PERMITS FOR TARGETED EXPORT OF RESEARCH FINDINGS

One suggested alternative to the censorship of Fouchier's H5N1 research findings was to allow the publication of a redacted article. According to David Resnik, this would have been a proportional response to the security challenge posed by these findings: 'a compromise between promoting scientific research and preventing harm'.⁶⁸ By omitting information on the precise methods used to mutate an influenza virus into a more transmissible form, 'terrorists' would have been denied 'a recipe for making a bioweapon' and other scientists would still have been able to learn more about H5N1.⁶⁹ However, a number of objections were or could be raised against opting for redaction. With regard to states' obligations under the BWC, for example, it might be a bad idea for a government to conceal from other governments the methods used in an experiment that it deems to be of biological weapons concern. Such concealment could give rise to international accusations that that government was developing (in a secret way) dangerous biological agents for a non-peaceful purpose in contravention of Article I of the Convention. And even if redaction of a dual-use

66 Rath (n 61) 1122.

67 *ibid* 1119.

68 David B Resnik, 'H5N1 Avian Flu Research and the Ethics of Knowledge' (2013) 43(2) *Hastings Center Report* 22, 30.

69 *ibid*.

technology publication were presented as consistent with the non-proliferation purpose of the BWC (Article III), it could also be perceived as a failure by a government to share with others (in accordance with Article X) a scientific technique that could be applied for peaceful purposes. Here, it is worth noting that, at a BWC meeting in December 2015, there was general agreement on the value of ensuring that all states have 'access to the benefits of biotechnology' including 'developments of special relevance to disease surveillance . . .'.⁷⁰

The omission of methodological data would instead inhibit access because the replication and testing of experiments requires this data. As such, a related objection is that redaction presents a barrier to researchers seeking to engage in further research, and that it thereby limits the scientific output essential to combat pandemic risk posed by influenza viruses.⁷¹ When NIH director Francis Collins briefed the NSABB, in March 2012, about the political problems with redaction in the H5N1 case, one of her arguments was that limiting access to methodological data might jeopardise the 2011 Pandemic Influenza Preparedness Framework.⁷² This international agreement to share influenza virus samples and related information relies critically upon confidence that developing countries (from which H5N1 samples are sourced) will benefit from influenza research carried out in the developed world. If confidence in the agreement were undermined by a perception that useful (albeit dual-use) technology was being deliberately withheld, the consequence might be a downgrading of international cooperation on disease surveillance and influenza vaccine development to the detriment of all.⁷³

Recent experience shows that redaction is also opposed by the editors of scientific journals. When resisting the idea of publishing anything less than a full account of research, they tend to refer to public health imperatives. For example, *Nature* editor Philip Campbell argued, in December 2011, 'It is essential for public health that the full details of any scientific analysis of flu viruses be available to researchers.'⁷⁴ He was responding to the NSABB's original recommendation that a redacted version of Fouchier's H5N1 paper be published, and the response of *Science* editor Bruce Alberts was similar:

Science has concerns about withholding potentially important public-health information from responsible influenza researchers. Many scientists within the influenza community have a bona fide need to know the details of this research

70 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, Geneva, 14–18 December 2015. BWC/MSP/2015/6, 22 February 2016, 5.

71 Engel-Glatzer (n 59) 372.

72 Maher (n 19) 434.

73 See 'WHO Concerned that New H5N1 Influenza Research Could Undermine the 2011 Pandemic Influenza Preparedness Framework' *World Health Organization* (30 December 2011) <www.who.int/mediacentre/news/statements/2011/pip_framework_20111229/en/>; 'Risk Assessment: Laboratory-Created A(H5N1) viruses transmissible between ferrets' *European Centre for Disease Control and Prevention* (29 February 2012) 5 <<http://ecdc.europa.eu/en/publications/Publications/TER-RA-120229-Laboratory-created-A-H5N1-viruses-transmissible-between-ferrets.pdf>>.

74 'Bird Flu: Research Row as US Raises Terror Fears' *BBC News* (21 December 2011) <<http://www.bbc.co.uk/news/world-us-canada-16279365>>.

in order to protect the public, especially if they currently are working with related strains of the virus.⁷⁵

Alberts later attributed his journal's 'default position' (full publication) to 'the absence of any mechanism to get the information to those scientists and health officials who need to know and need to protect their populations and to design new treatments and vaccines'.⁷⁶ Consistent with these statements, and on the basis of a survey of 127 journal editors in 27 countries, Daniel Patrone and his colleagues have predicted: 'editors will be reluctant to withhold publication of dual-use research without at least having practical mechanisms for identifying responsible researchers and organizations with legitimate needs for the information and for distributing the information to them'.⁷⁷

One practical mechanism worth considering, as an alternative to redaction, is the issuing of a permit for the targeted export of research findings that pose a dual-use dilemma. This would involve limiting the number of recipients rather than limiting the degree to which those findings were described. Arguably, if findings like Fouchier's could be disseminated directly to those 'scientists within the influenza community [who] have a bona fide need' for them,⁷⁸ the public health concerns expressed by journal editors would be assuaged. As an additional mechanism for governing intangible technology transfers under Regulation 428/2009, an EU system of PTEs might operate as follows:

1. Preliminary permit: After receiving an application for permission to transmit dual-use research findings electronically to a journal editor located outside the EU, a government issues a preliminary permit (an 'individual export authorization' as defined in Article 2 of the Regulation) for the sole purpose of allowing the scientific quality of the research to be scrutinised through the journal's normal peer-review processes.
2. Scientific quality certification: Following peer review, an applicant for an export permit submits to the government whatever letter he or she received from the relevant journal editor indicating that the research findings are fit to publish on scientific grounds.
3. Distribution list: If the research findings are certified as scientifically sound, but the government determines (after consulting relevant experts) that the risks of regular publication are too great, the applicant is invited to submit a list of individuals located outside the EU (names and addresses) to whom the intangible technology should be exported for the sake of public health.

75 Kathy Wren, 'Science: Editor-in-Chief Bruce Alberts on Publication of H5N1 Avian Influenza Research' *American Association for the Advancement of Science* (20 December 2011) <<http://www.aaas.org/news/science-editor-chief-bruce-alberts-publication-h5n1-avian-influenza-research>>.

76 Pallab Ghosh, 'Journal's Concern over Bird Flu Research' *BBC News* (17 February 2012) <<http://www.bbc.co.uk/news/17066147>>.

77 Daniel Patrone, David Resnik and Lisa Chin, 'Biosecurity and the Review and Publication of Dual Use Research of Concern' (2012) 10(3) *Biosecurity and Bioterrorism* 290, 292.

78 Wren (n 75).

4. PTE: The government issues a PTE, covering all individual recipients named on the applicant's list, enabling intangible technology to be lawfully transferred accordingly. Transmitted research findings could also be accompanied by a copy of the letter issued by a journal's editor indicating that its reviewers are satisfied with the scientific quality of the research. All the direct financial costs of technology transfer at this stage are borne by the authorising government.
5. BWC disclosure: Immediately after the issuing of a PTE, the government submits the applicant's research findings to the BWC Implementation Support Unit (within the UN Office at Geneva) to enable the transmission of the findings to the diplomatic representatives of all BWC Member States. Each Member State is at the same time also provided with the list of the individuals authorised under the PTE to receive this particular dual-use technology.

In a case similar to that involving Fouchier's H5N1 findings, the availability of the option to issue a PTE in this way would afford more scope for a government to respond to concerns about security risks and public health benefits in accordance with the proportionality principle. First, a PTE is clearly more likely to satisfy the 'least intrusive means' test than is an outright refusal of export authorisation (censorship). And secondly, regarding the principle's 'effectiveness' test, the PTE option has the advantage of facilitating the dissemination of information to individuals and governments who need to have it while also being effective in limiting the associated risk. At stages 1, 4, and 5 of the process outlined above there would still be potential for the authorised recipients of data to transfer it to others. For example, there might be nothing preventing persons outside the EU from forwarding on the data. Even so, preventing publication in major journals like *Science* and *Nature*, with their vast readerships, is what would prevent the greatest degree of information sharing. A PTE would not prevent *all* dissemination of a given intangible dual-use technology, but it would prevent at least some dissemination and possibly most of what would have occurred as a consequence of publication. With every successful replication (done by reference to a written methodology) of Fouchier's H5N1 experiment, for example, there is a chance the mutated virus will escape its laboratory confinement and enter the general population. For this reason, as Nicholas Evans has argued, '[i]t is prudent . . . to limit not just who reproduces the studies, but how often these studies are reproduced'.⁷⁹

In January 2012, virologists Michael Osterholm and Donald Henderson argued that there was no need to share Fouchier's H5N1 mutation data 'outside of a small select group of established researchers already working within the WHO [influenza] network'.⁸⁰ And Fouchier himself earlier estimated that he could have shared his findings with 'well over 100 organisations around the globe, and probably 1,000 experts'.⁸¹ However, this raises the question: why, then, did that intangible dual-use technology

79 Nicholas G Evans, 'Great Expectations—Ethics, Avian Flu and the Value of Progress' (2013) 39 *Journal of Medical Ethics* 209, 211.

80 Editorial, 'Influenza and Its Complications' *The Economist* (28 January 2012), <<http://www.economist.com/node/21543472>>.

81 Doreen Carvajal, 'Scientist in Bird Flu Study Says He is Not Convinced Censorship is a Safeguard' (New York Times, New York, 22 December 2011) A28.

need to be accessible also to the *hundreds* of thousands of people worldwide who read *Science*? Part of the answer might indeed be that the benefit for pandemic preparedness purposes would thereby be maximised. But it is also worth acknowledging that, for academic scientists especially, a researcher's professional self-interest is well served by authoring an article that appears in a prestigious journal. This means there might be a strong temptation for a scientist to regard publication as something inherently good for one's career more (or rather) than as something instrumentally good for public health. Moreover, as there is sometimes professional pressure also to be the *first* (among competing researchers) to publish, some scientists might sometimes feel disposed more towards haste than caution.⁸² As Brendan Maher has observed: 'It may be too much to expect scientists to coolly evaluate the risks of their own research against the benefits they gain personally from publication.'⁸³ For these reasons, it might sometimes be healthy from a governance perspective that scientists alone do not decide whether or when their research findings should be submitted to a journal.

If research findings were not published but rather disseminated through a PTE-based process, the career advantage for the individual researchers involved would probably be less. Already, there have been warnings that an inability to publish scientifically interesting results could have a chilling effect on certain kinds of pathogen research, driving ambitious scientists into other fields.⁸⁴ However, one way to approach this problem would be to align more closely the imperatives of individual career advancement and socially responsible scientific practice.⁸⁵ Governments could afford more job security to influenza virus researchers in academia, for example, and thereby reduce the pressure to publish early and often. And public sponsors of research, who typically require grant recipients to publish their findings in full, could instead regard targeted dissemination as sufficient in circumstances where the benefits of publication do not appear clearly to outweigh the risks.

V. CONCLUSION

Research on pathogenic microorganisms has the potential to contribute indirectly to the saving of many lives in the event of an infectious disease outbreak caused naturally, accidentally, or deliberately. National and international preparedness for an outbreak with global reach—an influenza pandemic—requires a strong scientific understanding of the changing properties and behaviour of influenza viruses. Yet, the pursuit of that understanding brings risks as well as benefits. Governments may therefore find it difficult sometimes to satisfy the competing governance imperatives of restrictiveness and permissiveness when it comes to the intended sharing of dual-use biotechnology. Within the EU context, the Fouchier case in the Netherlands has demonstrated this, and it has also exposed at least two problems with the existing export-control regime.

82 Bouvier (n 62) 1634; Martin Enserink, 'Public at Last, H5N1 Study Offers Insight into Virus's Possible Path to Pandemic' (2012) 336 *Science* 1494, 1495–96.

83 Maher (n 19) 434.

84 Peter Palese, 'Don't Censor Life-saving Science' (2012) 481 *Nature* 115; Sabrina Engel-Glatzer (n 59) 377.

85 See Filippa Lentzos and Nicholas Evans, 'Four Steps to Rebuild Trust in Biology' *The Guardian* (23 May 2016) <<https://www.theguardian.com/science/political-science/2016/may/23/four-steps-to-rebuild-trust-in-biology>>.

The first problem relates to the exempting of intangible dual-use technology from the requirement for official authorisation under Regulation 428/2009. Following the Dutch Court of Appeal decision in 2015 to overturn a 2013 District Court decision in the Dutch Government's favour, it remains unclear whether research into the transmissibility of influenza viruses qualifies as basic scientific research. Thus, it must be unclear to scientists inside the EU whether the publication of findings from such research requires an export permit. Given that the penalty for unauthorised export of dual-use technology is severe, this is a highly unsatisfactory state of affairs. National governments within the EU should therefore engage in further discussion of the meaning of 'basic research' and do so with a view to issuing guidance for scientists and government decision makers. Any such discussion should consider especially the practical difficulty of distinguishing basic from applied research. That is, in the everyday practice of science, there can be continuous interplay between the two categories: basic problems can inspire the development of new technologies, and the application of these can in turn open new avenues of basic research.⁸⁶ For this reason, a scientist might get away with claiming that particular research is 'applied' in order to win public funding but 'basic' in order to circumvent export controls. Such incoherence will need to be anticipated and addressed in an improved EU export-control regime.

The second problem discernible from the Fouchier case is that there are presently too few options available under Regulation 428/2009 for governing the intended communication of research findings that present a dual-use dilemma. Assuming that the Regulation was applicable at all in this case, the situation in which the Dutch Government found itself in 2012 was that, despite deep uncertainty about the balance of benefits and risks associated with sharing information about a mutated H5N1 virus, it could only choose between two extreme alternatives: censorship or full publication. However, this need not be the case in the future. When faced with the difficult challenge of satisfying non-proliferation and technology transfer imperatives simultaneously, a third option could be tried: permits for the targeted export of research findings. Such an arrangement for information sharing would address the dual need to reduce security risks and improve public health, although it would probably be less beneficial than publication to the careers of academic scientists. A further challenge, then, would be to maintain the professional attractiveness of pathogen research. Although limiting transfers of intangible biotechnology might be protective of human health in the short term, it could be anti-protective over time if it adversely affects too many scientists' ability and willingness to discover more about global infectious disease risks.

CONFLICT OF INTEREST STATEMENT

None declared.

86 Stephen Quake, 'The Absurdly Artificial Divide Between Pure and Applied Research' (New York Times, New York, 17 February 2009) <<http://opinionator.blogs.nytimes.com/2009/02/17/the-absurdly-artificial-divide-between-pure-and-applied-research>> accessed 31 August 2016.