Setting the Publication of «Dual-use Research» Under the Export Authorisation Process: The H5N1 Case

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Abstract

The main purpose of this article is to explore whether trade controls as currently implemented by national authorities in Europe and the United States represent a suitable means for monitoring research of dual-use concern. The narration of the 'H5N1 case' and the distinct paths followed by the Dutch and US authorities provide the impetus to draw three main lessons. First, setting the publication of research under the authorisation process is interwoven with certain legal and practical challenges. Second, the applicability of the 'basic scientific research' exemption is contentious in both the European and the US context. Third, trade controls are not the only tool available for overseeing dual-use research. Through a painstaking description of legal provisions, comments on the dual-use potential of life sciences and identification of shortfalls in the legal frameworks, the paper ends with some broader conclusions on the oversight and governance of dual-use research: Trade control implications are intensified in a research context and thus, the adoption of clear-cut laws or guidance by governments and regulatory authorities could be of great help; Both the US and the EU authorities strive to interpret trade control exemptions applicable to dual-use research; A combination of both self-governance initiatives and top-down regulatory and coordinating measures may constitute a way forward for the effective oversight of dual-use research.

Keywords

Dual-use research[1], basic scientific research, technology transfers, export controls, bio-security, genetics, non-proliferation, oversight of dual-use research of concern, gain of function research or experiments (GOF)

Introduction

The article explores how certain exemptions governing export controls *vis-à-vis* research are applied in practice and most fundamentally, seeks to answer whether trade controls represent an appropriate means

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for exercising control over the publication of sensitive dual-use research. The first section sets the scene of export controls towards 'dual-use research' by focusing on the EU law. The second section presents a much discussed case concerning the publication of two breakthrough studies containing methods and presenting findings of dual-use concern. It is the first time that the 'H5N1 case' is explained from an export controls perspective with a view to presenting the facts and identifying the European and the US approaches towards the publication of sensitive research. Thereafter, the 'lessons learned' section offers an analysis of the practical and legal issues linked to the application of export controls in research. Finally, the last section draws broader conclusions with a view to identifying a way forward for the oversight of dual-use research.

Setting the Scene

The advancement of our societies lies in the dissemination of knowledge and the diffusion and diversification of new technologies. Researching *i.e.* investigating, observing and collecting information systematically on a specific topic is the process by which knowledge is acquired. This process frequently involves the extensive interaction and collaboration between scientists coming from all over the world. For instance, the development of nuclear energy has been from the very beginning truly international as the ideas and work of scientists in one country stimulated and fertilized the minds of their colleagues in others[2]. It is not surprising then that knowledge and technology -that is the application of knowledge to the practical needs of societies- have always been in the hook of non-proliferation efforts.

Dual-use trade controls is an essential instrument for curbing the proliferation of sensitive materials, technologies and technical services that can be used for both civil and military applications.[3] The scope of such controls concerns a broad spectrum of 'cutting-edge' technologies and may affect both private and public legal persons trading export controlled commodities. Furthermore, trade control provisions have a far-reaching character pertaining to a wide range of activities. Apart from the export of materials and equipment, the provision of technical assistance on site or through verbal communication and the transfer of technical data and software by either tangible or intangible means may require an export authorisation. Nonetheless, there is some providence under national, European and international export control frameworks to mitigate the impact of such provisions by exempting certain types of research activities from the scope of controls. National authorities may also facilitate export controlled activities when these concern transactions with lawful end-users based in low-risk destinations, for instance, under general licenses.

Table I of the Annex provides an indicative but not exhaustive list of general instances where common research activities could potentially require an export authorisation under the EU trade control law, if certain conditions are satisfied. Admittedly, the technical parameters of the item or technology in question, the final destination and the end-use -especially in the view of catch-all controls and sanctions/ embargo prohibitions- are determinant factors. Further, the physical export of an item may comprise the transfer of technical data and/or the provision of technical assistance as well. In this regard, Annex I of the dual-use regulation EC 428/2009 -henceforth the EU or dual-use regulation[4]- provides that the approval of goods for export also authorizes the export to the same end-user of the minimum technology required for the installation, operation, maintenance and repair of the goods.[5] In the same section, it is stipulated also that technology for the development, production or use of controlled goods remains under control even when applicable to non-controlled goods. This essentially means that a technology transfer may

[2] Fischer, David. *History of the International Atomic Energy Agency: The First Forty Years (A fortieth anniversary publication* (Vienna: IAEA, 1997), p. 15.
[3] The terms trade controls and export controls are used interchangeably in this paper.
[4] *Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items,* European Council, Official Journal of the European Union (L 134) as of December 31, 2014 retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R0428-20141231&from=EN.
[5] See the Nuclear Technology Note (NTN), the General Technology Note (GTN) and the General Software Note (GSN) in the Annex I of the EU regulation, 23.

bring a license requirement even when exported to be used in connection with an uncontrolled item or process. This is very relevant for activities undertaken by researchers; the benevolent scientist preparing a publication will not have any intention to contribute to the construction of any weapon or to the conduct of an unlawful activity. However, according to the regulation the very act of transmitting or making available controlled methods, data or know-how abroad is licensable. Also, such a provision clearly implies that a controllable technology transfer does not take place necessarily in conjunction with the consignment of a controlled item.

The categorisation in table I concerns every actor dealing with dual-use items, software and technology coming either from an industrial or an academic research environment and as explained above each category is not necessarily disjointed from the other. In an academic research environment technology transfers as defined in the EU regulation and related international norms are much more likely to take place compared to the outflows of physical items. Scientific institutions primarily produce knowledge and they do not possess facilities for the mass production of marketable products. However, researchers may be commissioned to develop model products and prototypes for firms or come up with inventions that can be patented and commercialised afterwards by industry. In this regard, many universities have established technology transfer offices to facilitate the move towards the commercialisation of academic research.

National trade control regulations and related international norms are not specially coined to address or restrict research activities. Researchers must act in conformity with trade control law to the extent that they 'export' or 'transfer' items and technology in the meaning of the regulations. In Annex I of the EU regulation, also known as the dual-use list, there are 'de-control provisions' originating from the framework of international export control regimes and acknowledging implicitly the distinct status of research activities. As provided in the three general notes in Annex I, 'public domain information', 'basic scientific research' and software 'generally available to the public' are excluded from the scope of technology and software controls. According to the definitions first introduced in the framework of international regimes 'public domain information' and 'basic scientific research' should be understood as follows:

Public domain information means technology or software which has been made available without restrictions upon its further dissemination. Copyright restrictions do not remove technology from 'in the public domain'

Annex I of the EU Dual-use Regulation, 34

Basic scientific research means experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective.

Annex I of the EU Dual-use Regulation, 28

Whereas there is no specific rule requiring explicit authorisation of dual-use research in order to be published, the interpretation of certain provisions may result in the imposition of a license requirement for the publication of scientific work.[6] The H5N1 case sheds some light on how certain provisions are applied in practice and provides some evidence for associated problems.

The H5N1 Case Study: Background

The H5N1 case originated in 2011 and relates to two different research projects with similar objectives undertaken by Dr. Yoshiro Kawaoka for the University of Wisconsin (USA) in collaboration with the University of Tokyo (Japan) and Dr. Ron Fouchier for the Erasmus Medical Centre of the Erasmus University (Netherlands). The controversial manuscripts were submitted for publication in the well-

[6] Article 2 of the EU regulation affirms that dual-use trade controls target items including software and technology that can be used for both civil and military purposes.

established journals 'Nature' and 'Science' respectively and both explored the transmissibility of H5N1 avian influenza in mammals.[7] The findings were ground-breaking in that the experiments conducted in ferrets proved that the airborne transmission of the virus H5N1among mammals is possible when certain mutations in the strain of virus occur. The submission of the manuscripts to the peer-review process was followed by an unprecedented debate and publicity on whether the research results should have been published in the first place and most fundamentally, if such experimental work should have ever taken place.[8] Quite interestingly, the handling of the issue followed two distinct courses in the USA and the EU. In the first case, the US government did not resort to the export control quiver in order to deal with the sensitive publications. Instead, the then-newly established National Science Advisory Board for Biosecurity (NSABB) was called to give its opinion on the potential threat posed by these two publications. In contrast, in the EU the Dutch authorities concluded that an export authorisation should be asked for the publication of the Fouchier manuscripts. The international furor caused by the debate led to the voluntary declaration of a moratorium on certain types of controversial experiments involving the H5N1 avian influenza virus from the side of scientists which lasted till January 2013.[9] Most recently, in October 2014, the US government announced the temporary halt of all federal funding for selected 'gain-of-function' (GOF) research and called for a voluntary moratorium anew till the re-assessment of the risks and benefits relating to research altering a pathogen to make it more transmissible or deadly.[10]

The Timeline

The controversial findings were first announced by Dr. Fouchier at the 4th European Scientific Working group on Influenza (ESWI) Conference in September 2011.[11] The discussion in Europe concerned only Fouchier's manuscripts that are considered to be more sensitive in that the methods used appear to result in modified viruses of H5N1 with high pathogenicity in humans.[12] Dr. Fouchier and his team were informed by the Dutch licensing authority that the publication of manuscripts containing information controlled under the dual-use regulation required an export authorisation. Fouchier applied

[7] The avian influenza or, as it is commonly known the 'bird flu,' is a highly pathogenic virus affecting mainly chickens and other farm birds. This A (H5N1) virus subtype first infected humans in 1997 during a poultry outbreak in Hong Kong SAR, China. Most recently, a pandemic of the bird flu broke out in 2003 and spread from Asia to Europe and thenceforth incidents have been reported from Middle East and Africa to North America. The avian influenza can be spread to people, but is difficult to transmit from person to person. In fact, almost all people with H5N1 infection have had close contact with infected birds or H5N1-contaminated environments. When people do become infected, the mortality rate is about 60%. Information retrieved from the WHO's website available in: http://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/en/.

[8] Indicatively see few of the many articles in scientific news websites and blogs referring to the case: Interlandi, Jeneen. "Contagion: Controversy Erupts over Man-Made Pandemic Avian Flu Virus," *Scientific American Magazine*, as modified of December 09, 2011, retrieved from: http://www.scientificamerican.com/article/contagion-controversy-erupts/; Harmon, Katherine. "What Really Happened in Malta This September When Contagious Bird Flu Was First Announced?," *Scientific American (blog)*, December 30, 2011, retrieved from: http://blogs.scientificamerican.com/observations/what-really-happened-in-malta-this-september-when-contagious-bird-flu-was-first-announced/; Enserink, Martin ."Dual-Use Research: Dutch H5N1 Ruling Raises New Questions," *Science (news and analysis) Vol. 342: 6155* (2013):p. 178, doi: 10.1126/science.342.6155.178, retrieved from: http://www.sciencemag.org/content/342/6155/178.full.

[9] Malakoff, Martin. "H5N1 Researchers Announce End of Research Moratorium," *Science Insider News,* January 23, 2013, http://news.sciencemag.org/people-events/2013/01/h5n1-researchers-announce-end-research-moratorium.

[10] Indicatively see: Kaiser, Jocelyn and Malakoff, David. "U.S. halts funding for new risky virus studies, calls for voluntary moratorium," *Science Insider*, October 17, 2014, retrieved from: http://news.sciencemag.org/biology/2014/10/u-s-halts-funding-new-risky-virus-studies-calls-voluntary-moratorium, "Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research," United States White House, as of October 17, 2014, https://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research.

[11] The 4th ESWI Influenza Conference took place from 11 to 14 September (Malta). Information retrieved from: http://www.eswi.org/activities/eswi-influenza-conferences/fourth-eswi-influenza-conference.

[12] US National Institute of Health, "National Science Advisory Board on Biosecurity, Findings and Recommendations," March 29-30, 2012, p. 4, retrieved from: http://osp.od.nih.gov/sites/default/files/resources/03302012_NSABB_Recommendations.pdf.

on 24 April 2012 for a license under protest and succeeded in obtaining it three days later. Finally, the much-debated manuscript and the accompanying one assessing the likelihood of a mutated H5N1 to arise spontaneously in nature- were published in Science in June 2012, almost one month after the electronic publication of Dr. Kawaoka's paper in Nature. For the record, all articles are now accessible on line for free.[13] The issue however went on; Dr. Fouchier took legal action against the decision of the Dutch authorities to require a license.[14] The District Court in Haarlem that handled the case published on 23 September 2013 its decision: the claim of Dutch authorities to set an authorisation requirement for the publication of the study was justified by the related law; that is to say the EU regulation. Shortly after the ruling of the court, Fouchier filed an appeal against the court decision. Also, the European Society for Virology (ESV) sent a letter to the then President of the European Commission, J. M. Barroso expressing *inter alia* its concern to maintain the free exchange of scientific information in the interest of animal and public health.[15]

Finally, on 18 July 2015 the Appellate Court in Amsterdam adopted a rather unexpected ruling; the appeal is unfounded and also, the decision of the District Court should be annulled. The reasoning of this decision has as follows[16]: the researcher was granted an authorisation to publish his research without any restrictions or conditions. According to the Court an appeal is well- founded only if an eventual remedy can bring the applicant in a better position with regard to the contested decision. The researcher did not suffer any damage –apart from legal fees- and hence, no legal ruling can be requested solely on the basis of significance for possible future cases. Therefore, the Appellate Court concluded that the competent authorities should not have accepted the administrative appeal filed by the researcher and the case should not have been heard before the District Court of Haarlem. The Appellate Court's decision does not contribute to the actual issues at stake in the H5N1 case. However, it affirms the logic embraced by trade controls: the imposition of a licensing requirement does not necessarily equate to a prohibition of an export.

The Litigation[17]

Regardless of this recent outcome, the arguments presented in the original adjudication of the case by the District Court are of interest from an academic and policy point of view. As described in the court's reasoning underpinning the verdict, the overall debate on imposing an authorisation requirement for the publication of the manuscripts was centred around the 'basic scientific research' and 'in the public

[13] Herfst, Sander et al. "Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets," *Science 336* (2012), p. 1534-1541. doi: 10.1126/science.1213362; Russell, Colin A. et al. "The Potential for Respiratory Droplet–Transmissible A/H5N1 Influenza Virus to Evolve in a Mammalian Host," *Science 336* (2012), p. 1541-1547, doi: 10.1126/science.1222526; Imai, Masaki et al. "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets," *Nature 486* (2012): 420-428, doi: 10.1038/nature10831.

[14] As it is the case with many countries, the appeal process for export control cases in Netherlands may entail different steps and legal procedures. The first is the administrative appeal where the competent authority can re-consider its original decision. Then, there is the judiciary appeal which could be examined at the first instance by the Court of Haarlem, at the second instance by the Appellate Court in Amsterdam and finally the Supreme Court of Netherlands may adjudicate a case. During these different stages the tribunals have the possibility to refer the case to the European Court of Justice for a preliminary ruling. The final decision remains with the national court to be taken.

[15] In the letter, the ESV took a balanced stance by underlying the need to carefully consider the potential benefits and risks linked to the conduct of research handling viruses, fungi and bacteria listed in the dual-use regulation. They highlighted the implications of setting hundreds of scientific manuscripts to a screening process. Such an approach could unavoidably lead to serious delays for scientific publications or in some cases to the disruption of the free dissemination of data sometimes critical for enhancing preparedness against threats in public health. Moreover, the ESV noted their willingness to provide scientific advice to law officers at least till the establishment of more permanent mechanisms for the assessment of dual-use research.

[16] The decision of the Appellate Court of Amsterdam was published in the website of the Netherlands Judiciary on July 15, 2015 (in Dutch), retrieved from: http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:GHAMS:2015:2913&-keyword=ECLI%3aNL%3aGHAMS%3a2015%3a2913.

[17] This section draws from the reasoning underpinning the District Court's decision as published on September 23, 2013 in the website of the Netherlands Judiciary (in Dutch), retrieved from: http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBNHO:2013:8527

domain' exemptions. On the one hand, Dr. Fouchier supported that the overarching objective of such a scientific enterprise was to acquire new scientific and technical knowledge about the fundamental genetic principles governing air-born transmission. The project is not primarily directed towards a specific practical aim or objective and thus, the basic research exemption should be applicable. Moreover, the plaintiff argued that all methods described in the manuscripts have been already available in the existing literature since the techniques to genetically modify the influenza viruses have been first published in 2000. Likewise, the mutations described first occurred and were identified in the course of 20th century after the outbreak of global pandemics. Therefore, the researchers only used publicly available information in a systematic way in order to verify whether the avian influenza could be transferred via the respiratory route in mammals. In addition, they were the first to identify certain mutations that might lead to such a contingency in the future relying again on existing knowledge. As a consequence, the research pertains to the 'public domain.'

On the other hand, the Dutch Ministry of Foreign Affairs supported its claim to impose a license requirement by specifying the entries in Annex I of the regulation under which technology related to H5N1 is controlled and also opposed the arguments about the applicability of the exemptions. The two manuscripts pose a threat since they provide information that could be used for the production, development and use of the virus as a bio-weapon, they advocated. The manuscripts do not constitute necessarily basic scientific research because even if the overall objective could be justifiably considered as general and fundamental, the experiments undertaken during the individual phases had rather practical objectives. The first manuscript shows what mutations are required for rendering the virus transmissible by air and the second describes where these mutations already occur in nature and what strains are already fairly close to the required number of mutations. Moreover, the fact that the methods used were already known does not imply that the steps taken and the results obtained are not novel and therefore, the study does not necessarily belong to the public domain. The fact that the manuscripts were approved for publication in these journals proves the special character of the research.

The court settled the dispute by dismissing the allegations of the plaintiff. The court affirmed that it is indisputable that H5N1 virus is a controlled pathogen under item 1C352 of the Annex I of the regulation and that technology relating to this item is equally controlled under entry 1E001(see list I).[18] Besides, this was acknowledged by both sides. Concerning the dispute over the 'basic scientific research' and 'public domain information' exemptions, the court opposed the arguments of the plaintiff. Exemptions should be interpreted restrictively and in the light of the main purpose of the regulation which is above all the prevention of proliferation of WMD.[19] In other words, the judge weighed the risks against the benefits and decided that an authorisation requirement is justifiable. The exemption of basic research is not applicable because demonstrating how a strain of influenza can be adapted to be transmissible in mammals is a practical goal. Moreover, even though the methods used in the study to generate mutant viruses are not novel, Fouchier and his team took steps and made choices that led to entirely new outcomes. Nevertheless, the court accepted that imposing an authorisation requirement to publications of dual-use concern can be to some extent detrimental to scientific research mainly due to subsequent delays in the publication of the scientific work and/or restrictions in accessing the most sensitive findings. The importance of adequate and effective monitoring of proliferation sensitive activities must be however a higher priority according to the judges. Last, the objection of the claimant that such an approach could lead to the asymmetric implementation of export controls since no other EU Member State would require a license for a similar case was dismissed as a hypothetical argument that could not be substantiated.

[18] Currently, with the delegated regulation No 1382/2014 adopted by the Commission, the updated Annex I lists the 'avian influenza' virus under entry 1C351 and related technology remains controlled under 1E001 (EU Official Journal, L371, 2014, 63, 70), retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R1382&from=EN.

[19] According to the court, the main considerations underpinning the dual-use regulation are non-proliferation objectives. Recitals three and 15 provide for the establishment of an effective common export control system in compliance with the multilateral commitments of the EU Member States and the obligations set by UNSCR 1540 whereby the interests of non-proliferation should take precedence over other concerns.

The American Approach

The publication of the opinion of NSABB concerning both Kawaoka's and Fouchier's works preceded the decision of the court in Haarlem. In the USA, both cases are considered as 'Dual Use Research of Concern' (DURC) and thus, the NSABB, the advisory board for the oversight of research in life science, was called to assess the imminent risks stemming from the publication of the studies for the first time in the fall of 2011.[20] The board reached two important conclusions: first, the experiments conducted indeed confirmed that "the H5N1 has the potential to become mammalian transmissible and thus poses a threat of future pandemic"; second, the manuscripts should be published in a redacted version "with the omission of certain details that could enable the direct misuse of the research by those with malevolent intent."[21]

The goal was to deliver the critical information about the H5N1 potential for pandemic spread while minimizing the possible risk that the information could be used for nefarious purposes.

NSABB, Finding and Recommendations 2012, 1

Due to the issues at stake -public health and public security- in February 2012 the World Health Organisation (WHO) convened a technical consultation with participation from a variety of experts including doctors Fouchier and Kawaoka in order to clarify the key issues relating to their studies.[22] First, the WHO panel of experts recognised the potential for misuse of the results achieved and methods used in the studies. However, taking into account that the H5N1 continued to pose a great risk for causing a future pandemic -at least back at the time of discussions- they urged for the full disclosure of the manuscripts.[23] The redaction option is not a viable one, they noted. With a view to dealing with the dual-use problem, the idea of a mechanism ensuring the selective access only to those having a legitimate interest in sensitive research was tabled. It was accepted though that this is a challenging issue requiring time and further consultations with stakeholders from other professional communities most probably at the international level. Therefore, the launch of such a mechanism could be considered as an appropriate initiative to take on in the future.

Second, the participating experts examined specific questions relating to physical security and safety; what were the laboratory biosecurity standards observed during the conduct of the experiments? Were the modified viruses and related samples of H5N1 kept in safe locations? Is there a need for re-considering and enhancing the level of biosafety and security for such experimental works? The committee's participants did not contend any breach of the existing biosafety and security conditions applying to such type of research (BSL3+).[24] However, they called on competent authorities to re-evaluate the biosafety and security standards that should apply to related research in the future. In the interim, particular attention was drawn to raising awareness of scientists about potential risks and communicating to society the added value of such research endeavours.

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[20] Following the first review, "the NSABB recommended that the general conclusions highlighting the novel outcome be published, but that the manuscripts not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm". From the US National Institutes of Health website, "Press Statement on the NSABB Review of H5N1 Research," as of December 20, 2011, retrieved from: http://www.nih.gov/news/health/dec2011/od-20.htm

[21] "NSABB Findings and Recommendations," US National Institutes of Health, as of March 29-30, 2012, 1. Retrieved from: http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf.

[22] World Health Organisation (WHO), "Report on technical consultation on H5N1 research issues," (Geneva) as of February 16-17, 2012, retrieved from: http://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/en/

[23] According to the committee's overview the dissemination of the controversial research findings could offer significant benefits to global health; the findings could be used to improve sensitivity of public health surveillance, facilitate the early detection of potentially pandemic H5N1 strains, and might aid the development of vaccines and other countermeasures.

[24] Biosafety level 3+ (enhanced) containment laboratory.

Finally, the NSABB convened again in March 2012 to review the newly revised manuscripts in the light also of the opinion provided by the WHO.[25] The NSABB Findings and Recommendations report is accessible in the web and describes the final deliberations on the issue that took place on 29-30, March 2012. The Board reversed its stance and concluded that in spite of the fact that the manuscripts still raise dual-use concerns the benefits for publishing the work outweigh the risks. The majority of the Board's members recommended the full communication of the revised Kawaoka's paper. Concerning the Fouchier study, in a 6 to 12 decision the NSABB concluded that the manuscripts could be communicated but some further clarifications should be made prior to the publication.

Lessons Learned and Further Remarks

Drawing from the case study above, some further remarks could be suitable here. Controlling the publication of research on the basis of existing export control provisions is not a straightforward issue. It exemplifies both practical difficulties and a weakness of the legal framework to clarify several fundamental issues.

Lesson I: The Implementation of Export Controls vis-à-vis the Publication of Dual-use Research is Inextricably Linked to Practical and Legal Challenges

Given the potentiality the publication of research to constitute a form of 'export', certain issues would need clarification. First of all, who must be considered as the exporter and who the end-user of any given publication? For example, during the peer review process the academic might send an article containing technical knowledge of dual-use nature to the editor and the editor could afterwards make available such information to the evaluators. According to the export controls practice, the issue of location is very crucial and thus, if both the editor and the reviewers are established in non-EU countries more than one export authorisations may be required. That said, it is unclear if the legal responsibility must be borne by the original expediter of the sensitive information *i.e.* the academic or by the editor or whether both should share it. Moreover, the publication of a research work would basically mean the unhindered dissemination to anyone having access to the Journal's website or a certain library regardless of the country where she/he is based. For physical exports, article 2 of the dual-use regulation considers as 'exporter' any natural or legal person or partnership holding the contract with the consignee in the third country and having the power to determine the sending of the item out of the customs territory of the EU. Most of the time, neither the academic nor the editor and the evaluators hold a transfer contract and even if the academic signs a publishing contract it will be impossible to exclude consignees established in certain third countries. For electronic transfers, article 2 of the regulation considers as 'exporter' any natural or legal person or partnership that decides to transfer or make available controlled software or technology. Again under this contingency, both the academic and the editorial board may transfer controlled information and the problem of the end-user stands also here as an inextricable question.

In the H5N1 case, the Dutch government set an authorisation requirement for the export of the manuscript to a US-based peer-reviewed journal. In that sense, a physical export was taking place from the EU to the US. The stated end-use was publication in a scientific journal and the academic was considered as the exporter given that the author holds the right to withdraw the article any time before the publication. One could argue that the aim of the authorisation was actually to block the release of the information in general, worldwide until the evaluation of the risks and benefits associated with the study was completed. This way the competent authorities used the time in order to decide on a crucial issue and also, rendered the scientists aware of the dual-use potential of their work. Nevertheless, if the ESV is right in its estimations, Dutch scientists alone publish an average of 100 manuscripts per year containing information

[25] The degree of revision done by the authors is rather unclear. From the context, one may assume that the revision was not extensive. Instead, it seems that the revisions were limited to eliminating certain terminology and highlighting the added value of the research in question.

about pathogens listed in the Annex I of the regulation. Setting all these manuscripts to the approval of the competent authorities can be cumbersome for both licensing officers and scientists.

Lesson II: The Applicability of the 'Basic Scientific Research' Exemption is Contentious

The interpretation of exemptions applicable to research activities is a challenging issue due to ambiguities in the legal framework at the European and international level. The 'H5N1 case' demonstrates this problem. On the one hand, the researcher's argumentation was that the purpose of research was solely to explore mammalian transmissibility of an influenza strain and thus, the manuscripts justifiably fall within the basic research realm. On the other hand, the Dutch authorities supported their stance to impose an export authorisation by highlighting that making the H5N1 airborne is a practical goal and thus, the exemption is not applicable. From the Court's reasoning one could deduce that the defendant resorted to the definitions of basic and applied research as provided in the OECD's 'Proposed Standard Practice for Surveys of R&D' also known as the 'Frascati manual'[26] to make his case in the court[27]. It should be noted, that the EU regulation and consequently, the international regimes draw from these definitions originally established in the said manual. In fact, both refer solely to the definition of basic research without clarifying further the concept. According to these definitions, the main difference between basic and applied research is that the latter is directed towards a specific practical aim or objective. Apparently, such a general criterion can lead to different interpretations and it is not of help to regulators and practitioners dealing with the dual-use problematic.

Fundamental or basic research *is defined as the experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.*
Applied research *is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.*

'*Frascati Manual', 77-78*

The distinction between basic and applied research merits some further discussion. Generally speaking, 'basic research' is a poorly defined term that takes different nuances depending on the given circumstances under which it is used. The paper of Calvert and Martin provides an interesting summary of the different characteristics conferred to basic research as recorded in interviews with scientists coming mainly from physics and biology as well as policy makers.[28] At an epistemological level, basic research can be unpredictable, novel, and theoretical or it may describe things in reductionist terms. It may be also curiosity driven, oriented to benefit social welfare or without any practical usefulness at all. The basic research concept can embody contrasting elements and, virtually for almost any of the characteristics conferred to it there will be some evidence for their relevance to applied research, too. As Calvert and Martin observed already 15 years ago, the concept of basic research is characterised by complexity, flexibility and adaptability making it a persistent and long lasting term used regularly in the various interactions between scientists and policy-makers.[29] At the same time, this element of flexibility means

[26] The 'Frascati manual' was first issued 50 years ago by the Organisation for Economic Co-operation and Development (OECD) and, it is considered as the cornerstone of OECD efforts to increase the understanding of the impact of science and technology on economy. It deals exclusively with the measurement of human and financial resources devoted to research and experimental development (R&D) and it has become a worldwide standard for surveys measuring the input of R&D activities. The document was written by experts originating from the OECD member countries and its latest sixth edition (2002) is accessible in the OECD's website:http://www.oecd.org/sti/inno/frascatimanualproposedstandardpracticeforsurveysonresearchandexperimentaldevelopmen6thedition.htm.

[27] The 'Frascati Manual' is not explicitly mentioned in the Court's reasoning. However, it is the sole source where internationally accepted definitions for both basic and applied research are provided.

[28] A number of 49 professionals were interviewed on their understanding of basic research.

[29] Calvert, Jane and Martin, Ben. "Changing Conceptions of Basic Research? Background Document for the Workshop on Policy and Measurement of Basic Research," Science and Technology Policy Research (SPRU), University of Sussex (2001): 22-23, retreived from: http://www.oecd.org/sti/sci-tech/2674369.pdf.

that what constitutes basic research may depend to a large extent on the perception of whosoever speaks.

From an export control perspective, it seems that the 'basic research' concept connotes the exceptional character of research and aims at protecting its role in advancing science and society. Simply put, it saves scientists from undue hindrance in the conduct of lawful research and public authorities from a high volume of unnecessary export control applications. However, in practice, using the basic research term may increase the nebulous landscape of export controls for both 'exporters' and export control authorities for a number of reasons.

First, the boundaries between basic and applied research are indiscernible and are bound to become even more so due to the intensification of collaborations between universities and corporations. More particularly, basic research is publishable but applied research can be published as well. Private firms do not only produce greater numbers of publications but they also embark on collaborative publications with universities or other public research organisations. The 'paper-patent' divide which has been long used to signify the basic-applied boundary is becoming increasingly less appropriate.[30] Also, whereas basic research is generally not intended towards commercialisation, for certain emerging technologies the time lapse from very basic research to the production of marketable products is very short.

Furthermore, collaborations between universities and private corporations are increasingly favoured by governments and industry and public funding is not directed exclusively to public institutions and basic research. As a consequence, researchers can adapt the objectives of their projects in order to receive funding and thus, there is usually room for manoeuvring from knowledge of a more general and fundamental nature to practical applications. This factor implies that the institutional locus and the public or private funding of research activities cannot be a sufficient criterion for defining basic research. This is vividly illustrated in the responses of some of the participants in the study of Calvert and Martin: "if you walk into a laboratory how do you know whether they are doing basic or applied research?" "The sequencing of the human genome undertaken by a private initiative it would be basic research if it was being done in a university for non-profit purposes." [31]

Second, interpreting basic research on the basis of internationally accepted definitions established and analysed in the 'Frascati Manual' and the 'Manual for Statistics on Scientific and Technological Activities' is a rather challenging task.[32] The Frascati Manual highlights four characteristics for clarifying the basic scientific research concept:

- First, the performer of research may not know about actual implications when doing the research;
- Second, the results of basic research are not generally sold but are usually published in scientific journals or circulated to interested colleagues;
- Third and most important from the point of view of non-proliferation, occasionally, basic research may be classified for security reasons;
- Fourth, basic research can be distinguished to 'pure' and 'oriented'. This subdivision is suitable due to the admitted fact "that basic research can be oriented or directed towards some broad fields of general interest, with the explicit goal of a broad range of applications in the future."[33]

Pure basic research *is carried out for the advancement of knowledge, without seeking long term economic or social benefits or making any effort to apply the results to practical problems or to transfer the results to sectors responsible for their application.*

[30] Ibid, 20.
[31] Ibid, 9.
[32] OECD, "Frascati Manual", 75-82 and UNESCO, "Manual for Statistics on Scientific and Technological Activities", Division of Statistics on Science and Technology - Office of Statistics (1984): 17-30, retrieved from: http://www.uis.unesco.org/Library/Documents/STSManual84_en.pdf.
[33] Ibid, 77.

Oriented basic research *is carried out with the expectation that it will produce a broad base of knowledge likely to form the basis of the solution to recognised or expected, current or future problems or possibilities.*

'Frascati Manual', 78

On the other end of the spectrum, applied research involves considering the available knowledge and its extension in order to solve particular problems. As clarified in the Frascati Manual, the results of applied research are intended primarily to be valid for a single or limited number of products, operations, methods or systems. Further, applied research gives operational form to ideas and, the knowledge or information derived from it is often patented and it may be kept secret.[34] That said, one could reasonably ask the following question: Where does the H5N1 case actually fall? Should it be considered as (oriented) basic research or as applied research? To conclude, there are many conceptual and operational problems associated with the concept of basic research and its usefulness for trade controls is questionable.

The US government maintains a distinct approach towards this issue. According to the recently revised Chapter 15, Part 734.8 of the Code of Federal Regulations (CFR) administered by the Department of Commerce 'fundamental research' (this is the term used) shall mean[35]:

Basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community. Such research can be distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary reasons or specific national security reasons as defined in Part 734.11(b)

In the same provision it is clarified that fundamental research may be:

1. University based;
2. Based at a Federal Agencies or Federally Funded Research and Development Centres (FFRDCs) within any appropriate system devised by a such agency to control the release of information;
3. 'Corporate' research or research based elsewhere as long as researchers are free to make scientific and technical information resulting from the research publicly available without restrictions or delay based on proprietary concerns or specific national security controls as defined in part 734.11.

In all three instances, research stops being considered as fundamental when its results are subject to prepublication preview due to proprietary reasons, patent rights or other specific national controls as mentioned in Part 734.11(b).[36] Therefore, fundamental research should be understood in connection with the absence of non-disclosure provisos and other restrictions due to proprietary or security reasons and it shall be published freely.[37] Also, federally funded research may contain special clauses for non-

[34] Ibid, 78.

[35] The electronic version of the Code of Federal Regulations is accessible in the following link: http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

[36] According to the Part 734.11(b) examples of 'specific national security controls' include requirements for prepublication review by the Government, with right to withhold permission for publication; restrictions on prepublication dissemination of information to non-U.S. citizens or other categories of persons; or restrictions on participation of non-U.S. citizens or other categories of persons in the research. A general reference to one or more export control laws or regulations or a general reminder that the Government retains the right to classify is not a 'specific national security control'.

[37] Part 734.3 specifies that technology regulated under the jurisdiction of another agency, as well as printed books, publicly available technology, technology that has been or will be published, technology that arises during or results from fundamental research, educational technology, and technology in certain patent applications should be considered as fundamental research. On the contrary, proprietary research, industrial development, design, production, and product utilization the results of which are restricted and government funded research that specifically restricts the outcome for national security reasons are not considered as fundamental research.

dissemination removing thereby the 'fundamental' character of a study. The H5N1 manuscripts were meant to be published, did not contain non-disclosure clauses under proprietary or security reasons and therefore, they do qualify as fundamental scientific research and shall be published freely and without prior restraints in accordance with the First Amendment of the Constitution protecting the free expression of speech.

The US legislation is not limited in repeating the definition of fundamental research as set forth in the framework of international export control regimes. The fundamental research concept may include both basic and applied research undertaken presumably by any type of organisations. Academic research does not fall necessarily outside the scope of controls and industrial research does not always require an export authorisation in order to be transferred. This is in line with the role and nature of research in today's world.

However, the logic underpinning the implementation of the fundamental research exemption is a rather peculiar one. Proprietary restrictions and patent rights connote the non-public character of the research in question and a potential risk for misuse. It seems that there is a logical leap here. On the one hand, patent rights and proprietary restrictions connected with a research endeavour will admittedly imply an innovative achievement or a company's competitive advantage with regards to formulas, processes, and methods used in the R&D and production phases. On the other hand, proprietary restrictions do not necessarily imply a potential threat from an export control perspective. In that sense, their presence can be indicative, but not determinant. Moreover, the fundamental research exemption does not take into account a different contingency; what about academic research achieving a breakthrough discovery of dual-use concern for which no proprietary restrictions are applicable or sought? This is not a science fiction scenario if one looks at the H5N1 case. Naturally, a single regulatory framework may not always be in a position to effectively address all resulting questions and, export controls are not the only available tool for controlling sensitive research.

Lesson III: Export Controls: One Option Among Others

The US authorities did not resort to trade controls in order to deal with the controversial manuscripts presumably because they have a distinct approach to interpreting the basic scientific research exemption. Otherwise, one could assume that although both research works were submitted to leading US based journals, the export control authorities could have claimed that the publication by these journals requires an export authorisation since it equates to an export from the US to unauthorised destinations and end-users. To this end, the editorial boards of the two Journals would have been required to ask for an export authorisation from the Department of Commerce. Regardless of this hypothetical case, the US approach provides for a further mechanism to be considered. Research proposals and manuscripts of 'dual-use concern' can be evaluated by an advisory committee specially devised to assess sensitive scientific proposals and production of dual-use nature in life sciences. Such a committee should be composed of experts coming from all different authorities concerned and it would bring together the research and the security communities (*e.g.* intelligence, national security authorities, and public health and bio-safety experts). In the USA this role is entrusted to NSABB, the federal advisory committee addressing issues related to biosecurity and dual use research at the request of the United States Government.[38]

As highlighted in the landmark document 'Biotechnology Research in an Age of Terrorism', also known as the 'Fink report', almost all biotechnology in service of human health can be subverted for

[38] From the NSABB website: 'The NSABB has up to 25 voting members with a broad range of expertise including molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and other related fields. The NSABB also includes non-voting ex officio members from 15 federal agencies and departments'. Retrieved from: http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb.

misuse by hostile individual or nations.[39] This premise about the dual-use potential of bio-technology led the authoring committee of the Fink report to recommend the creation of 'an advisory board for biodefense' and eventually to the foundation of the NSABB. The same report stresses the importance of overseeing dual-use research already in the phase of planning instead of screening completed research works ready for publication. In this regard, the recommendation 'Review of Plans for Experiments' in the Fink report determines seven classes of experiments that could have a high potential for misuse. Among them categories four and five 'experiments that would increase transmissibility of a pathogen' and, 'experiments that would alter the host range of a pathogen' seem to match with the main objectives pursued in the H5N1 research.[40]

The increased domestic and international expenditure in basic and applied public health and bioterrorism defence research will inevitably create an increased number of research activities that raise concerns about miscue.

'Fink Report', 2004, 109

As prophetically mentioned in the conclusions of the 'Fink report' the number of dual-use research experiments in bio-science is expected to get higher for two reasons: first, scientists need to know what exactly makes certain microbes pathogenic and virulent in order to produce appropriate vaccines and second, the funding spent on bio-defence is anticipated to continue increasing in the future in the US and globally due to the importance of preparedness for the public health security.[41] The importance given to dual-use research in life sciences is evidenced also by the fact that there is a specific definition for identifying such sensitive research. The US Department of Health and Human Services provides as follows:

'Dual-Use Research of Concern' (DURC) in life sciences, is 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, materiel, or national security.

US National Institutes of Health (NIH) website[42]

The definition implies correctly that it is not all dual-use research that poses an imminent and perceivable threat but only the most sensitive one. What most sensitive means exactly is left apparently for the NSABB to decide upon and certainly includes research that can be 'directly misapplied'. Strange enough, dual-use research is defined solely in the context of life sciences and most frequently, in connection with bio-safety and biosecurity aspects and the broader discussion on the 'ethical conduct of research' taking place in this area.[43] However, dual-use research can relate to a variety of scientific fields from nuclear research that is the most evident case to ICT research and software development (*e.g.* in relation to cyber security purposes). It is worth wondering then why there is not an all-encompassing definition at national, European or international level or, certain criteria for identifying controlled dual-use research.

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[39] National Research Council (USA). *Biotechnology Research in an Age of Terrorism (The Fink Report)* (Washington, D.C.: The National Academy Press, 2004), preface.

[40] Recommendation two clarifies that based on the available information experiments of concern currently posing or expected to pose a high risk in the close future are those that: 1. demonstrate how to render a vaccine ineffective; 2. confer resistance to therapeutically useful antibiotics or antiviral agents; 3. enhance the virulence of a pathogen or render a non-pathogen virulent; 4. increase transmissibility of a pathogen; 5. alter the host range of a pathogen; 6. enable the evasion of diagnostic/detection modalities; 7. enable the weaponisation of a biological agent or toxin. National Research Council (USA), *Biotechnology Research in an Age of Terrorism,* 5.

[41] National Research Council (USA), *Biotechnology Research in an Age of Terrorism,* 109.

[42] Information retrieved from: http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern

[43] For the relevance of the dual-use concept to the ethical discourse indicatively see the paper below:
Rath, Johannes Ischi, Monique and Perkins, Dana. "Evolution of Different Dual-use Concepts in International and National Law and its Implications on Research Ethics and Governance," *Science and Engineering Ethics 20 - Springer* (2014): 769-790, doi 10.1007/s11948-014-9519-y.

Conclusion

The dual-use concept as mirrored in national, European and international trade control frameworks is a dynamic one. The dual-use control lists are amended frequently and trade control provisions evolve depending largely on external factors reshaping the international environment. Nuclear and bio-terrorism was not a perceivable threat, transporters and brokers did not have liabilities under export control law and controls in intangible transfers of technologies were not even conceivable few decades ago. Inevitably, there is a trend to include in the scope of controls a wider ensemble of actors, processes and objectives with a view to furthering non-proliferation and broader security imperatives. For instance, the current discussion on the reform of the EU trade control system explores the possibility of introducing explicitly human security aspects under the objectives of the dual-use regulation, a request first worded by the European Parliament.

In this regard, the Wassenaar Arrangement recently adopted controls on certain ICT technologies and software that could be used for mass surveillance. That said, research activities deal with a wide array of materials and above all technologies and software that are currently or may be controlled in the future under dual-use and arms control regulations. Making the publication of research subject to an export authorisation process is not explicitly provided in the export control law. However, sending a manual containing controlled technical data to a proscribed destination by post or e-mail is a licensable activity unless certain exemptions are applicable. In the USA where the Export Administration Regulation (EAR) and the International Traffic in Arms Regulations (ITAR) have admittedly a more far-reaching character compared to the European one, American universities have implemented internal compliance systems already for many years. European universities are moving slowly towards the same direction, too. In any case, the debate on the role of export controls *vis-à-vis* research has been intensified during the last years and the scope of trade controls has been expanding ever since their creation. Whether certain provisions addressing directly dual-use research are to be established in national, European or international level remains to be seen.

The H5N1 case study illustrates *inter alia* that trade control implications are intensified in a research context and therefore, clear-cut guidance and legal provisions could be of great help. The applicable legal framework in national, European and international level falls short of providing a definition of dual-use research controlled under the export control law or certain criteria for assessing such research. This relates certainly to the absence of an internationally accepted definition of the 'dual-use' term and the nature of the dual-use problem in general. Almost all items or scientific fields may have some potential for misuse. Naturally, this does not imply that everything is export controlled. More crucially, the lack of a common definition can lead to misconceptions and misunderstandings by the scientific community. For instance, ethical concerns are not necessarily identical with national and international security issues dealt with under trade controls. University ethical committees should acknowledge this difference and researchers should be made aware of both the role of trade controls and the consequences linked to their violations (administrative and criminal penalties).

In their effort to apply export controls provisions without constraining unduly the free conduct of research, US export control authorities employ a rather peculiar approach in interpreting the basic scientific research exemption; research that is restricted due to proprietary reasons does not qualify as fundamental and it will require a license. On top of this, 'basic scientific research' and 'public domain information' are two interrelated concepts. Public domain information is widely available and thus, it must remain unhindered. Basic scientific research is to be published and shared freely and therefore, it belongs normally to the public domain, as well. One could argue that this flexible approach allows trade control authorities to oversee cutting edge technologies and software that can be critical from a security point of view. It does not ensure however that sensitive research is always caught and it may put undue hindrance to certain research projects given that non-disclosure norms do not imply necessarily a threat. This interpretation of basic research is not applicable only in the USA. Although there is no common EU

stance on the issue, different Members States such as Germany and the UK have implemented the basic research exemption on the basis of the distinction between proprietary and publicly available research. However, as the H5N1 case demonstrated, in Europe scientific research may be restricted or require an export authorisation before being available to the public.

Finally, one could claim that setting the publication of academic research under the export authorisation process is but one of the available options. In the US for instance, the oversight of sensitive research is done through different regulatory frameworks and channels; funding and regulatory agencies may impose non-disclosure clauses for sensitive research, export control authorities evaluate on a case by case basis export applications for proprietary research and also, the NSABB may contribute to the assessment of DURC in life sciences. Consequently, establishing an advisory committee tasked to evaluate the potential of dual-use research should be explored at national or European level. The role of such a committee could be to oversee dual-use research originating from the whole range of scientific fields affected by export controls and certainly 'applied sciences', not just life sciences. The added value of such an initiative could be enhanced by further actions undertaken by governments (*e.g.* for the coordination of different national committees) and self-governance measures to be undertaken by research organisations.

Annex

Table I: Examples of controllable activities under EU law

I. Transfers of equipment and materials		**II. Transfers of technical data and software**		**III. Provision of technical assistance***	
Tangible means	Provision of equipment, materials (*e.g.* under a multilateral contract)	*Tangible & intangible means*	Sharing data/ software by electronic means (*e.g.* e-mail, upload on websites) or by post	*Intangible means*	Teaching/ Providing assistance in third countries (*e.g.* in int. campuses & conferences)
	Decommissioning of reactors and dismantling of labs (e.g. selling or giving away used equipment)		Publishing scientific research (in printed or e-versions)		Oral provision of assistance over the phone from the EU (*e.g.* consulting services)

* The provision of technical assistance is covered partly by the Council Joint Action 2000/401/CFSP

Supplement to table I

(a) 'technical assistance' means any technical support related to repairs, development, manufacture, assembly, testing, maintenance or any other technical service, and may take forms such as instruction, training, transmission of working knowledge or skills or consulting services;

(b) 'technical assistance' includes oral forms of assistance;

Article 1 of the Joint Action 200/401/CFSP

'Technology" means specific information necessary for the development, production or use of goods. This information takes the form of 'technical data' or 'technical assistance'.
'Technical data' may take forms such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read-only memories
"Software" means a collection of one or more 'programmes' or 'micro-programmes' fixed in any tangible medium of expression.

Annex I of the Regulation p. 42-43

List I: Entires under which H5N1 is controlled

1C351 (Materials): Human and animal pathogens and "toxins", as follows:
a. Viruses, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material including living material which has been deliberately inoculated or contaminated with such cultures, as follows:
[….]
4. Avian influenza virus, which are:
a. Uncharacterised; or

b. Defined in Annex I(2) EC Directive 2005/94/EC (O.J. L 10 14.1.2006, p. 16) as having high pathogenicity, as follows:
1. Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1,2; or
2. Type A viruses of the subtypes H5 or H7 with genome sequences codified for multiple basic amino acids at the cleavage site of the haemagglutinin molecule similar to that observed for other HPAI viruses, indicating that the haemagglutinin molecule can be cleaved by a host ubiquitous protease;

1E001 (Technology):

"Technology" according to the General Technology Note for the "development" or "production" of equipment or materials specified in 1A001.b., 1A001.c., 1A002 to 1A005, 1A006.b., 1A007, 1B or 1C.