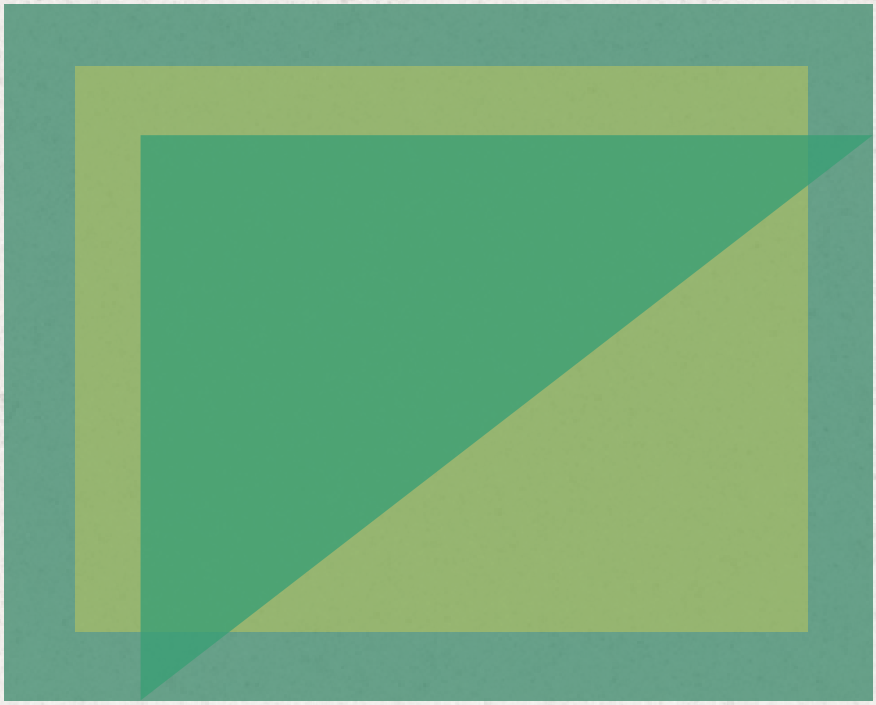
Food and Agriculture Organization of the United Nations

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



The impact of the Nagoya Protocol on Foot-and-Mouth Disease

Report

September 2023

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

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Vademos
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GVS
Global vaccine security

POv
Vaccine prequalification

PCP
Progressive control pathway

PSO
Pcp practicioner officers

PPP
Public private partnership

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.

Contents

Executive Summary

The Nagoya Protocol is an international agreement that came into force in 2014, governing access and benefit-sharing (ABS) with respect to genetic resources. It is relevant for a variety of commercial and non-commercial sectors involved in the use and exchange of genetic resources. The fundamental role of the agreement is to prevent misappropriation of natural resources, and, through benefit sharing, create incentives for the conservation and sustainable use of biological diversity (1).

Fair and equitable sharing of the benefits arising out of the utilization of genetic resources is a universally supported concept. However, since 2020, several key stakeholders involved in the control of foot-and-mouth (FMD) have expressed the view that the way in which the Nagoya Protocol is currently being transposed into national ABS legislation has the unintended outcome of placing constraints on the control of transboundary livestock diseases, including foot-and-mouth disease (FMD).

Acting through a Multistakeholder Platform on Vaccine Security for Foot-and-mouth And Similar Transboundary (FAST) animal diseases, the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) has prepared this report which identifies the practical impacts of the Nagoya Protocol and related ABS frameworks on FMD research and development, presents a problem statement on these impacts in relation to FMD control, provides an assessment of options for possible solutions, and proposes an approach for stakeholders to develop a preferred solution for FMD in the context of a wider consideration of veterinary pathogens.

The key conclusions of the report are that:

1. The way in which the Nagoya Protocol is currently being transposed into national ABS legislation is increasingly having an unintended and negative effect on FMD control. The unintended effect is that the requirement to adhere to complex and demanding ABS legislation is severely constraining the exchange of FMD viruses (FMDV).

2. The negative impacts are felt both by both provider countries which do not gain access to new diagnostics and vaccines developed through utilisation of their genetic resources and by recipient countries which are not able to access the genetic material necessary for research and development of new control tools. As a result, vaccine security is negatively impacted. This has the potential to adversely affect animal health in both FMD-free countries and in countries where the disease is endemic, leading to a possible increase of FMD, with all the animal health and economic impacts that that entails.

3. FMD is not unique, and the same challenges have been identified for other human and animal diseases. Solutions to the problems are available and are already being applied in the human health sector in relation to diseases such as SARS-CoV-2 and human influenza. This report reviews these solutions and their potential for application in the veterinary domain, particularly with respect to FMD.

4. Awareness of these issues is currently low, and the first action required is to improve the level of understanding of the challenges and potential solutions. Communication needs to be directed both to the stakeholders that are directly involved and to the political bodies that will be responsible for developing and implementing solutions in the veterinary domain, notably the World Organisation for Animal Health and the Food and Agriculture Organization. Provider countries need to be involved from the outset in developing solutions to the problems identified.

5. Stakeholders should not wait until an emergency situation arises due to the emergence of a strain of FMDV for which current vaccines are ineffective and to which manufacturers are unable to gain

access due to the constraints of ABS legislation. Action must be taken now to ensure that when such a situation arises, ABS agreements are already in place that allow access to novel strains for the commercial development of control tools without delay.

6. The challenges arising from the way in which the Nagoya Protocol is being implements affect all veterinary pathogens but are particularly acute in the case of FMD due to the nature of FMD virus and the disease it causes. EuFMD will therefore work with all involved parties to develop an approach that allows simplified and timely access to FMD genetic resources whilst respecting the principles of the Nagoya Protocol. Whilst focussing its efforts on FAST diseases, EuFMD will take account of, and foster, initiatives to develop solutions at a political level that promote access to, and exchange of, veterinary pathogens as a whole.

List of abbreviations

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
CNA	Competent National Authority
COP10	Tenth meeting of the Conference of the Parties to the CBD
COVID	Coronavirus disease
CVV	Candidate Vaccine Virus
DSI	Digital Sequence Information
EuFMD	European Commission for the Control of Foot-and-Mouth Disease
FAO	Food and Agriculture Organization of the United Nations
FMD	Foot-and-mouth disease
FMDV	FMD virus
GF-TAD	Global Framework for the Progressive Control of Transboundary Animal Diseases
GISRS	Global Influenza Surveillance and Response System
LMIC	Lower- and middle-income countries
MAT	Mutually Agreed Terms
MERS-CoV	Middle East respiratory syndrome coronavirus
MSP	Multistakeholder Platform on Vaccine Security of the EuFMD
MTA	Material Transfer Agreement
NFP	National Focal Point
NICs	National Influenza Centres
PCP-FMD	Progressive Control Pathway for Foot-and-Mouth Disease
PIC	Prior Informed Consent
PIP	Pandemic Influenza Preparedness
SIMTA	Seasonal Influenza Material Transfer Agreement
SMTA	Standard Material Transfer Agreement
TADs	Transboundary Animal Diseases
WHO	World Health Organization
WOAH	World Organisation for Animal Health

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Definitions

Term	Definition
Access and benefit sharing (ABS)	Refers to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers). ABS arrangements are governed by the legislation in place in provider countries. The requirements in national legislation may directly reflect the requirements in the Nagoya Protocol or may establish national requirements that supplement or differ from the requirements of the protocol.
Competent National Authority (CNA)	The role of the CNA in the context of the Nagoya Protocol is to determine, authorize and certify access in accordance with national ABS frameworks, and they are responsible for giving advice on access procedures and requirements.
The Secretariat of the Convention on Biological Diversity (CBD Secretariat)	The CBD Secretariat was established to support the goals of the Convention. Its principal functions are to prepare for, and service, meetings of the Conferences of the Parties (COP) and other subsidiary bodies of the Convention, and to coordinate with relevant international bodies. It also plays a significant role in supporting implementation of the CBD, including the Nagoya Protocol.
Mutually agreed terms (MAT)	Mutually agreed terms are the terms agreed between provider country/provider of the genetic resource and the users, on the conditions of access and utilization of the resources, and on the benefits to be shared between both parties in accordance with the Nagoya Protocol to the Convention on Biological Diversity.
Material transfer agreement (MTA)	A contract that governs the transfer of tangible research materials between two organisations when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the rights and obligations of the recipient with respect to the materials.
National focal point (NFP)	A national institution within a country tasked with making information on ABS available. Each Party to the Nagoya Protocol must allocate one institution to operate as an NFP. Its functions include informing potential users of the application procedures for accessing genetic resources and traditional knowledge associated with genetic resources and sharing information on CNAs and relevant stakeholders. The NFP also acts as the primary contact between the Party and the Secretariat of the Convention on Biological Diversity.
Prior informed consent (PIC)	The permission given by the CNA of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework.

Background, preparation and objectives

In 2020 the EuFMD established a multistakeholder platform (MSP) on vaccine security[1]. The MSP brings together experts from all of the key stakeholder groups involved in vaccine security including manufacturers of FAST vaccines, reference laboratories, international animal health organisations 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 meeting was that the MSP should develop a problem statement on the impact that the Nagoya Protocol of the Convention on Biological Diversity (CBD) as this was perceived by participants to be having a negative impact on access by manufacturers and others to strains of FMDV for the purpose of research, including the development of new FMD vaccines (2). During the period 2020 to 2023, 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. In response to these rising concerns, in January 2023, EuFMD organized a consultation with invited experts 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 organisations, law firms with expertise on the Nagoya Protocol, NGOs (GALVmed) and the secretariat of the CBD.

There was considerable support for the view expressed by the MSP in the report of their meeting in 2020 (2) that the way in which the provisions of the Nagoya Protocol are currently being transposed into national legislation governing access and benefit sharing (ABS) with respect to genetic resources is leading to substantial challenges in terms of access to genetic material of FMDV and other human and veterinary pathogens. The 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 Expert 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 meeting, the experts involved reviewed and provided extensive input into a preliminary draft of this 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 problems identified in the short, medium and longer term. The resulting draft report was endorsed by the MSP at a meeting on 29 March 2023 leading to publication of this final report following a process of review and consultation within EuFMD and FAO.

The objective of this report is to raise awareness of the issues arising from implementation of the Nagoya Protocol and to initiate the process of developing solutions to the challenges identified. In view of the early stage of discussion, the views expressed should not be taken to represent the formal position of EuFMD, FAO or any other organisation to which the experts involved in preparing this report are affiliated.

[1] In this context the term 'vaccine security' means assuring the supply of a sufficient amount of an appropriate vaccine of assured quality when required.

Background to the current situation

History and motivation for the Nagoya Protocol

The "Global North" benefiting from the appropriation of resources from the "Global South", often without fair recompense, is a common theme in history, and the exploitation of the natural biodiversity and resources present in developing nations by developed countries is still a topic that is widely discussed (3,4,5). In order to address aspects of this inequity, the international community recognized that all countries should have sovereign rights over their own biological resources, and advocated for regulation of bioprospecting activities conducted in biodiversity-rich countries by users based in other countries (5,6). The creation of a global framework for ABS of genetic resources was presented as a way to ensure that the users of biological resources share the benefits (financial and other) generated through their use with those countries that provide the resource, and for the provider countries to then reinvest those benefits into conservation of biodiversity.

These concepts were formally recognized with the CBD, which was adopted in May 1992 with near universal ratification. The three overarching objectives of the CBD are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (7).

Building on this framework, the Nagoya Protocol was adopted at the tenth meeting of the Conference of the Parties to the CBD (COP10), held in Nagoya, Japan in 2010 (8) which came into force in 2014. The Nagoya Protocol is a supplementary agreement to the CBD, expanding on and acting as a mechanism to implement the third objective of 'benefit-sharing'. The principle of this legally binding framework is that ABS measures are agreed on a bilateral basis between users and the provider country through the negotiation of prior informed consent (PIC) and mutually agreed terms (MAT). The PIC must ensure that the party providing consent is aware, and fully understands, how the user intends to make use of the genetic resource, and the MAT acts as an agreement as to what the expected benefits will be (monetary or otherwise) and how they will be shared.

The Nagoya Protocol aims to ensure international equity with regard to "sharing of benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components" (1).

Scope of the Nagoya Protocol

A key principle recognized by the CBD and further operationalized under the Nagoya Protocol is that genetic resources are owned by the country where they have been found, thereby giving countries the ability to determine, control, and monitor the use of any such resources accessed within their territory.

The scope of the Nagoya Protocol encompasses the genetic material of plants, animals and microorganisms, or more specifically, "any material of plant, animal, microbial or other origin containing functional units of heredity". Human genetic material is specifically excluded from the scope (1). The Nagoya Protocol focuses on 'utilization of genetic resources' which is defined to mean "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention" (Art. 2(c)). Therefore, ABS can also apply to derivatives and biochemical compounds extracted from genetic resources in some situations (5). The terms negotiated for the sharing of benefits arising from the utilization of such resources can cover a range of monetary and non-

monetary benefits, including royalties and licence fees, data management, dissemination of research and development results, collaboration in scientific programmes, technology transfer and capacity building (1,9). Importantly, this can also include greater equity in access to medical advances, such as vaccines, to provider countries, which historically has been lacking. Of note is that ABS regulations only apply to research and development, so any activities that do not encompass research and development fall outside the scope of the Nagoya Protocol (5). Since countries have sovereign rights over their genetic resources, the actual scope of the ABS framework is defined by national law. These national laws often provide for a broader scope than the Nagoya Protocol.

How pathogens fit into the scope of Nagoya Protocol has been a contentious issue. Article 8(b) of the Nagoya Protocol calls on parties to pay due regard for expeditious access to pathogen genetic resources during public health emergencies of international concern (1,10). Similarly, Article 8(c) requests consideration of the importance of genetic resources for food and agriculture and their special role for food security (1). However, in practice, adhering to these 'special considerations' is complicated by unclear definitions of what constitutes an imminent emergency and the complex and varied rules and regulations implemented by each country, with some adopting specialised measures for pathogens important for human and/or animal health and others yet to address the issue. The impact of the Nagoya Protocol on pathogen research is discussed further below.

Whether or not digital sequence information (DSI) on genetic resources (such as sequences from pathogens) is to be regarded as a genetic resource, as defined by the CBD, is controversial. However, various countries have already included DSI in their ABS legislation. This can impact access to and exchange of DSI, for example, between international reference laboratories or in sequence databases. At the most recent COP15 of the CBD, held in December 2022, discussions on DSI led to an agreement by Parties to establish a multilateral mechanism for benefit sharing from the use of DSI on genetic resources, including a global fund to support the implementation of the Kunming-Montreal Global Biodiversity Framework of which this activity is part.

Legal complexity of the Nagoya Protocol

Since the Nagoya Protocol is an international treaty, its principles and provisions are to be further operationalized by its Parties and the actual ABS obligations are defined by national laws, policies and administrative measures. This results in a high level of heterogeneity in definitions, obligations and procedures among provider countries (11,12). Establishing effective national legislation can be hindered by lack of budget or technical expertise, lack of strong governmental structures or political support, as well as by conflict over ownership of the genetic resources of interest (13). In addition, an increased administrative burden and multi-layer decision-making process can cause complications and confusion for both providers and users.

Legislation on the sourcing and use of genetic resources includes administrative procedures and enforcement policies that vary from country to country. In its simplest form, to initiate the process of access to genetic resources, a foreign researcher/company will usually contact the provider country's national focal point (NFP; an administrative contact person) to obtain information on the procedure to follow in the country concerned. At the same time, or subsequently, the prospective user will contact the country's national competent authority (NCA) to initiate negotiations on the PIC and MAT. In principle, the NCA is usually the ministry of the environment, but may be a ministry of health, indigenous issues, interior, or some other department, and in some countries multiple ministries may claim jurisdiction over the same resource (14). The PIC and, if appropriate MAT, finally agreed will detail the conditions of access, the intended use, the arrangements for any further sharing of the genetic resource and the sharing of benefits arising from its utilization.

As the actual extent of any benefit cannot be known with certainty at the time of supply, the ABS arrangements specified in the MAT may be quite complex with conditionality at different stages depending on progress with utilization. This can mean that significant resources are wasted on negotiating complex MATs in the case that utilization is ultimately unsuccessful.

Non-compliance with (national) ABS laws can potentially have severe consequences, including fines and criminal sentences (14). This applies whether or not a country is a party to the Nagoya Protocol and the situation is further complicated by the fact that certain obligations arise from the CBD itself as the Nagoya Protocol only operationalises some of its provisions. If a genetic resource originates from a country that is party to the CBD that has not ratified the Nagoya Protocol, but has implemented ABS legislation (examples include Iran (Islamic Republic of), Thailand, Australia) compliance with that Party's measures is equally required. In addition, if a genetic resource originates from a country that has ratified the Nagoya Protocol, additional compliance measures in the country of utilization might be required. For example, in the EU, prior to the release of a product onto the market, any product or technology based on a genetic resource will be subject to specific due diligence obligations. From this superficial explanation, it is clear that there is a great deal of legal uncertainty, especially in this complex heterogenous environment, and this uncertainty creates legal risks for companies and institutions.

Given that the negotiation of terms can be a lengthy process, during the original discussions on the Nagoya Protocol concerns were raised about access to pathogenic materials relevant to human health. Consequently, broad guidance that frameworks governing the use of genetic resources should avoid impeding the research community, especially in emergencies, was included in the Nagoya Protocol. The Preamble makes reference to the WHO's International Health Regulations, requesting that parties be aware of their international duties in health security. Article 8(b) states that parties "Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health" and "may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources" (1,15). However, while the Protocol encourages member countries to exercise leniency and promotes utilization of genetic resources in the absence of PIC or MAT in cases of emergency, Article 8(b) is not so much a legal obligation to take specific measures in emergency cases, but rather an obligation to take such cases into consideration. The details of what is meant by "consideration" remain undefined, the possibility of using a fast-track process and its scope are determined by the individual countries. The majority of countries consider only pathogens of importance to human health, and as of 2022, only 12 countries had public health emergency exceptions in place. Article 8(c) refers to the consideration of genetic resources important for food security but fails to make the link to the sharing of pathogens or imminent emergencies.

There is an urgent need to clarify the ABS framework and related processes for both users and providers and for a greater science-policy dialogue both within and among countries to ensure a better understanding and more effective implementation of the Nagoya Protocol and related ABS measures. At COP15, parties to the CBD also adopted the Kunming-Montreal Global Biodiversity Framework, comprising four global goals contributing to the three objectives of the CBD. The third goal specifically refers to sharing of benefits from the use of genetic resources. The framework seeks to facilitate enhanced synergy between the CBD, its Protocols and other relevant multilateral agreements, and international organisations and processes. It notes the importance of One Health and food security and encourages taking effective legal, policy, administrative, and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilisation of genetic resources and from DSI. Whether or not this framework will promote better cooperation, understanding, and solutions for ABS in relation to pathogens remains to be seen, but

the focus on a comprehensive approach to ensure effective measures at all levels should be supported.

The impact of access and benefit sharing arrangements on pathogen research and development in general

Despite the widespread acknowledgement of the importance of, and need for, a mechanism to ensure fairer sharing of benefits from resources accessed from provider countries, a number of negative impacts of the Nagoya Protocol and the concept of viral sovereignty on pathogen research and development, or in outbreak situations, have become apparent in recent years. Real life examples of such impacts involving influenza, SARS-CoV-2, Zika virus, Ebolavirus, Middle East Respiratory Syndrome coronavirus (MERS-CoV), and others have been documented (6,12,16–21). Similar accounts and protestations have arisen from experts in the microbiology field (22,23).

The legal frameworks governing the use of genetic resources are necessary to ensure transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies, and in principle should increase vaccine access for developing countries. Yet despite the general willingness of both researchers/companies and provider nations to work together to achieve these goals, the lack of a harmonized system across countries, uncertainty over the implementation and requirements of the Nagoya Protocol, and extensive delays in sample sharing have severely obstructed the exchange of pathogen samples. The WHO reported that the implementation of ABS requirements for sharing pathogens had a negative effect on outbreak responses (24). This has sparked some arguments against the inclusion of pathogens under the Nagoya Protocol from multiple sectors, with many advocating that they should not be treated in the same way as other genetic resources (12,16,17,21,24).

The multistep, multiparty negotiations that are currently necessary to put in place ABS arrangements that comply with national legislation in provider countries, whether or not they have implemented the Nagoya Protocol, is ill-suited to the timely sharing of rapidly evolving pathogens, particularly highly variable RNA viruses like influenza virus and FMDV. Experience in both human and veterinary medicines has shown that complex ABS arrangements inhibit global collaborations and the rapid sharing of pathogens and information that is needed to identify and produce the necessary diagnostics, vaccines, and other treatments. In a pandemic situation, these delays can have devastating effects. Whilst it is understandable that provider countries wish to benefit through access to novel health tools arising from utilization of their resources, the current way in which the Nagoya Protocol is applied through national ABS laws appears to hinder rather than help to achieve this objective.

In the case of highly transmissible transboundary diseases, the causative agents do not respect national borders, and travel and trade provide endless opportunities for spread, so the concept of any one country claiming ownership or having control over ABS on pathogen genetic resources does not intrinsically fit with their biological nature. This also means there is no incentive for researchers to deal with complex bureaucracy if there is an option to acquire a pathogen from a neighbouring country not party to the Nagoya Protocol. Another consideration is the true fairness of benefit sharing in such a situation. Despite an initial local presence of a virus, there may be rapid cross-border spread and international impacts, potentially meaning a country equally requiring or deserving of access to vaccines (or other benefits resulting from research on the pathogen) is different to the country from which the virus it thought to have originated (20).

Finally, the predominant focus on monetary benefit sharing has the potential to result in ‘overvaluing’ of pathogen resources and over-politicization of scientific endeavours, especially where there is disconnect in provider countries between those negotiating the MAT and those in the human or

animal health sectors responsible for disease control. One potential consequence is that provider countries may lose sight of the actual purpose of the Nagoya Protocol and see it as a potential source of income rather than a tool to protect biodiversity and to ensure adequate access to much needed vaccines or other medical interventions. Implementation of the Nagoya Protocol, and any national ABS laws, needs to balance the legitimate expectations of the provider country with the need to adopt a simplified and equitable process that does not impede the development of tools that are required for global health and food security.

Impacts of the concept of viral sovereignty

Viral sovereignty is the concept that viruses located or isolated within the territorial boundaries of a country are that country's sovereign property – a key concept in the CBD and in the application of the Nagoya Protocol to pathogen sharing. This came into focus in the mid-2000s when Indonesia was reluctant to share its H5N1 influenza viruses with the WHO's Global Influenza Surveillance and Response System (GISRS) until agreements granting it access to antivirals and vaccines were formulated. Indonesia challenged the expectation that virus samples should be shared with WHO without consideration of fair access to any vaccines resulting from those samples, highlighting the potential for exploitation of developing provider countries. This was the first time the CBD was explicitly applied to human pathogens (14,20). However, this concept, combined with political complexities, has been shown to have negative impacts on public health situations. Monitoring the evolution and spread of influenza viruses is a continuous process, requiring the sharing of thousands of virus samples from as many countries as possible, and therefore necessitating the successful functioning of the GISRS. In the wake of the stance by Indonesia, the WHO established the Pandemic Influenza Preparedness (PIP) framework, adopted in 2011 (14). The main objective of the PIP framework is to improve the GISRS, working within ABS principles, thereby improving pandemic influenza preparedness and response while facilitating fair and equitable distribution of benefits to provider countries. With the PIP framework, researchers enter into material transfer agreements (MTAs) with the WHO (rather than individual countries) in exchange for access to potentially pandemic strains of influenza. However, this only applies to influenza viruses with pandemic potential. Delays and disruption in the sharing of samples of seasonal influenza are still common (16). A report by the WHO Director General stated that the sharing of influenza virus samples was being increasingly impacted by national ABS requirements (6). The implementation of the Nagoya Protocol has been responsible for significant delays in sharing influenza viruses globally, including from national influenza centres in Southeast Asia, South America and Europe, due to lack of clarity on national ABS legislation and the consent process, directly impacting seasonal vaccine production (12).

Similar scenarios have been reported for other viruses, with delays or direct refusal to share samples, specifically related to the ABS requirements linked to implementation of the Nagoya Protocol. These cases have highlighted the poor fit of this framework to pathogens.

In 2016, access to Zika virus samples and data from the outbreak in Brazil was inhibited largely due to the Brazilian ABS laws affecting material transfer (14,24). Extensive negotiation of access terms ended (or rather became unnecessary) with the spread of the virus to Puerto Rico facilitating easy access by researchers at the US Centres for Disease Control and Prevention (19,20). Similarly, controversy regarding sovereignty and ABS claims by the Saudi government over MERS-CoV prevented sample sharing and impeded research on antivirals and vaccines against the virus (6,14,19).

The problems and issues described above are equally pertinent to FMDV (and other transboundary animal diseases). Similar to influenza virus, continuous monitoring of the virus in multiple countries and global sharing of samples is necessary for surveillance and for important fundamental research as well as new vaccine development. The fact that FMD is exclusively a disease that affects animals and does not have any zoonotic potential may cause the regulatory agencies involved in negotiating PIC

and MAT to assign FMDV a lower priority than exclusively human or zoonotic pathogens, thus further retarding ABS negotiation processes related to access to FMDV genetic material.

The impacts of access and benefit sharing arrangements specifically on FMD research and control

FMD is an economically important disease of livestock and is present in Africa, Asia, and parts of South America. In endemic countries, FMD causes major economic losses to the agriculture sector, while in countries that are free from the disease it poses the continuous threat of devastating outbreaks with impacts far beyond the agriculture sector (18). Vaccination is widely used to protect animals and ensure the sustainability of livestock production and thus food supply in FMD endemic countries (25). 'Freedom from FMD with vaccination' may be an interim stage in the Progressive Control Pathway for FMD (PCP-FMD) for countries seeking to achieve the status of freedom from FMD without vaccination. FMD-free countries rely on strategic stocks ("banks") of broadly protecting antigens that can be formulated quickly in response to incursions of the disease. Vaccination is therefore used in different ways to control FMD but remains an important tool, irrespective of the income level or disease status of the country. For vaccination to remain effective there is a constant need to (i) monitor the antigenic diversity of field viruses (necessitating access to viruses by international reference laboratories) and (ii) ensure that new vaccine strains can be produced that are tailored to antigenically distinct lineages.

Concern has now been raised by key stakeholders, including the FAO, WOAH, the WOAH/FAO FMD Reference Laboratory Network and FMD vaccine manufacturers, regarding the impacts of the Nagoya Protocol and national ABS laws on the ability to guarantee that FMD vaccines matching the epidemiology in the field will continue to be available in the future. Global FMD surveillance activities undertaken by national and international reference laboratories play a central role in this process since FMDV positive samples collected from the field represent the starting materials for academic research and for the development of new FMD vaccines strains by commercial companies.

Features of FMD of relevance to implementation of the Nagoya Protocol

There are certain characteristics of FMD that make application of the Nagoya Protocol to this field particularly complex and burdensome. Specifically:

The complex and dynamic nature of FMD epidemiology

FMDV has a very dynamic and complex epidemiology, with six actively circulating serotypes (a seventh serotype, type C, has most likely been eradicated). There is no cross-protection between serotypes and, even within serotypes, cross-protection can be limited, with several antigenically distinct topotypes identified. The error-prone replication of FMDV generates viral lineages that deviate over time from vaccine strains. Thus, new viral mutants that escape neutralization by use of existing vaccine strains can lead to devastating outbreaks. This means that there is a constant need for vaccine matching data (necessitating access to viruses by international reference laboratories) and capability to develop new vaccine strains in a timely manner. In principle, the exchange of material for the purpose of diagnosis and surveillance is outside the scope of the ABS requirements of the Nagoya Protocol. With most countries, PIC and MAT are only required if there is an intention to use the transferred material for research, including for evaluation of field strains as potential new vaccine strains. In such cases, PIC and MAT can be put in place retrospectively following identification of the need for a new vaccine as a result of the diagnostic tests applied to samples submitted for surveillance. In practice, arranging PIC and MAT retrospectively is complex, time consuming and may not ultimately be successful, with no agreement on mutually acceptable terms. There is concern among reference laboratories that increased awareness of the Nagoya Protocol and the proliferation of divergent national ABS laws carry the risk of reducing the submission of samples for both diagnosis and research. This can arise if submitting countries are not completely familiar with the complex interplay of requirements depending on the proposed use and therefore seek to avoid the bureaucracy surrounding application of the Nagoya Protocol by not submitting samples to reference laboratories in the first place.

A global disease with regional epidemiology

Due to trade of live animals or fresh meat and dairy products, and animal movement across multiple countries, FMDV strains are typically organized into pools of similar epidemiology where the virus is subject to cycles of emergence and spread (usually identified as seven regional pools). Consequently, development of vaccine strains that are tailored for each region is necessary. To facilitate the identification and potential production of relevant vaccine strains on such a regional level, vaccine manufacturers are obligated to know the local ABS laws and need to try to establish relationships with both the Nagoya Protocol NFPs and the NCA responsible for control of material from FMD infected animals in many countries, convoluting and delaying the process.

The penalty for success in eradication

Many of the major FMD vaccine producers are located in FMD-free zones or countries. Commonly, it was the existence of these companies and their manufacturing sites within these regions during the period when FMD was being eradicated that led to the local eradication of FMD. Existing biosafety/biosecurity (BSL3+) infrastructure and expertise form a good business case for export of quality vaccines at acceptable cost of goods. However, in order to provide vaccines for the entire world, these companies rely on sourcing genetic material from FMD-endemic countries. Whereas human vaccine manufacturers can sometimes take advantage of sourcing a pathogen from the "returning traveller," this is by default not possible for manufacturers engaged in FMD, since the Terrestrial Animal Health Code of the World Organization for Animal Health prohibits any traffic of FMD susceptible animals or products from infected animals from endemic zones. The same situation applies to research and reference laboratories for FMD. Some laboratories with long histories and

prominent roles on the global FMD stage are located in FMD-free countries and now face the complexities of the Nagoya Protocol in order to continue their research and monitoring functions.

A disease predominantly present in the developing world

FMD is typically endemic in developing, less industrialized countries that are either not yet engaged, or at an early stage of implementing, the Progressive Control Pathway for FMD as part of the Global FMD Control Strategy of the FAO and WOAH. Many of these countries using vaccination as part of a control or eradication policy rely on imported vaccines from the large international manufacturers, a tendency driven by the efficiencies of large-scale production and confidence in their quality. The Nagoya Protocol was established in part to protect these developing countries from 'biopiracy' by industrialized countries. Some manufacturers have reported unrealistic expectations of the financial benefits that may become available for sharing, either monetarily or through contributions to capacity development, in the country of origin of the genetic resource.

FMD is strictly an animal disease

Despite being the most economically relevant disease world-wide and being of high importance for food security and livelihoods, especially of smallholder farmers, the fact that FMD does not cause disease in humans means it does not attract the same level of attention or perception of importance as human diseases. Nevertheless, Resolution No. 15 of the 81st General Assembly of the WOAH (formerly OIE) in 2013, considered (*inter alia*) that, "All information about FMD viruses that can lead to the development of more effective prevention and control policies is a global public good and should be put into the public domain without delay" and recommended that "OIE Member Countries report outbreaks of FMD to the OIE, while sharing FMD viral material and information about FMD viruses with OIE Reference Laboratories to enable timely vaccine matching and monitoring of the spread and emergence of new virus strains". Thus, the control of FMD has been declared by WOAH to be a "Public Good" and FMDV listed as a pathogen for which rapid sharing of materials for diagnosis and vaccine development purposes is critical. Article 8(b) in the Nagoya Protocol explicitly calls upon states to ensure that the normal ABS rules and procedures do not interfere with public health efforts or, as detailed in 8(c), with food and agriculture (and consequently food security). However, only a small minority of countries have translated these articles into their local law, and even less have implemented measures to fast-track pathogen sharing in the face of an imminent emergency. Even if they have, laws rarely provide specific acknowledgment of inclusion of animal health diseases as a form of imminent emergency, again causing legal uncertainty for sourcing veterinary pathogens.

Specific impacts on key FMD stakeholders

Diagnostic/reference laboratories

Global surveillance of FMD coordinated by the WOAH/FAO FMD Reference Laboratory Network (www.foot-and-mouth.org) involves the characterization of FMDV positive samples collected from field cases. For example, in 2021, 1 672 clinical samples from suspect cases of FMD were tested by laboratories in the WOAH/FAO Network (and associated laboratories) which is typical of the annual surveillance performed by the laboratory network on an annual basis, subject to some variation due to various factors (in 2014, 3 240 samples were tested and in 2018, 2 500). These samples were collected from 30 countries representing all seven FMD endemic pools. As discussed above, while these immediate diagnostic activities are usually considered to fall outside of the scope of 'utilization' as defined by the Nagoya Protocol, the long-term storage for purposes other than diagnosis, distribution and further use of these diagnostic samples and/or field isolates may fall within scope of the legislation governing ABS arrangements of the provider country. It is important to note that scientists within international FMD reference laboratories and their partners in FMD-endemic

countries often lack specific expertise on the Nagoya Protocol or ABS requirements and currently do not have the knowledge or resources to make contact or prepare agreements with the NFPs or NCAs in the relevant country. Furthermore, since virus detection and strain characterisation for the purposes of diagnosis and surveillance are generally considered to fall outside of the scope of the Nagoya Protocol, the NFPs do not normally have oversight of these activities, particularly as samples are sent to international reference laboratories at the discretion of local laboratories. Therefore, whilst laboratory staff are experienced in the despatch and receipt of diagnostic samples, they are often uncertain about the potential liability in terms of ABS obligations with respect to the downstream utilization of these materials by third parties. This situation is complicated by the collaborative relationships that are often established to share samples, where co-authorship of scientific papers is usually considered to be the most appropriate way to equitably share the benefits of the work associated with the use of field materials.

In addition to the use of these materials for basic and applied research activities, FMD reference laboratories often play an important role in supplying field isolates to commercial vaccine companies so that they can develop new seed strains to cover emerging viral strains.

Vaccine manufacturers

Whilst in principle the Nagoya Protocol provides a clear process for demonstrating legal compliance with the CBD, in practice, due to the way in which it is currently implemented, the protocol frequently results in great difficulty in obtaining the required legal certainty in any reasonable time frame for vaccine manufacturers and thereby directly impacts their ability to adapt new strains for FMD vaccines in a timeline that is relevant for what is a fast spreading and evolving disease.

In endemic areas, FMDV may evolve rapidly requiring vaccine manufacturers to update FMD vaccines periodically to match the changing epidemiology of the virus in the field. The sourcing of pathogens for the development of a vaccine is considered “utilisation of genetic resources” and as such falls within the scope of the Nagoya Protocol. Since the implementation of the Nagoya Protocol and national ABS laws, companies need now to first conduct their due diligence on the existence and content of the local ABS laws, try to understand the procedure for permitting access in any given country and eventually negotiate PIC and MAT that includes fair and equitable benefit sharing. Vaccine manufacturers are frequently constrained by commercial confidentiality from making public the basis on which they obtain the strains of FMDV used in their vaccines. Nevertheless, at least one manufacturer has highlighted that, to their knowledge , no pharmaceutical company has achieved this with respect to FMD viruses in countries which have started to implement ABS provisions at national level (26). It should also be noted that the requirement to establish separate agreements with individual countries, and often the legal requirement to source viruses from a local laboratory rather than the World Reference Laboratory, may constrain the ability of the companies to screen a wide range of viruses to quickly select those with the best characteristics for use as potential vaccine candidates. In situations where there is an urgent need for a new vaccine strain to control a newly emerged field strain, any delay to new vaccine development has a direct impact on people’s livelihoods, food security and risk for incursion in FMD free areas. The delay currently caused by the need to negotiate PIC and MAT means that manufacturers located in countries other than the country of source no longer have the ability to respond in well-established timeframes to help prevent epizootics of newly emerged strains of FMDV. The observation that here have not been any major epizootics to date involving countries blocking access to strains of FMDV for which current vaccines are ineffective does not diminish the need to be prepared for when such a situation arises. Experience from the human domain highlights how important it is to anticipate such situations in advance and to put in place frameworks for exchange of pathogens in advance of need rather than attempting to tackle this complex issue during a crisis.

The discrepancy between production of vaccines in developed countries versus sourcing of potential new vaccine strains in the lower- and middle-income countries (LMICs) can create a tension of unrealistic expectations. While international manufacturers respect the principle of sovereignty of genetic resources and agree with the principle of fair benefit sharing, experience has shown that there may be unrealistic expectations among provider countries about the scale of potential monetary benefits from using FMD viruses as vaccine strains that arise from comparison with the human health market. The profit generated per dose from selling FMD vaccines is low compared to human vaccines and low even when compared to other animal health products especially in the companion animal sector. These expectations can stifle the business case for developing new FMD vaccines, and consequently companies may redirect investment to lower risk activities and faster growing markets. This has a negative impact on global vaccine security with overall fewer FMD vaccines being produced and the absence of investment into updated high-quality and antigenically relevant vaccines. Similar constraints exist for other commercial actors such as diagnostic companies and pharmaceutical companies that may wish to utilise FMDV materials for new tests or therapeutics.

In principle, one possible solution would be to produce FMD vaccines in provider countries thereby avoiding the need for complex ABS arrangements. In practice, this is rarely a practical solution as it is technically challenging to produce FMD vaccines to a consistent high quality in large amounts and requires dedicated manufacturing facilities associated with a high capital cost to meet standards of Good Manufacturing Practice (GMP) and biosecurity. Manufacture of modern conventional inactivated FMD purified vaccines requires high containment facilities and the ability to carry out technically sophisticated up-stream production of FMD viruses and down-stream processing and purification of highly labile antigens. Even where suitable local manufacturing facilities exist, there may be a need for international cooperation in terms of technology transfer and exchange of potential seed viruses, particularly when developing vaccines based on newly emerged strains of FMDV. For this reason, increased local production of vaccine should remain a long-term objective, particularly if novel vaccine and/or manufacturing technologies open new opportunities in LMICs. However, until such opportunities have been realised, urgent attention needs to be given to overcoming the difficulties with transferring FMD materials from provider countries to manufacturers with the experience and technology required for large scale vaccine production, wherever these manufacturers are located.

Researchers

The Nagoya Protocol presents a complex framework for regulating the ability of all scientists (including at universities, institutes, and not-for-profit organisations) to conduct FMD research, particularly related to collaborations with LMICs. This includes researchers in provider countries, whose own research can be hindered by the Nagoya Protocol and ABS processes. Access to viruses, samples and data are crucial to facilitate the development of new diagnostics, therapeutics, and vaccines but also to develop new tools to understand the evolution, mechanisms of replication and infection, pathogenesis, immune responses, and host-cell interactions of FMDV. Due to the nature of scientific research, the majority of projects do not yield tangible benefits to be shared, yet significant time is required to negotiate and agree ABS terms. As a consequence, researchers in both the provider and receiver countries may be disincentivised to collaborate due to insufficient advice, information, and assistance when negotiating ABS exchanges. This situation may be exacerbated by those responsible for negotiating ABS terms often being different from those actually involved in the research. Several research funding organisations now make it a condition of funding that researchers can demonstrate that they have conducted due diligence with respect to ABS legislation for all relevant research materials and may conduct audits to ensure compliance. Such requirements increase the pressure on researchers both to have detailed knowledge of the requirements of the Nagoya Protocol and to ensure compliance with its provisions.

Provider countries

A perhaps overlooked stakeholder also impacted by restrictions on FMD research and development are farmers and livestock keepers in the provider countries. One of the principle aims of the CBD is to ensure that the tools and products arising from the utilization of genetic resources are used to directly improve livestock productivity in those countries that have provided the source material. As discussed above, although FMD is endemic in LMICs, few of them have the capacity to manufacture large amounts of FMD vaccines locally and therefore rely on vaccines from companies in other countries. The observation that no new FMD vaccine strains developed from materials supplied subject to PIC and MAT in compliance with the Nagoya Protocol have been marketed, leads to the conclusion that the impact of the Nagoya Protocol is already resulting in reduced access for these countries to new vaccines. Even with the ABS legislation in the hands of the relevant country's government, the complexities in achieving PIC and MAT described above can severely impede and protract the resource sharing process, leading to unfavourable timelines for development and provision of vaccines based on new strains. Additionally, with poor or no links between ministries involved in Nagoya Protocol administration and ministries controlling human and/or animal health, there can be a lack of understanding of the importance of vaccines and missed opportunities to meet the countries' health objectives. Failure to reach agreement on MIC and MAT for supply of FMD materials from one country may end up being detrimental not only to the provider country itself but also to other countries in the region which are linked through circulation of epidemiologically related strains of FMD.

Summary conclusion on the impact of the Nagoya Protocol and ABS legislation on FMD stakeholders

Taken together, it seems prudent that all parties involved in FMDV research and vaccine development should work on a common approach to compliance with the Nagoya Protocol and national ABS laws to enable sharing of viruses and data relating to FMDV to continue. In the absence of a solution to the challenges raised by the need to negotiate complex ABS arrangements, the long-term consequences could be extremely detrimental for national and international initiatives to control FMD, including reduced availability of vaccines and diagnostics, breakdown of international partnerships, and withdrawal of pharmaceutical companies from the sector. Inability to select, develop and use vaccine strains in line with the prevailing epidemiological situation will negatively affect the ability of countries to participate in the Global FMD Control Strategy of the WOAH and FAO. The case for FMD should also be used as a benchmark for other transboundary animal diseases (TADs), which face the same impacts due to the way in which the Nagoya Protocol and national ABS laws are currently implemented.

Developing an approach to addressing ABS arrangements with respect to foot-and-mouth disease

Proposed scope of a solution for FMD

The sections above detail the difficulties that are being experienced in accessing FMD materials due to the way in which the Nagoya Protocol and national ABS legislation are currently being implemented. Above all, the complex and interlocking sets of legal requirements in provider and recipient countries introduce legal uncertainty and therefore risk. This section explores options for a solution for FMD that considers the stakeholders, resources and existing infrastructure that already exist for this disease. Any model established for FMD may also be suitable for transfer to other TADs. However, to ensure the best chance of success, the initial focus is limited to FMD. The authors are aware that other groups are also exploring solutions for similar problems that have arisen from the application of the Nagoya Protocol and national ABS arrangement to other animal diseases such as avian, equine or

other animal influenza viruses or other veterinary pathogens. The international organisations responsible for animal health, mainly FAO and WOAH, have responsibility for a wide range of animal diseases. It is therefore likely that potential solutions for shared problems related to the Nagoya Protocol and national ABS arrangements will be sought in relation to a number of different animal pathogens and these organisations may ultimately seek a high level and overarching solution rather than disease-specific solutions. The intention of this report is to identify how options for such an overarching solution may be explored by the relevant organisations at an international level whilst at the same time developing an FMD-specific solution that can be applied by FMD stakeholders in a pragmatic way in the short to medium term. Following this twin track approach should allow organisations involved in FMD to build up practical experience in developing operational ABS arrangements that can be fed into the higher-level discussion on an over-arching solution that will inevitably take several years to develop.

It is proposed that the solution for FMD should focus on physical samples only in the first instance. While DSI is considered an important issue, with discussions on the COP15 DSI multilateral agreement ongoing, inclusion of DSI in any framework for FMD should only be considered at a later stage. To include DSI in the initial scope could make the problem more diffuse and more difficult to solve. The difference between human and veterinary vaccines has been taken into consideration in proposing this approach. For certain human diseases mRNA vaccines can be constructed on the basis of DSI alone and there is no need for access to physical materials. This is not currently the case for FMD and there is no immediate prospect of vaccines based on DSI alone. Consequently, all of the challenges identified to date in relation to the Nagoya Protocol with respect to FMD relate to the exchange of physical material and not to exchange of DSI. It is therefore reasonable to develop a solution for transfer of physical material in the case of FMD whilst bearing in mind that in future, and for other diseases, solutions that also address DSI will be required. A comprehensive definition of the physical samples/materials to be included within the proposed solution for FMD will be needed to ensure clarity on this issue and to take account of the different national ABS laws.

In principle, exchange of material for the purpose of diagnosis and surveillance alone does not fall within the scope of the Nagoya Protocol as the scope of the protocol is limited to utilization for the purpose of research and development. However, in practice, the ultimate use of materials at the time of submission may not be known and, to complicate matters further, some countries have implemented national ABS legislation with a wider scope than the definitions in the Nagoya Protocol that may include exchange of materials for any purpose including diagnosis and surveillance. Although material may initially be submitted primarily for diagnosis, depending on the result of this diagnosis, the material may also ultimately go on to be used for research, including evaluation for use as a new vaccine strain. To date, experience has shown that the problems arise only at the stage where the proposed use of the material changes from diagnosis to research or commercial use. It is at this stage that the practical issue of agreeing ABS arrangements arises and where problems are encountered in agreeing what the potential benefits are and how they could be equitably shared. It is important that any proposed solution does not introduce any new constraints on exchange of materials for the purpose of diagnosis and surveillance.

There is a risk that increased awareness of the Nagoya Protocol could perversely act as a disincentive to submission of samples as countries could become reluctant to submit materials unless agreement is reached in advance on ABS in the event that the material is ultimately used for research and development. To date, this has not been a problem as exchange has generally taken place between trusted partners within the FMD Network. However, as discussion is extended to the wider community of organisations responsible for the Nagoya Protocol, the potential for a more cautious approach could result in a reduced willingness of provider countries to submit samples. This risk needs to be managed

carefully by increasing awareness that diagnosis and surveillance are not generally considered as falling within scope of the Nagoya Protocol, by ensuring that trust is maintained in relation to the use of submitted material and that use for research and development will only take place in the context of a system that assures fair and equitable ABS. The GISRS, as described in section three below is an example of a solution that relies on trust between partners within the network, underpinned by formally agreed terms of reference and MTAs.

Stakeholders

The stakeholders identified to date include:

- Disease control authorities:
    - at national level (generally animal health authorities)
    - at regional level (various regional commissions and other coordinating bodies such as regional commissions on TADs and EuFMD)
    - at global level (principally WOAH and FAO)
- Vaccine manufacturers and their industry associations
- Diagnostics manufacturers and their industry associations
- Reference laboratories for FMD
- Veterinary laboratories at national level that may handle diagnostic samples
- Research organisations carrying out research on FMD
- Indigenous people and local communities (as rights holders rather than stakeholders)
- National Competent Authorities for administering the Nagoya Protocol
- Nagoya Protocol Focal Points.

Appendix 1 summarizes the current role and proposed engagement of each of these stakeholders, or classes of stakeholders, in reaching a solution for FMD.

Options for consideration

The following section considers options to resolving the problems arising from implementation of the Nagoya Protocol and national ABS arrangements with respect to FMD. The overall objective of any solution is to address issues related to ABS that arise from exchange of FMD materials in a way that is compliant with the Nagoya Protocol. Developing any solution will require detailed examination of a wide range of complex legal and logistical issues that are beyond the scope of the report. The objective at this early stage of exploring this topic is therefore limited to outlining a range of potential approaches, identifying those that deserve further exploration, and suggesting a possible way forward to address the issues identified in the short, medium, and longer term.

1. Exclusion of FMDV from the Nagoya Protocol

One possible solution that has to be addressed would be to seek the complete exemption or exclusion of FMDV from the scope of the Nagoya Protocol. This option would not be the simple solution it appears at first to be. First, it would require changes to the text of the Nagoya Protocol and consequential changes in a wide range of implementing instruments and, second, it is likely to be considered inappropriate by a wide range of stakeholders because it goes against the policy objectives of the CBD.

For this option to be further explored, a case would need to be made to explain why FMD is such an exception that it should be treated differently to other human and veterinary pathogens that would remain within scope. Whilst implementation of the Nagoya Protocol undoubtedly causes problems in relation to control of FMD, these problems are similar in nature to the problems that arise with other pathogens, such as human influenza and COVID19. It would therefore be difficult to justify exemption of FMD on the basis of exceptionality. The status of pathogens within the Nagoya Protocol has been a long-standing topic of discussion at the Conference of the Parties and, if any changes are proposed in this area, the issues related to FMD should be considered as part of a wider solution for human and animal pathogens as a whole rather than as any form of exception.

To reopen the international treaty that took many years to negotiate and came into force in 2014 would take significant political focus and resource that would take many years to progress even if it was considered a potentially feasible option.

For these reasons, the option of excluding FMD from the scope of the Nagoya Protocol is not considered further.

2. Creating of an overarching specialised international instrument for agreeing ABS in relation to FMDV

In other sectors, overarching solutions for resolving ABS issues arising in relation to exchange of genetic material have been developed that could serve as useful models for animal pathogens, including FMDV. The FAO Commission on Genetic Resources for Food and Agriculture published a document entitled ABS Elements: Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture (27). Of particular relevance to FMDV, the document describes the use of microbial culture collections (MCC) as a means of maintaining and exchanging strains of microorganisms. The model for MCC described is similar to that which has been used for FMDV to date, being based on historic collections and collaboration between depositors and acquisitors that is largely informal and based on trust. The report highlights that MCC are introducing more formal MTAs for both acquisition and deposition of materials that take into account the need for compliance with ABS requirements of the Nagoya Protocol. Generally, MCC have in place standard agreements that allow acquisition for non-commercial purposes but require the acquiring party to negotiate MAT and PIC with the country of origin if the purpose is commercial exploitation of the material. This is broadly the way in which FMD reference laboratories operate at the present time and does not overcome the challenges outlined in this report. The FAO report describes solutions identified in other sectors such as plants, forests, animals and aquaculture that have been developed to reach agreement between stakeholders on ABS for the respective genetic material. In developing a long-term solution with respect to FMD, the FAO Commission on Genetic Resources for Food and Agriculture should be engaged as an important stakeholder with considerable experience of negotiating multi-partner solutions for ABS. Potential solutions could take the form of a variety of international instruments such as a treaty, international code of conduct or a Global Plan of Action.

Article 4 of the Nagoya Protocol covers the relationship between the protocol and other international agreements and instruments. Art 4 (4) foresees that the protocol will not apply in situations where "a specialised international access and benefit-sharing instrument applies that is consistent with and does not run counter to the objectives of the Convention and this Protocol". The CBD secretariat have published guidance on the relationship between such instruments and the Nagoya Protocol (28) The possibility of including FMD within the scope of such an international instrument should be considered at an appropriate stage.

The CBD secretariat with contributions from various United Nations structures oversee the operation of the CBD and the Nagoya Protocol. To achieve an over-arching solution at international level that includes FMD, these groups, together with the Convention of the Parties to the Protocol, would first need to agree that a high level solution is actually required to address the challenges identified in this report and then that the solution identified either operates within the context of the Nagoya Protocol or operates in a manner consistent with the principles of the Nagoya Protocol, as is the case for Specialised International Instruments referred to in Article 4.4 of the Nagoya Protocol. The Kunming-Montreal Global Biodiversity Framework may help to steer such a solution with its more holistic approach and its target to foster joint technology development and strengthen scientific research and monitoring capacities.

3. Specialised multilateral ABS agreements between concerned stakeholders

For several diseases, the challenges of agreeing ABS in the context of exchange of genetic material has been addressed through setting up specialised multilateral ABS agreements. This section summarizes a selection of these agreements that are most relevant when considering solutions for FMD.

Human Influenza

Global Influenza Surveillance and Response System The closest parallel that can be drawn between FMD and a human pathogen is for human influenza. For both diseases there is a need for continuous surveillance and the development of new vaccine strains in response to antigenic change. In the case of human influenza, two distinct systems exist: the GISRS and the PIP Framework. Both systems rely on the network of laboratories that constitute the GISRS. This network has been operational under different names since the 1950 and includes National Influenza Centers, WHO Collaborating Centers, WHO H5 Reference Laboratories and Essential Regulatory Laboratories operating under Terms of Reference (ToR) that are set by the WHO. There are many similarities in the way that the GISRS operates and the way that the WOAH/FAO Reference Laboratory Network for Foot-and-Mouth Disease operates. The key function on the GISRS is to conduct surveillance for seasonal influenza and, when the need for new vaccines strains is identified, to act as the source for candidate vaccine viruses. Both activities require the ability to exchange viruses with minimum delay and bureaucracy. In a similar way, continuous surveillance of FMDV at global level is important for early detection of the emergence of new strains for which existing vaccines may not be effective. Differences between the operation of the networks also need to be recognized such as the smaller scale of the FMD network, the lower level of human and financial resources that are available in the veterinary sector, the formal role of WHO in recommending the strains of influenza virus that should be included in seasonal influenza vaccines, and that new vaccines strains are required for seasonal influenza vaccines at least annually whilst significantly diverging strains of FMDV arise less frequently.

The rules governing exchange of materials between the different categories of laboratories are complex, but the common factor is that exchange between members of GISRS takes place in the context of standardized terms of reference defined by WHO and agreed by laboratories as part of their agreement for becoming part of the network. This system has been shown to work well in terms of exchange of viruses within the network and for the generation of Candidate Vaccine Viruses (CVV) and

reference materials that can be directly supplied to manufacturers to accelerate the process of introducing new vaccine strains in line with periodic recommendations from WHO. There is less standardization in terms of how a new CVV is actually transferred to manufacturers once WHO has recommended its inclusions in the seasonal influenza vaccine. In some cases, such transfers from members of the GISRS to manufacturers as third parties take place on the basis of historic agreements using well established partnerships. Increasingly, some countries are exerting their rights under the Nagoya Protocol for agreement on ABS within the terms of an MTA permitting transfer to a manufacturer for commercial use. To address this trend, GISRS has developed the Seasonal Influenza Material Transfer Agreement (SIMTA) as a special MTA that integrates Nagoya Protocol compliance by including terms that establish agreement on PIC and MAT and allows commercial development of vaccines, diagnostics, and antivirals. Adoption of SIMTA aims to remove the need to bilaterally negotiate terms for each transfer of a CVV to a manufacturer. SIMTA has not yet been used operationally to our knowledge.

This model of utilising standardized Terms of Reference defined by an 'overseeing' international organisation to exchange viruses within an established network for non-commercial purposes combined with a standardized MTA to cover exchange with a third parties for potential commercial exploitation should be explored further by the WOAH/FAO Reference Laboratory Network for Foot-and-Mouth Disease. The need for transfer of candidate FMD vaccine viruses between FMD reference laboratories and commercial vaccine manufacturers is even greater in the veterinary than the human domain as few, if any, FMD reference laboratories are funded to perform the studies necessary to evaluate candidate vaccine viruses as happens routinely for human influenza viruses within the GISRS.

i. *Pandemic Influenza Preparedness Framework and the proposed WHO Pathogen Access and Benefit Sharing System*

The PIP framework was set up to "improve and strengthen" GISRS by encouraging the sharing of H5N1 and other influenza viruses with human pandemic potential. The PIP Framework was placed on top of, and integrated into GISRS, although its requirements do not apply to seasonal influenza viruses (28). The PIP Framework aims to promote the collection of samples of influenza viruses with pandemic potential (called "PIP biological materials") by GISRS network members and facilitate access by entities that wish to use the PIP biological materials for research and development, including for commercial purposes. These two activities are covered by standard MTAs; SMTA 1 applies to the sharing of samples between laboratories affiliated with the GISRS and SMTA 2 applies between the WHO (acting as the framework's trustee) and any institution outside the GISRS, including those who seek to utilise genetic resources for commercial purposes. As part of SMTA 2, the recipient institution must select from a series of different benefit-sharing options detailed within these agreements that then constitute ABS arrangements that are considered compliant with the Nagoya Protocol. The PIP Framework aims therefore to 'carve out' influenza viruses that have pandemic potential from the routine exchange of seasonal influenza viruses so that PIP biological materials can be treated exceptionally and expeditiously. The intention is that transfer to parties outside the GISRS network is accelerated by having agreed ABS terms in advance through their inclusion in SMTA 2 terms of agreement. The system has yet to be tested in practice and has been criticized by some stakeholders for both high cost and that a large proportion of the fees paid in the form of voluntary Partnership Contributions goes to running the secretariat. The existing PIP Framework and the proposed PABS System (see below) should be reviewed as part of developing an approach to sharing of FMD viruses. For PIP to be relevant it would be necessary to be able to 'carve out' FMD viruses with epizootic potential from other FMD viruses that are exchanged in the interests of routine surveillance. This would require creating a strict definition as applies in the case of PIP Biological Material (29). If this can be achieved the potential advantage in this approach would be that it would be possible to focus

efforts at facilitating exchange onto those FMD viruses that represent the greatest risk. However, whilst it is possible to define human influenza viruses with pandemic potential on the basis of specific genetic changes, no such genetic 'signature' exists for pandemic FMD viruses and any FMD virus has the potential to cause a pandemic if epidemiological factors are favourable (e.g. high density of susceptible animals, low immunity to the strain concerned, favourable conditions for transmission etc). Furthermore, it is important to emphasise that PIP 'sits on top' of the routine exchange of seasonal influenza viruses within GISRS and is not a replacement or alternative for this exchange. Whatever system is put in place for FMD will need to take account of both the routine exchange of viruses for surveillance and exchange of viruses for potential commercial exploitation, making the PIP model less attractive in the case of FMD.

It is beyond the scope of this report to elaborate in detail on the benefits and drawbacks of the current PIP framework but, due to the challenges identified in responding to the COVID pandemic, under the auspices of the WHO, an Intergovernmental Negotiating Body is currently negotiating a WHO Convention, agreement or other international instrument on pandemic prevention, preparedness and response. This is being referred to as the Pandemic Accord. Article 12 of the most recent draft (May 22, 2023) of the Pandemic Accord contains the WHO Pathogen Access and Benefit Sharing System (the PABS System) for pathogens with pandemic potential in humans. It seems unlikely that the PABS could be extended to include veterinary pathogens such as FMDV within its scope unless they have pandemic potential for humans. Nevertheless, the high level of activity related to negotiating this internal accord will undoubtedly raise awareness and knowledge of ABS issues among key stakeholders.

In the case of human pathogens, WHO plays a prominent role in facilitating the negotiation of solutions between the interested parties and, in cases such as the Pandemic Influenza Preparedness (PIP) framework, plays a functional role in acting as the repository and agreement holder for transfer of genetic material. There is no single institution that plays the same role as the WHO in the veterinary domain. International collaboration for veterinary diseases is managed by cooperation between the WOAH and the FAO, each respecting their particular mandate and responsibilities. WHO may also be involved, particularly when there is a zoonotic perspective to the health issue concerned (e.g. rabies and antimicrobial resistance). In the case of FMD, both WOAH and FAO are involved in efforts to control and eradicate the disease, particularly through the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) and the Progressive Control Pathway for FMD (PCP-FMD), except for the Americas, where the Pan American Health Organization, the Regional Office for the Americas of the WHO, has been coordinating the FMD eradication efforts in this region through its Pan American Foot and Mouth Disease Centre (PANAFTOSA), Rio de Janeiro, Brazil. FAO, WOAH and other key international organisations such as PANAFTOSA should therefore be key drivers in any solution identified for FMD at a global level.

4. Non-surveillance networks and biological repositories

In addition to sharing as part of surveillance networks, a number of physical or virtual systems have been put in place that act as repositories of biological materials. Examples include the WHO Biohub and the European Virus Archive, as described below.

WHO BioHub System for Preparedness and Response to Epidemics and Pandemics

Following the COVID-19 pandemic, the WHO initiated the development of a biobank (WHO BioHub System for Preparedness and Response to Epidemics and Pandemics), which will apply the concept of the GISRS to other emerging pathogens considered as risks to public health. This would act as a system for sharing pathogens and clinical samples, to facilitate research and development for disease control

measures (6,20). The pilot phase was launched in May 2021 with SARS-CoV-2 and one facility with planned expansion to other pathogens and connection to other laboratory networks.

European Virus Archive

Another multilateral ABS model is the EVA. The EVA offers a centralized catalogue of virus strains and derivatives, accessed via a decentralized biobanking structure composed of an international network of 43 laboratories worldwide (24). An expert legal team ensures ABS compliance in advance and access to samples is via a material transfer agreement, however with this particular model the genetic resources are not available for commercial research purposes, and if this is wanted a separate licensing agreement with the provider country is prepared. The running costs of the EVA are substantially lower than PIP (4 mil Euro vs 26 mil USD [24 mil Euros approx.] annually) (24).

The operating model of these non-surveillance networks and biological repositories should be taken into account when developing solutions of FMDV. Laboratories within the WOAH/FAO Reference Laboratory Network for Foot-and-Mouth Disease already act as repositories for FMD viruses as many parties that seek FMD viruses currently approach the network as the most likely source of such material. FAO has expressed interest in principle in exploring further the possibility of establishing an international FMDV repository, under agreements with the FAO, with the option to expand to other veterinary viruses of importance at a later stage. If there is an intention to establish a biological repository on a more formal basis, then the main challenges identified in this report will need to be addressed. In particular, it currently remains the responsibility of the recipient organisation to negotiate an MTA with the party registered as the provider of the sample. For this reason, although viruses of interest may be held by reference laboratories in their repositories, laboratories may not be able to supply them to third parties for research or utilization and can only refer interested parties to the original provider to make their own arrangements for access to the same or similar materials. Any solutions involving biological repositories must therefore overcome the need for case-by-case bilateral negotiations, possibly by only accepting materials into the repository on the basis of MTAs including standardized ABS terms for onward transmission to third parties.

Elements required for a solution for FMD

The preferred option for FMD should be based on the specific issues identified in the problem statement, the existing infrastructure for collection, storage and exchange of FMDV biological material, and the history of trust that has been built up over many years within the FMD Laboratory Network and other institutions working in the field of FMD such as WOAH, FAO, PANAFTOSA and EuFMD.

The following elements for a solution are identified:

1. *Raise awareness*

The first step in developing a solution is to raise the awareness of the wide range of stakeholders listed in Appendix 1 that a problem exists with respect to control of FMD due to the way in which the Nagoya Protocol and national ABS arrangements are currently implemented. The objective should be to reach a common understanding on the nature of the problem, the cause, and the approach to follow to identify and implement a solution.

Currently the level of knowledge of the Nagoya Protocol varies widely between countries and between the various stakeholder groups within countries that are involved in its implementation with respect to FMD. As mentioned above, this can lead to a lack of understanding of what activities do and do not fall within scope of the protocol and, for materials that are considered in scope, how to agree MAT and PIC within a reasonable timeframe. Further complexity is added by elements such as whether or

not a country has ratified the protocol, the date on which ratification took place, and the way in which the protocol is implemented within national ABS legislation (e.g. what materials and activities fall within the scope defined in national legislation, the date the national legislation came into force and if it applies retrospectively to material already supplied).

One approach to raising awareness would be to gain 'buy in' from organisations at international, regional and national level that a problem exists and to prepare common training and communication material to explain the current situation. The training material could make clear that the activities of diagnosis and surveillance are generally considered to fall outside the scope of the protocol. Some countries interpret their national legislation as requiring PIC and MAT for these activities despite their falling outside the scope of the protocol. Increased awareness can identify where this situation arises and assist in developing solutions that comply with national ABS requirements. Prioritizing this activity in the first instance should manage the risk mentioned above that raising awareness could have the perverse outcome of reducing the submission of materials for diagnosis and surveillance.

Awareness raising activities should take place within the context of existing frameworks in the first instance. WOAH and FAO are actively engaged with regional and national authorities responsible for implementing the PCP-FMD in the context of the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs). The first step should be to raise the awareness of the governing bodies of these organisations to engage them with the issue and to gain their support to seek solutions to the problems identified. Regional meetings of these organisations and initiatives would be an efficient and effective means of engaging with national and regional contact points. Similarly, the WOAH/FAO FMD Laboratory Network could be used to raise awareness among laboratory stakeholders.

Organisations that are engaged with controlling FMD will already be aware of the importance of exchange of biological materials for effective disease control. Other authorities, such as the Nagoya Protocol Focal Points or the National Competent Authorities for Nagoya, may be less aware of these issues and should therefore be a priority for targeted awareness raising. A 'cascade' approach would therefore be appropriate, whereby the national FMD contacts can use the ready prepared training and communication material to raise awareness of the Nagoya authorities at national level.

In summary, raising awareness is an essential prerequisite to developing a solution and focus in the first instance should be given to developing a communication plan that encompasses the wide range of stakeholders included in Appendix 1.

2. *Identify or develop an operational framework for submission, storage and access to FMD material*

The first step in any system for ABS is to put in place a system for access to strains of FMDV when required. In the case of FMD there is already the WOAH/FAO Reference Laboratory Network. This is a well-established network that has operated for decades. The laboratories function as reference laboratories on the basis of letters of agreement, or other contractual arrangements, with WOAH and FAO. The Network has established contact with a global network of national laboratories. There is frequent exchange of strains between members of the Network. Exchange is based on a combination of long-established trust supplemented, where appropriate, with formal MTAs. In situations where viruses are supplied to third parties such as manufacturers, it is usually the responsibility of the third party to gain the necessary consent for their intended purpose directly with the original source of the virus concerned. Any solution should build on this existing and effective network, supplementing existing arrangements where necessary to ensure compliance with ABS requirements in a way that reduces the bureaucratic burden to the minimum possible.

Other networks have put in place standard MTAs to cover the different types of exchange that take place. Usually, one standard MTA covers exchange of materials within the network for non-commercial purposes that are outside the scope of the Nagoya Protocol, such as diagnosis and surveillance. A second MTA covers exchange of material between a member of the network and an external party for a commercial purpose such as the development of a vaccine strain or a new diagnostic. It is the second type of MTA that currently causes problems and where there is the greatest scope for agreeing in advance standardized terms that cover MAT and PIC, thereby avoiding the need for case-by-case negotiation of terms each time that a sample is shared with a third party. Introducing these types of standardized MTAs could represent a solution to the problems identified in this report that is relatively simple to implement, provided that suitable standard terms for inclusion in the MTAs can be agreed.

One issue that will need to be addressed in using the existing WOAH/FAO Reference Laboratory Network as the operational framework for providing access to FMD material will be the increased administrative burden that will fall on the network if responsibility for compliance with the protocol moves from the third party acquiring the material to the laboratory supplying the material on the basis of a standardized MTA. Examples of such additional work will include ensuring that the ultimate source of all samples is known, and that due diligence is performed to ensure that the standard MTA is appropriate for both the donor and recipient taking into account the date that samples were received in relation to ratification of the Nagoya Protocol by the country concerned and if additional national legislation applies. The need for a highly skilled secretariat rapidly becomes evident for which a source of funding will be required. Funding the operation of the network in a Nagoya-compliant manner in the interests of ensuring that new vaccine strains can continue to be developed could become one of the shared benefits that provider countries may be willing to include as part of a shared ABS system, as discussed in the following section.

3. *Agree a system for sharing benefits that arise from commercial use of FMD genetic resources as biological materials*

To date, the greatest challenges in terms of implementing the Nagoya Protocol have arisen from defining what constitutes a benefit and agreeing how benefits should be shared. This is an entirely new area with respect to FMD and will require considerable discussion between stakeholders to reach agreement on defining, quantifying, collecting or creating, and disbursing the benefits that arise from commercial use of FMD genetic resources as biological materials.

It is beyond the scope of this paper to consider these issues in depth, but it is useful to consider an overall approach. The first step would be to gain agreement between stakeholders that there are benefits to be gained by both companies and ABS beneficiaries in moving from case-by-case negotiation to a harmonized system for ABS that is agreed in advance and implemented when required. Key factors that would then need to be addressed would include how to quantify benefits in monetary or other terms and how to agree whether benefits should be pooled or disbursed to individual participants in response to a particular contribution. Non-monetary benefits could include activities such as capacity building or developing shared facilities or assets that benefit the network as a whole rather than an individual contributor.

In developing a framework for FMD the experience gained from the other networks discussed in this report should be taken into account, such as GISRS and PIP. The considerable differences between the human and veterinary domains will need to be considered, including the limited size and resources available in the veterinary domain, the small size of the veterinary vaccine market as compared to the human market, the fact that most disease control activities ultimately rely on the private rather than the public sector and the challenges in raising issues of animal health to a high enough political level

to agree change at an international level. The overall objective would be first to agree a harmonized system for ABS and the respective standard terms to include into the MTAs that govern transfer of materials from a member of the network to a third party for commercial use. These terms will cover both the benefits to provider countries, or to the network, from agreeing to allow release of material to the third party and the obligations of the third party that result from receiving the material.

Developing an agreed framework for ABS will require engagement with those stakeholders outside the WOAH/FAO Reference Laboratory Network that are responsible for agreeing PIC and MAT. The aim will be to bring together those with experience of utilising FMD genetic resources with those responsible for negotiating agreements under the protocol. By seeking consensus at a global level, rather than on a case-by-case basis, it should be possible for all parties to achieve a common understanding of the scale and possible nature of the benefits that may arise. This approach should reduce the risk experienced to date of overestimating the potential benefits from exploitation of individual strains.

As mentioned above, bearing in mind that the ultimate objective of any solution is to ensure ready access to new strains of FMD whilst ensuring fair and equitable sharing of benefits, careful consideration will need to be given to ensuring that one of the benefits that arises is the long-term sustainability of the system itself. In the case of FMD, it is likely that the costs of operating the system will consume a large proportion of any financial benefits that arise. The operating model and business case therefore need to take this into account when sharing tasks and funds to ensure equity between the different parts of the network and that funds are not concentrated in any one part alone.

4. *Put into operation the solution identified*

Any solution will require formal approval and implementation by the organisations and institutions that are responsible for exchange of FMD biological materials and local Nagoya Protocol competent authorities. It is therefore envisaged that WOAH, FAO, other international bodies involved in animal health and the various bodies responsible for implementing the Nagoya Protocol will be engaged in the process of developing a solution from the start. This will ensure that any solution meets the objectives and operational model of the organisations with responsibility for its implementation so that it can ultimately be recommended to the governing body of the organisation for adoption.

The complex nature of the problem and the wide variety of stakeholders involved mean that it is likely to take several years to reach agreement on an over-arching solution. For this reason, a phased approach is proposed that aims to provide a workable solution for exchange of strains in the short term for those parties that volunteer to engage with it. At the same time the full range of stakeholders will engage at high level to develop an over-arching and long-term solution. If successful, the short term, voluntary process may act as a proof-of-concept that will be useful in developing the long-term solution and gaining its widespread acceptance.

In this approach, the WOAH/FMD Reference Laboratory Network would seek to create a ‘coalition of the willing’ who are interested and have in place the appropriate legislation and implementation framework to operate a voluntary system based on the principles described above. This would involve reaching agreement between participants in the project on standard MTAs for exchange of viruses within the network and between members of the network and third parties. Participants would include members of the laboratory network, provider countries and vaccine manufacturers. Discussion would take place to define benefits and establish a system for fair and equitable sharing of these benefits between participants.

Next steps

This report aims to raise awareness of the animal health impact of the Nagoya Protocol and national ABS arrangements and to initiate a discussion on how to resolve the issues that exist. It is premature and beyond the scope of this report to go into detail on any particular solution, rather the document aims to outline an approach to developing a solution that takes into account the considerable experience gained in addressing similar issues with other disease.

The role of the EuFMD in producing this report is currently limited to raising awareness of the issue. At the 45th General Session of the EuFMD in May 2023, the new EuFMD strategy 'Move FAST, get prepared' was endorsed that includes vaccine security as a priority. EuFMD therefore considers that finding solutions for the Nagoya Protocol with respect to FMD is a priority activity that falls within its mandate. EuFMD has already established the Vaccine Security Multistakeholder Platform that either currently includes or could be expanded to include all the key stakeholder groups identified in Annex 1 that are necessary for finding a solution. EuFMD, through its Multistakeholder Platform, is therefore well positioned to bring together the organisations and individuals to develop solutions that could operate at global level. EuFMD recognizes that it does not have the mandate or responsibility to implement the necessary measures itself but is well placed to foster their uptake once agreed and adopted by the respective international organisations.

The next step is therefore to bring this report from the Multistakeholder Platform to the attention of the various stakeholders listed in Annex 1 and to Member Nations of the EuFMD. The intention of raising awareness is to seek a mandate to continue the activities of the Multistakeholder Platform in the next EuFMD work programme aimed at fostering resolution of the issues raised in the interests of improved control of FMD.

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Appendix 1: Preliminary analysis of stakeholders involved in implementing a solution for FMD with respect to the Nagoya Protocol and national ABS arrangements

Stakeholder	Current role	Engagement in solution
Disease control authorities at national level (generally animal health authorities)	• Responsible for policy development and implementation in respect to FMD control at national level • May act as National Competent Authority for Nagoya Protocol with respect to FMD biological materials (or other authority such as GMO) or environment ministry • May act as National Focal Point	• Need for increased awareness of Nagoya Protocol and national ABS arrangements in relation to submission of biological materials for diagnosis, surveillance, research and development • Need to be informed and engaged in development of solutions • Need for improved communication between laboratories and National Focal Points for Nagoya Protocol (and possibly Nagoya Competent Authority)
Disease control authorities at regional level (various regional commissions and other coordinating bodies such as regional commissions on TADs and EuFMD, the Pan American Foot and Mouth Disease Centre (PANAFTOSA))	Coordinate FMD control activities in the context of regional and international programs such as GF-TAD and PCP-FMD	Useful forums for engagement of disease control stakeholders at regional level on discussion of ABS in relation to FMD
Disease control authorities at global level, principally WOAH and FAO	• Set the terms of reference of operation of FMD reference laboratories • Contribute to funding of the laboratory network • Coordinate animal disease control at global level • Oversee implementation of global control programmes such as GF-TAD and PCP-FMD	• Key international organisations responsible for liaison with Conference of the Parties of the CBP in agreeing any solution with respect to the Nagoya Protocol • Responsible for agreeing and implementing any solution for FMD that involves the WOAH/FAO FMD Laboratory Network
Vaccine manufacturers and their industry associations	Conduct surveillance and develop new vaccine strains when required	• Engage in discussions on equitable ABS arrangements for use of new strains • Ultimately responsible for disbursement of benefits in line with any ABS agreement reached
Diagnostics manufacturers and their industry associations	Develop diagnostics for newly emerged FMD strains	• Engage in discussions on equitable ABS arrangements for use of new strains

		• Ultimately responsible for disbursement of benefits in line with any ABS agreement reached
Reference laboratories for FMD	Receive strains for diagnosis and surveillance, conduct R&D, operate an archive of strains and supply strains to manufacturers and researchers	• Key for agreeing and implementing any solution that involves a central role for reference laboratories in assuring compliance with the Nagoya Protocol in receipt, storage and distribution of FMD viruses
Veterinary laboratories at national level	National diagnostic laboratories collect and submit samples to national or international reference laboratories • National reference laboratories analyze and submit samples to international reference laboratories	• Need for increased awareness of Nagoya Protocol and keep informed and engaged in development of solutions • Improve exchange of information between laboratories and national focal points for Nagoya Protocol in provider countries
Research organisations carrying out research on FMD	• Receive samples for FMD research and development either directly from source or, more frequently, from national or international reference laboratories • Responsible for ensuring compliance with ABS requirements of the Nagoya Protocol with ultimate source of biological material	• Need for increased awareness of Nagoya Protocol and keep informed and engaged in development of solutions • Improve exchange of information between recipient research organisation and national focal points and National Competent Authorities responsible for Nagoya Protocol in provider countries
		•
National Competent Authorities and National Focal points responsible for administering the Nagoya Protocol	Responsible for operation of the Nagoya Protocol at national level in provider and recipient countries	• Need for increased awareness of the impact of the implementation of the Nagoya Protocol on control of FMD • Need to be engaged in discussion on developing a framework equitable ABS for FMD
Indigenous people and local communities	Indigenous people and local communities are frequently considered as 'rights holders' rather than 'stakeholders' in relation to the Nagoya Protocol. Indigenous people should be the ultimate beneficiaries of the benefits that arise from exploitation of genetic material. In the case of FMD the benefits	• Need to ensure that any solution takes account of the full value chain related to FMD vaccines including that the benefits arising from ABS result in measurable benefits to local people in terms of improved FMD control • Research on the value chain for FMD vaccines and how to

	would arise through improved control of FMD by ensuring that strains used in vaccines are relevant to the strains circulating in the field that cause disease in cattle owned by local communities	measure the benefits to the different parties along the chain is currently being carried out by a number of organisations, including EuFMD. The outcome of this research could be used in future to measure the impact of ABS measures on indigenous people and local communities.

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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