Food and Agriculture Organization of the United Nations

European Commission for the Control of Foot-and-Mouth disease

The impact of the Nagoya Protocol on vaccine security for foot-and-mouth disease research and development: options for a solution

Third multistakeholder meeting on vaccine security. Report

March 2023

European Commission for the Control of Foot-and-Mouth Disease

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Prioritization of antigen management with international surveillance tool

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Vademos
FMD vaccine demand estimation model

GVS
Global vaccine security

POv
Vaccine prequalification

PCP
Progressive control pathway

PSO
Pcp practicioner officers

PPP
Public private partnership

Third Multistakeholder Meeting on Vaccine Security

The impact of the Nagoya Protocol on vaccine security for foot-and-mouth disease research and development: options for a solution

29 March 2023

Contents

Background and outcome of the meeting

In 2020 the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) established a multistakeholder platform (MSP) on vaccine security. The MSP brings together experts from all the key stakeholder groups involved in vaccine security including manufacturers of Foot-and-mouth And Similar Transboundary (FAST) vaccines, reference laboratories, international animal health organizations including the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (WOAH), NGOs, regulatory authorities, national animal disease control authorities, and animal disease risk managers. A key recommendation arising from the first meeting of the MSP was that a problem statement should be developed on the impact that the Nagoya Protocol of the Convention on Biological Diversity (CBD) as the protocol was perceived by participants to be having a negative impact on access by manufacturers and others to strains of foot-and-mouth disease virus (FMDV) for the purpose of research, including the development of new FMD vaccines[1]. Since this meeting, there has been increasing awareness in the wider health community of the challenges arising from the way in which the Nagoya Protocol is currently being implemented with respect to a wide range of human and animal pathogens. Several initiatives have been taken with respect to human diseases to address the issues arising from access and benefit sharing (ABS) legislation implemented by national authorities in compliance with the provisions of the Nagoya Protocol. In contrast, in the veterinary domain, there has been no concerted attempt to define the problems arising with respect to veterinary pathogens and any measures to address ABS requirements have been implemented on a disease-by-disease basis, including for FMD.

Exchange of strains of FMDV is essential for diagnosis, surveillance and research and any constraints on this exchange represents a risk to vaccine security. In response to rising concerns, in January 2023, the EuFMD organized a consultation to discuss the challenges that have arisen since the implementation of the Nagoya Protocol in relation to sharing of strains of FMDV for the purpose of surveillance, research and the development of new vaccine strains. Experts included representatives from the FAO, WOAH, the Pirbright Institute, other FMD reference laboratories, FMD vaccine manufacturers, pharmaceutical industry organizations, law firms with expertise on the Nagoya Protocol, NGOs (GALVmed) and the secretariat of the CBD. This expert consultation recommended that EuFMD support the WOAH/FAO Reference Laboratory Network for Foot-and-Mouth Disease to publish a scientific paper in a peer-reviewed journal to raise awareness of the issue among the laboratory and research community working on FMD. The consultation recognized that the issue is highly complex and could not be covered in adequate depth in a short scientific publication. During and after the expert consultation meeting, those involved reviewed and provided extensive input into a draft report prepared by the EuFMD secretariat elaborating and exploring the problem statement in depth and proposing a framework by which stakeholders could develop solutions to the issues identified in the short, medium and longer term. The resulting draft report was presented to the MSP at their meeting on 29 March 2023 for discussion and endorsement.

The final outcome of the MSP meeting therefore takes the form of two reports:

[1] Explore options to improve security of vaccine supply against Foot-and-Mouth and other similar transboundary diseases. Rome, Italy (2020). https://www.fao.org/3/ca7778en/ca7778en.pdf

1. The report entitled “The impact of the Nagoya Protocol on Foot-and-Mouth Disease; A report by the Multistakeholder Platform on Vaccine Security of the European Commission for the Control of Foot-and-Mouth Disease on the implications for animal health of access and benefit sharing arrangements in the context of the Nagoya Protocol with respect to Foot-and-Mouth Disease”.

This report is intended as a ‘standalone’ report covering the entire scope of the work carried out in relation to the impact of the Nagoya Protocol on FMD. The report identifies the practical impacts of the Nagoya Protocol and related ABS frameworks on FMD research and development, presents a problem statement on these important issues, provides an assessment of options for possible solutions, and proposes an approach for the stakeholders to develop a preferred solution for FMD in the context of a wider consideration of veterinary pathogens.

2. The detailed report of the MSP meeting of the 29 March 2023 contained in this document.

This is a report of the third meeting of the Multistakeholder Platform on Vaccine Security of the European Commission for the Control of Foot-and-Mouth Disease. The report provides summaries of the presentations given by stakeholders at the meeting and of the discussion that took place before adoption of the report detailed above at (1). This report is provided to enable readers to understand the background to the report and the views of the contributing stakeholders.

Report of the third multistakeholder meeting on Vaccine Security

"The impact of the Nagoya Protocol on vaccine security for foot-and-mouth disease research and development: options for a solution", 29 March 2023, online.

Executive Summary

This was the third meeting of the Multistakeholder Platform on Vaccine Security convened by the EuFMD. Following an expert consultation in January 2023, EuFMD had prepared a 'Draft Report on the animal health implications of implementation of the Nagoya Protocol with respect to Foot-and-Mouth Disease'. This report was shared with participants in advance of the meeting with a view to comment and potential endorsement at the meeting. During the meeting, presentations on the Nagoya Protocol and its impact on FMD, and other human and animal diseases, were given by a number of stakeholders including HealthforAnimals, the Secretariat for the Convention on Biological Diversity, Boehringer Animal Health, and the Pirbright Institute. During the final session of the meeting the following recommendations for actions were agreed.

The Multistakeholder Platform **recommended:**

- **the EuFMD** to publish the draft report on the impact of the Nagoya Protocol on FMD following receipt of final comments from members of the MSP.
- **All parties** to raise awareness of the impact of the NP on animal health with respect to FMD and engage with stakeholders in provider countries in discussions on ABS.
- **FAO and WOAH** to consider taking action together with involved stakeholders to address the impact the NP is having on animal health with respect FMD, FAST diseases and other veterinary pathogens.
- **FAO/WOAH FMD Laboratory Network** to consider establishing a working group to assist WOAH and FAO on the development of a system for improved ABS for FMD materials, aligned with the principles of the NP.
- **FMD vaccine manufacturers** to engage with discussion on ABS in relation to FMD materials for research and development, including the development of new vaccines.
- **EuFMD** to seek a mandate in the context of the next strategy (2023–2027) to continue to foster solutions, in close coordination with FAO and WOAH, that promote vaccine security by improving access to FMD materials for research and development whilst ensuring fair and equitable access to the benefits for provider countries that align with principles of the NP. The work in relation to FMD should be taken forward within the wider context of other animal diseases to ensure the greatest possible level of support for developing solutions that are appropriate for the veterinary sector as a whole.

Opening of the meeting

The meeting was chaired by M. Ilott (EuFMD). The meeting agenda is shown in Appendix 1. The meeting took place online, with 106 participants.

Introduction by F. Rosso (EuFMD, Deputy Executive Secretary)

The introduction to the meeting was presented by F. Rosso, Deputy Executive Secretary of the EuFMD. The MSP on vaccine security was established three years ago with stakeholders from public and private sectors meeting to discuss issues affecting vaccine security and identify key aspects and action points related to the quality of vaccines, forecasting of vaccine use and the assessment of the impact of the NP on vaccine security. Vaccine security is a critical part of the EuFMD workplan with a primary focus on FMD, however this also extends to other FAST diseases. It is evident the implementation of the NP is having an impact on the exchange of viruses for FMD research and development, including vaccine development, with potential adverse effects on FMD control. These impacts were highlighted at the MSP vaccine security meetings in 2020 and 2022 and the EuFMD Open Session 2022, and it was agreed a problem statement should be developed to understand the issues for all stakeholders. A working group was organized in January 2023 to bring together different perspectives and discuss the challenges. The objective of this meeting was to develop a problem statement on the impact of the NP on FMD and formulate possible solutions, while respecting the principles of the Protocol and ABS. A need to work with all relevant stakeholders and provider countries to develop a framework for a solution was identified. From this meeting, a report detailing the options for a solution was prepared and has been shared with a larger audience of stakeholders and will be the basis for today's meeting. The objective of this meeting is to raise awareness of the impacts of the NP and make tangible steps towards a solution to the issues identified.

Presentations

Carel du Marchie Sarvass (Executive Director, HeathforAnimals)

Perspectives: Animal health innovations and the Nagoya Protocol

HealthforAnimals is a global association representing animal health companies and associations. The presentation recognized the principles of ABS enshrined in the NP and the need for companies to be compliant. However, often expertise and resources in national bodies implementing NP are lacking and therefore it can be challenging to identify the steps companies must follow to get the necessary agreements to utilize genetic materials from provider countries. There is also competition for research and development funding within companies and therefore, where there is uncertainty, funding may be directed away from veterinary public health support for FAST diseases. There is also a general lower availability of funds in animal health compared to human or plant health, and this is perhaps not always appreciated. Industry is eager to find a solution and understand that it would need to meet several criteria. These include respecting the spirit of the NP, be designed for FMD but with other FAST diseases in mind for future application, work for all involved, large or small, public or private, be simple and affordable, have broad support, including political support, and be driven by public entities, with industry involved at a distance.

Bart Van Vooren (Covington & Burling)

Seasonal influenza and pandemic influenza pathogen sharing and the Nagoya Protocol.

Mr Van Vooren provided background on the Convention on Biological Diversity and the Nagoya Protocol. He explained the complexity that arises due to the fact that the provisions of the Nagoya Protocol are implemented through national legislation governing access and benefit sharing. Each country implements ABS legislation at different times, with different scope and with differing detailed requirements. This makes it extremely difficult and time consuming to identify exactly what ABS requirements apply in a particular country and to draw up corresponding agreements on Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) in line with the Nagoya Protocol. He outlined the various arrangements that have been put in place for exchange of human influenza viruses within the Global Influenza Surveillance Response System (GISRS) and how limitations in this system led to the subsequent development of the Pandemic Influenza Preparedness Framework (PIP). Various elements of these systems including the use of standard material transfer agreements were highlighted as relevant when developing an appropriate system for exchange of FMD viruses. Finally, he made recommendations on lessons that should be learnt from the human experience when developing a veterinary-specific solution.

Taukondjo Shikongo (Secretariat of the Convention of Biological Diversity (CBD))[2]

The Convention on Biological Diversity and the NP on ABS

This presentation summarized the history and principles of the NP, including why the NP was created to help implement the provisions of the CBD related to ABS with greater legal certainty, clarity and transparency. It was noted that the Nagoya Protocol focuses on 'utilization' of genetic resources. Provisions are related to access, benefit sharing and compliance. If dealing with any country, that country's ABS laws must be complied with, even if the country is not party to the NP.

Information was given on special considerations such as Art. 8(b) (relating to health emergencies), Art. 8(c) (relating to food security), Art. 4 (relating to specialized international ABS instruments) and Art. 19 and 20 (encourages sectoral model contractual clauses for MAT and development of best practices and standards in relation to ABS). The status of digital sequence information (DSI) in the Nagoya Protocol was also described. DSI emerged as an issue in 2016. COP-15 adopted a decision on benefit sharing and establishing a mechanism including a global fund for sharing benefits of DSI.

The Kunming-Montreal Global Biodiversity framework, a plan to bring about a transformation in societies relationship with biodiversity by 2050, was highlighted. This has four goals, and goal C relates to ABS – that benefits from the use of genetic resources are shared and sustainably increased.

It was also noted that it is important to take into consideration the concerns and perspectives of both sides, and while the challenges access rules may have created in the FMD sector are valid, only by acknowledging the concerns of those who have advocated for ABS laws can trust be built. All parties, including industry, should come together to discuss finding a solution. The focus will need to be on understanding the underlying root causes of the challenges and the various needs, interests, and concerns of all involved. Once these are understood, then meaningful and informed adaptive solutions will emerge.

[2] The Secretariat of the Convention on Biological Diversity participated in the meeting as a resource person and the views expressed in this report do not necessarily reflect those of the Secretariat.

Elke Abbeloos (Boehringer Ingelheim)

Implementation of Nagoya and ABS laws hampers FMD vaccine development

This presentation gave a detailed account of the problems faced by industry in respect to the Nagoya Protocol, with a focus on FMD. It was emphasized that the entire animal health market is only a fraction of the size of the human vaccine market and the global FMD market is estimated to be only 1 to 5 percent of the global animal health market. There is a tendency for provider countries to overestimate the financial benefits that may accrue to a company from the development of a new vaccine strain for FMD. FMD companies source potential new vaccine strains from regions where the disease is endemic and where new variants of FMD emerge. Only a limited number of countries have ongoing active surveillance and are sending strains of a representative number of outbreaks to the reference labs. As a result, manufacturers are already technically restricted in their choice of strains to become potential vaccine candidates. Companies must then assess and comply with the respective ABS legislation of that country or region and come to an agreement before assessing the technical viability of that strain as a vaccine candidate. A written agreement in the form of a prior informed consent must already be in place before a potential vaccine strain identified for development. Often authorities are only willing to issue such PIC when strains are directly sourced through the local reference lab instead of the World Reference Lab, which needs the involvement of a local partner and increases complexity, legal uncertainty, and timeline even more. The different steps of the vaccine development process were explained and the various points where the Nagoya Protocol impacts was noted. Some examples of real cases were given where impediments in accessing virus strains had occurred as a result of the Nagoya Protocol. No strains requiring compliance with the Nagoya Protocol and national ABS laws have been obtained to date. Companies are willing to share the benefits that arise from developing new vaccine strains provided that the solution for benefit sharing is simple to administer and fair to both the company and provider countries. The intrinsic value of the vaccine's availability, in terms of improving control, eradication or prevention of future incursion should be emphasised as a benefit and understood as generally surpassing any monetary value a company may be able to provide a result of sales of a new vaccine. Contributing to capacity building and sharing expertise is also possible but may be challenging to the company long term due to the drain on limited internal resources. Keys to a way forward were suggested including creating greater awareness with agricultural ministries (who are already familiar with the risks of FMD and other Transboundary Animal Diseases) on the challenges that the Nagoya Protocol represents by limiting access to new strains. At the same time, awareness needs to be raised of Nagoya Protocol focal points (who may already be familiar in general terms that pathogens fall within the scope of the Nagoya Protocol) of the economic cost of FMD and the intrinsic value of vaccines. Any potential solution would best be trialled in a few pilot countries, particularly those with (i) a high interest in FMD eradication and which actively send samples to the FMD world reference laboratory (WRL) and (ii) are known to have in place a functional system for negotiating PIC and MAT for Nagoya Protocol.

Donald King (FMD WRL, The Pirbright Institute)

Nagoya Protocol - Implications at reference laboratories and research organisations

This presentation gave some background on the role of reference laboratories and the global FAO/WOAH FMD Reference Laboratory Network. The Nagoya Protocol has been on the agenda of the

network since 2017 and in 2022 the network agreed to prepare a problem statement. A summary of material that is within scope and out of scope was shown. It is generally considered that the core work of the reference laboratory in terms of diagnosis and surveillance does not fall within the scope of the Nagoya Protocol. However, these same samples are often subsequently used, either within the receiving laboratory or by a third party, for activities that count as 'utilization' with the scope of the Nagoya Protocol. The outcomes of this often leads to improved tools to control FMD, feeding back to the provider countries. Mr King emphasised that any action taken with respect to facilitating compliance with the Nagoya Protocol must not have the perverse outcome of impeding existing global surveillance activities.

The types of challenges faced by the FMD Reference Laboratory network were discussed, including the lack of understanding on the requirements across the board, difficulties communicating with the national focal points, and the legal complexity of the implementation of the Nagoya Protocol in national ABS legislation. Reference laboratories often act as the provider of materials to the utilising institution/company, but generally deal with researchers or vets, not the NFPs or legal teams.

Challenges are also faced by academic researchers where research projects can be highly speculative and may not yield benefits to be shared, yet PIC and MAT need to be agreed before work can start. Any solution needs to start with awareness raising and to engage all stakeholders in the chain for supply and use.

Discussion

The discussion, moderated by D. Mackay (EuFMD), was focussed on the emerging findings and considerations arising from the 'EuFMD draft report on the animal health implications of implementation of the Nagoya Protocol with respect to Foot-and-Mouth Disease', and the conclusions and recommendations from the meeting.

Background

In understanding the background to the report and the current meeting, it was noted that previous meetings of the EuFMD Vaccine Security MSP have identified the current implementation of the Nagoya Protocol as a major issue limiting access to FMD materials for the purpose of developing new vaccine strains. While the WHO is the lead organisation for such issues for human diseases, no single organisation plays the same role for veterinary pathogens leading to uncertainty as to who should address this problem for veterinary pathogens, including FMD virus. The EuFMD considers that ready exchange of FMD materials, particularly for the development of new vaccine strains, is essential for vaccine security and falls within Pillars I and III of its work programme. While EuFMD cannot be responsible for implementing solutions, is well placed to bring together the wide range of stakeholders necessary to develop a solution that addresses the specific challenges of FMD. Any solution for FMD needs to be cognisant of the same challenges that exist for other veterinary disease, particularly FAST diseases. To address this, EuFMD convened a meeting of experts and prepared the draft report that was circulated in advance of the meeting.

Emerging findings and considerations

Promoting access to genetic resources

It is important to identify how to move forward with resolving the challenges, but also to note that some activities are outside the scope of the Nagoya Protocol, and any solution should not interfere with these. An effective system for exchange of FMD materials between members of the FAO/WOAH Network of FMD Reference Laboratories and laboratories in provider countries already exists for the purpose of diagnosis and surveillance, and it is important this can continue unimpeded.

EuFMD is currently not the organization responsible for implementing any solutions, however FAO, WOAH and other involved stakeholders may wish to explore options to develop an approach to facilitate exchange of FMD materials between the Network laboratories and third parties for the purpose of research and development, including the development of new vaccine strains.

Any approach must comply with the requirements of the Nagoya Protocol, particularly with respect to ABS. It should also take into account the experience gained from other diseases where exchange of materials between a network and a third party for research and development is based on one or more standard MTAs that include standard terms aligned with the NP in relation to PIC and MAT. Additionally, a means of supporting the considerable additional human and financial resources that would be required for implementing any NP compliant solution is required.

Questions and comments

- Regarding the role of WOAH in developing a solution, Francois Diaz (WOAH) commented that WOAH is interested in this issue and has sought feedback from member countries on the impact of the implementation of NP for a number of years. Similar to WHO's focus on influenza, it is a good idea to investigate a solution for FMD, and in future this could be applied to other veterinary pathogens. WOAH could be involved but requires a recommendation from its Member Nations, which could stem from this meeting, as a first step to take action.

- A question was raised about whether the current activities of the WRL (of receiving/collecting strains) actually fall under the scope of the Nagoya Protocol. It was noted that diagnosis and surveillance are not generally considered to fall within scope, and that PIC and MAT agreements generally pertain to downstream utilisation of the collected strains, if they occur. B. van Vooren added that while NP does stipulate 'utilization', meaning research and development, the individual country ABS laws are varied in their definition of what utilisation actually is, e.g. some may consider supply itself to be a form of utilisation. The recommendation was to not be too focused on what is in or out of scope of the NP, but rather develop an outline of what an agreement for FMD could look like, focussing on the key objectives for access and a mechanism to ensure fair and equitable sharing of any benefits.

- In relation to the relevance of strains from countries who have not ratified the NP, it was noted that when devising a solution, the objective should be a framework that not only considers the NP but looks at wider ABS issues to ensure exchange of FMD materials and considers how

benefits can be fair and equitably shared, taking into account that benefits may not only be financial but also improving the technology and capacity of provider countries.

Sharing of benefits arising from utilisation

There are a number of different solutions, treaties, biobanks, GISRS, PIP etc. for other diseases, adapted for their particular needs. The focus of EuFMD is FMD and therefore it is important to consider an approach that fits FMD, and what is required for FMD, considering the existing infrastructure.

Reviewing the process by which FMD materials are made available for research and development, including the development of new vaccine strains, provides an opportunity to better define the benefits that provider countries may gain from sharing of their genetic resources. Provider and recipient organisations, and their respective hierarchies, should work together to agree what constitutes a benefit with respect to FMD and how such benefits might be shared fairly and equitably.

Analysis of benefit sharing should extend beyond financial benefits. The intrinsic value of having a vaccine available to control FMD may be of significantly greater value to the provider country than direct monetary benefits. There needs to be a wider discussion on what benefits could be made available by companies and what benefits are of most interest to provider countries. For example, how to improve access by provider countries to the technologies, including FMD vaccines and their manufacture, that arise from utilisation of the genetic resource. There needs to be greater awareness of the commercial realities of FMD vaccine manufacture, and the resources required for developing the capacity of the FMD network in provider countries and how they will be funded.

Questions and comments

- T. Shikongo commented that the presentations have described the impacts of NP on vaccine security. However, it must be noted that the NP has provided a new set of rules on ABS, and this led to countries creating their own laws relating to ABS. And it is more the impacts of the challenges from ABS national implementation that impacts vaccine security. There is lack of capacity to implement ABS laws, inability to negotiate blanket agreements with governments, and lack of uniformity on what is seen as benefits and fair sharing of benefits.
  Quantifying benefits at the time of access is challenging. Therefore, we need to consider modalities to determine the potential benefits and generate data to guide on this.
  Technology transfer and capacity building is wanted. By assisting countries to develop their own tools and expertise, it may result in a country's own researchers facing challenges because of their national ABS legislations and this may lead to some unlocking of the challenges. NFPs are generally not scientists or lawyers, so there is a need for capacity building at multiple levels to ensure harmonisation of legislation. Importantly, all players must be at the table for discussions and meaningful exchanges between partners, including industry, to identify a solution to address the concerns of all involved.
  A dialogue between FAO, WOAH, CBD and industry would be beneficial.

- B. van Vooren added it is indeed the divergence in ABS laws that causes many of the issues, but it is the ambiguities and vagueness in the international instrument of the NP that resulted

in this. Therefore, it is important that the solution for FMD starts at the international level and has overarching clarity and clear definitions.

- Comments were made that any framework for a solution for FMD must keep other pandemic and zoonotic disease in focus. However, due to the nature of FMD and the resources available it was considered that it would be better to focus on FMD initially and use the model as a basis for other pathogens rather than try to get a global animal pathogen solution in the first instance. FMD could act as a pilot for other diseases.

- A standard MTA could be a possible option for FMD. A 'coalition of the willing' including selected countries (both environment and animal health ministries), the Reference Lab Network, WOAH, FAO and manufacturers getting together to discuss such an MTA may be a good basis for developing a solution in a relatively short time frame.

Conclusions and recommendations

- The MSP endorses the finding of the EuFMD draft report that the current implementation of the NP, and related national ABS laws, with respect to FMD both limits access to FMD materials and reduces the likelihood that provider countries will benefit from the utilisation of these materials.

- The MSP considers that the first step in addressing the challenges identified is to raise awareness of the animal health consequences of the current approach to the implementation of the NP, and related national ABS laws, with respect to FMD and other animal diseases and encourages MSP participants to make use of the EuFMD report as a tool for raising awareness. If resources are available, EuFMD may facilitate an awareness campaign.

- The MSP recommends that all stakeholders work to improve ABS with respect to FMD materials when used for the purpose of research and development, including the development of new vaccines. All stakeholders include international organisations, reference laboratories, research institutes, vaccine manufacturers, national laboratories, representatives of industry and representatives for bodies responsible for agreement at a national level in provider and recipient countries. It is highly important the point of view of provider countries is considered in these discussions.

- A proof-of-concept initiative among parties (including countries) willing to participate and start finding a solution such as an agreement that addresses the NP principles and well-defined benefits may be a first step for a broader solution for FMD.

The MSP endorses the following recommendations for action:

- **Recommended the EuFMD** to publish the draft report on the impact of the Nagoya Protocol on FMD following receipt of final comments from members of the MSP.
- **Recommended all parties** to raise awareness of the impact of the NP on animal health with respect to FMD and engage with stakeholders in provider countries in discussions on ABS.
- **Recommended FAO and WOAH** to consider taking action together with involved stakeholders to address the impact the NP is having on animal health with respect FMD, FAST diseases and other veterinary pathogens.
- **Recommended FAO/WOAH FMD Laboratory Network** to consider establishing a working group to assist WOAH and FAO on the development of a system for improved ABS for FMD materials, aligned with the principles of the NP.
- **Recommended FMD vaccine manufacturers** to engage with discussion on ABS in relation to FMD materials for research and development, including the development of new vaccines.
- **Recommended EuFMD** to seek a mandate in the context of the next strategy (2023-2027) to continue to foster solutions, in close coordination with FAO and WOAH, that promote vaccine security by improving access to FMD materials for research and development whilst ensuring fair and equitable access to the benefits for provider countries that align with principles of the NP. The work in relation to FMD should be taken forward within the wider context of other animal

diseases to ensure the greatest possible level of support for developing solutions that are appropriate for the veterinary sector as a whole.

Appendix 1: Meeting agenda

Time	Title/Activity	Speaker
13:00 - 13:10	Opening remarks from EuFMD	F. Rosso (EuFMD)
13:10 - 13:20	Opening remarks from industry	C. du Marchie Sarvaas (HealthforAnimals)
13:20 - 13:40	The Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit-Sharing	T. Shikongo (CBD Secretariat)
13:40 - 14:00	Seasonal and pandemic influenza pathogen-sharing and the Nagoya Protocol	B. Van Vooren (Covington & Burling)
14:00 - 14:20	Implementation of Nagoya and Access and benefit sharing laws hampers FMD vaccine development	E. Abbeloos (Boehringer Ingelheim Animal Health)
14:20 - 14:35	Nagoya Protocol: implications at reference laboratories and research organizations	D. King (The Pirbright Institute)
14:35 - 14:45	Break	
14:45 - 15:30	Emerging findings and considerations arising from the 'EuFMD draft report on the animal health implications of implementation of the Nagoya Protocol with respect to foot-and-mouth disease' Discussion of the issues and options for a solution	Moderator: D. Mackay (EuFMD)
15:30 - 16:00	Conclusions, recommendations and next steps	F. Rosso (EuFMD)

Appendix 2: List of Participants

Name and surname	Affiliation
Dominic Muyldermans	ABS-int, Bruges, Belgium
Charlotte Germain-Aubrey	Access and Benefit-sharing Unit, CBD Secretariat
Taukondjo Shikongo	Access and Benefit-sharing Unit, CBD Secretariat
Caroline Guittré	ANSES
Stéphan Zientara	ANSES
Labib Bakkali-Kassimi	ANSES
Cecilia Caldevilla	Biogenesis Bago
Danny Goovaerts	Biogenesis Bago
Rodolfo Bellinzoni	Biogenesis Bago
Fernando Barroumeres	Biogenesis Bago
Ana María Espinoza	Biogénesis Bagó
Sharon Reynolds	Biological Assessment Team, United Kingdom (VMD)
Salah Zahi	BioPharma
Farid Amraoui	Biopharma
Pascal Hudelet	Boehringer Ingelheim Animal Health
Elke Abbeloos	Boehringer Ingelheim Animal Health
Fayçal Aberkane	Boehringer Ingelheim Animal Health
James Wood	Cambridge University, United Kingdom
Sacha Seneque	CEVA
Olivier Espeisse	CEVA
Ronan O'Neill	Department of Agriculture, Food and the Marine (Ireland)
Fabrizio Rosso	European Commission for the Control of Foot-and-Mouth Disease (EuFMD), Food and Agriculture Organization of the United Nations (FAO)
Martin Ilott	EuFMD, FAO
David Mackay	EuFMD, FAO
Habeeb Oyedele	EuFMD, FAO
Jacquelyn Horsington	EuFMD, FAO
Valentina Busin	EuFMD, FAO
Shahin Baiomy	EuFMD, FAO
Wilmot Chikurunhe	EuFMD, FAO
Zorana Mehmedbasic	EuFMD, FAO
Kiril Krstevski	EuFMD, FAO
Goran Filipovic	EuFMD, FAO
Polly Compston	EuFMD, FAO
Katherine Gibson	EuFMD, FAO
Etienne Chevanne	EuFMD, FAO
Samia Metwally	Food and Agriculture Organization of the United Nations (FAO)
David Blancato	FAO
Morgane Gourlaouen	FAO

Name and surname	Affiliation
Akiko Kamata	FAO
Artem Metlin	FAO
Carmen Bullón	FAO
Sten Mortensen	Fødevarestyrelsen, Denmark
Michael Eschbaumer	Friedrich-Loeffler-Institut
Bernd Hoffmann	Friedrich-Loeffler-Institut
Adelaide Ayoyi	GALVmed
Jeffrey Hammond	GALVmed
Carel du Marchie Sarvaas	HealthforAnimals
Brian Perry	Independent Consultant
Mohammad ali Eliasi	Islamic Republic of Iran
Tamir Goshen	Israel Chief Veterinary Officer
Santina Grazioli	IZSLER (Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna)
Abraham Sangula	Kenya, Directorate of Veterinary Services
Rosario Bullido	Medicines and Medical Devices Spanish Agency (Spain)
Abdelhamid Bazid	MEVAC
Paul Vermeij	MSD Animal Health
Ljubisa Veljovic	NIVS, Serbia
Kris De Clercq	Sciensano
Nick De Regge	Sciensano
Tamas Petrovic	Scientific Veterinary Institute "Novi Sad"
Tamar Baisonashvili	State Laboratory of Agriculture, Georgia
Elizabeth Parker	Texas A&M AgriLife Research
David Paton	The Pirbright Institute
Donald King	The Pirbright Institute
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PROTECT
RESPOND
CONTROL

MOVE FAST

FAST, Foot-mouth
And Similar Transboundary
animal diseases.

EuFMD Committees

Executive Committee, Standing Technical Committee (STC), Special Committee for Surveillance and Applied Research (SCSAR), Special Committee on Biorisk Management (SCBRM), Tripartite Groups.

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Thinking of the environmental footprint

Together against wasting resources, think twice before printing

SUSTAINABLE DEVELOPMENT GOALS