SCIENTIFIC Conference

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Europe

IABS

International Alliance for Biological Standardization

Preparedness and response to emerging veterinary disease outbreaks

March 25 & 26, 2025

BRUSSELS, BELGIUM

www.iabs.org

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About the Conference

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Emerging infectious diseases in livestock are on the increase in the European Union (EU), as well as the rest of the world. In the last four years, Highly Pathogenic Avian Influenza, Bluetongue and Epizootic Haemorrhagic Disease have had a profound effect on farmers and the food supply chain. And the trend continues with other emerging (or re-emerging) diseases like Peste des Petits Ruminants and Sheep and Goat Pox. Proven strategies exist to help control the impact of emerging and re-emerging diseases, including surveillance, epidemiological modelling, animal movement control, biosecurity and vaccination. Appropriate vaccines are not always readily available, however, especially in emergency situations.

IABS recognizes the financial and animal welfare consequences that result due to this gap between the (re-) emergence of an infectious animal disease and the availability of appropriate vaccine(s) in the EU. To help address this gap, the IABS is conducting a conference on the topic, which will take place on 25 and 26 March 2025 in Brussels, Belgium.

PREPAREDNESS AND RESPONSE TO EMERGING INFECTIOUS ANIMAL DISEASES

After a review of the current legal, regulatory, epidemiological and economic landscape in the EU, the conference will sponsor presentations from a series of expert speakers from different EU stakeholders that will analyse the issues preventing (or delaying) access, availability or use of relevant vaccines. Regulatory procedures, economic incentives and disincentives, surveillance policies and legal and policy framework will be examined by the presenters with careful attention to barriers that must be addressed to expedite vaccine availability and improved emerging disease control. Regulatory officials, disease control experts, veterinarians, academia, animal health companies, and allied industries will all participate in this phase of the meeting.

The conference will conclude with an open general session allowing all participants to input. The aim will be to propose practical solutions that should lead to having relevant vaccines more quickly available in the EU in case of emergence or crisis.

Scientific & Organizing Committee

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Scientific Committee

Frédéric Descamps, Co-Chair, Zoetis
Gabor Kulcsar, Co-Chair, Nébih
Jean-Christophe Audonnet, IABS-EU
Max Bastian, FLI
Ron Bergevoet, Wageningen University & Research
Annemarie Bouma, Dutch Ministry of Agriculture
Ivo Claassen, European Medicine Agency
Sjaak de Wit, GD Deventer
Olivier Espeisse, IABS-EU
Cyril Gay, USDA
Miia Jakava-Viljanen, IABS VBC Chair, Finnish Food Authority
Carmen Jungbäck, IABS-EU
David Mackay, IABS VBC Member
James Roth, Iowa State University

Organizing Committee

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Gabor Kulcsar, Co-Chair, Nébih
Olivier Espeisse, IABS-EU
Madinina Cox, IABS Secretariat

Scientific Program

Conference on Preparedness of Veterinary Emerging Diseases
Tuesday, March 25, 2025

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1:30 - 2:00 *Registration & Welcome Coffee*

2:00 - 2:10 **Introduction**
Olivier Espeisse, IABS-EU, France

2:10 - 2:20 **Preparedness for the day**
Olivier Espeisse, IABS-EU, France

Session I: Review of current status and obstacles

Moderator: Frédéric Descamps

2:20 - 2:40 **Animal Health Legislation**
Francisco Reviriego-Gordejo
EU Commission, DG Health and Food Safety

2:40 - 3:00 **Veterinary medicinal product Legislation**
Dries Minne, EU Commission, Policy Officer

3:00 - 3:20 **Regulatory Implementation**
Ivo Claassen, EMA

3:20 - 3:40 **Ten years of EU funded research on vaccine development**
Jean-Charles Cavitte
EU Commission, DG Agriculture and Rural Development

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Experience of Member States

3:40 - 4:00

1. The Netherlands
Annemarie Bouma
Ministry of Agriculture, Nature and Food Quality, The Netherlands

4:00 - 4:20

2. France experience with poultry HPAI vaccination
Olivier Debaere, Ministry of Agriculture, France (virtual)

4:20 - 4:40

3. Make them available – a bumpy road to the BTV-3-vaccine
Max Bastian, Friedrich-Loeffler-Institut (FLI), German

4:40 - 5:10

Break

5:10 - 5:30

What is happening outside the EU?
Dónal Sammin, Eu-FMD, Italy

5:30 - 5:50

Point of view of EU Pharmaceutical Industry
Ely Bénéré, AnimalHealthEurope, Belgium

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Session II – Panel discussion

Moderator: Jean-Christophe Audonnet

5:50 - 6:20

Francisco Reviriego-Gorderjo, EU Commission, DG Health and Food Safety, Belgium

Dries Minne, EU Commission, Policy Officer, Belgium

Ivo Claassen, EMA, Netherlands

Jean-Charles Cavitte, EU Commission, DG Agriculture and Rural Development, Belgium

Annemarie Bouma, Ministry of Agriculture, Nature and Food Quality, The Netherlands

Olivier Debaere, Ministry of Agriculture, France (virtual)

Nancy De Briyne, Federation of Veterinarians of Europe, Belgium

Ely Bénéré, AnimalHealthEurope, Belgium

Dónal Sammin, Eu-FMD, Italy

Max Bastian, Friedrich-Loeffler-Institut (FLI), Germany

6:20

End of day 1

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8:30 - 9:00 *Registration & Welcome Coffee*

Session III – Review of remedies

Moderator: Gabor Kulcsar

9:00 - 9:20 **Economic aspects of vaccination**
Analysis from the situation in The Netherlands
Ron Bergevoet, Wageningen University & Research Center, The Netherlands

9:20 - 9:40 **Drivers of emergence of infectious animal diseases: what are the challenges?**
Claude Saegerman, University of Liège, Belgium

Regulatory and Technological responses

9:40 - 10:00 **A regulatory perspective on authorisation under exceptional circumstances, the BTV-3/NET2023 case**
Jacqueline Poot, Medicines Evaluation Board, The Netherlands

10:00 - 10:20 **2. Perspective from EU Pharmaceutical Industry**
Ely Bénéré, AnimalHealthEurope, Belgium

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Session IV – Panel discussion

Moderators: Gabor Kulcsar & Frédéric Descamps,

10:20 - 11:00

Panel Discussion with all Stakeholders
Focus on solutions to key barrier

Ron Bergevoet, Wageningen University & Research Center, The Netherlands

Claude Saegerman, University of Liège, Belgium

Jacqueline Poot, Medicines Evaluation Board, The Netherlands

Ely Bénéré, AnimalHealthEurope, Belgium

Martin Beer, Friedrich-Loeffler-Institut, Germany (virtual)

11:00 - 11:30

Break

Session V – Recommendations

Moderators:

11:30 - 12:30

All participants

12:30

Closing remarks
Jean-Christophe Audonnet, IABS-EU, France
End of Meeting

ADVANCING PREVENTIVE MEDICINE TO TACKLE EMERGING DISEASES AND CONTRIBUTE TO PREVENTING FUTURE PANDEMICS

At Ceva, our commitment goes beyond animal health. In practice, this means we are a One Health company, convinced that the health of animals, humans, and our planet are deeply interconnected.

This is why we continuously invest to develop innovative health solutions that prevent animals from getting sick in the first place. In doing so, we contribute to:

- Foster animal well-being, by preventing illnesses and sparing them unnecessary suffering;
- Support farmers worldwide in feeding the planet more sustainably;
- Protecting human health by actively fighting zoonotic diseases, preventing them from spreading to humans and potentially turning into the next global pandemics.

Global trade and climate change are accelerating the emergence of new diseases and their propagation. A world moving towards 10 billion inhabitants needs the scientific and industrial expertise of companies like Ceva to ensure an adequate level and safe supply of animal proteins across the globe.

INNOVATION AT THE CORE OF CEVA'S MISSION

At Ceva, innovation drives our fight against emerging diseases, and it can take two equally effective forms:

Internal innovation – We develop cutting-edge solutions in-house, like our nucleotide-based avian influenza vaccine for poultry.

This next-generation vaccine was developed in less than 250 days, showcasing our ability to respond rapidly to emerging threats.

Innovation through partnerships - Collaboration is key to accelerating innovation. A perfect example is our alliance with the Spanish laboratory CZV, which allowed us to quickly provide a vaccine against Epizootic Hemorrhagic Disease (EHD) to affected farmers in Northern Europe.

Beyond these efforts, more than 10% of our revenue is dedicated to research. We invest in cutting-edge technologies, such as dbDNA technology, which enables rapid, high-purity enzymatic DNA production while eliminating antibiotic resistance genes.
In 2024, we opened a new state-of-the-art research facility: the new Biogenovac genomics lab in Beaucouzé, France, specializing in the development of next-generation vaccines. Using advanced sequencing and bioinformatics, we are creating the vaccines of tomorrow.

COLLABORATION: A KEY TO SUCCESS

We cannot act alone. Regulatory bodies need to keep pace with scientific advances to properly and timely assess breakthrough technologies. It is essential that they are equipped to respond to emerging health challenges as swiftly as animal-health industrial leaders do, enabling life-saving technologies to realize their full benefits for producers, their animals, and consumers.

Upcoming IABS Conferences and Workshops

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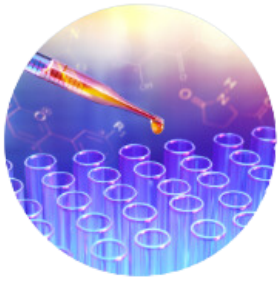
Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

Brussels, Belgium
May 14-15, 2025



AFSA – IABS Conference about Animal testing replacement for vaccines: A One Health View: global outlook and future strategy

Bangkok, Thailand
December 2-4, 2025

Workshop on Global Harmonization of Specification: Implementing A Patient-Centric Control Strategy

Tokyo, Japan
June 23-25, 2025

Advances in Analytical Technologies for Biopharmaceutical Products

Rockville, MD, USA
March, 2026

Biosketch

Jean-Christophe Audonnet DVM, PhD

IABS-EU member
DVM and holds a Ph.D. in Molecular Bacteriology and a Molecular Virology degree from Pasteur Institute Paris

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Jean-Christophe AUDONNET is a DVM and holds a Ph.D. in Molecular Bacteriology and a Molecular Virology degree from Pasteur Institute Paris. After 3 years at Virogenetics (Troy NY, USA) he was in charge of multiple research and innovation responsibilities from 1992 until 2021 at Rhône Mérieux, then Merial and lastly at Boehringer Ingelheim Animal Health (vaccinology, immunology, technical platforms for protein expression). Along these internal and external R&D collaborative partnerships, he built a strong international experience (USA, Canada, Europe, China, Singapore). Jean-Christophe Audonnet has been the Coordinator of the European project IMI ZAPI (March 2015 - July 2021) (www.zapi-imi.eu). He is now retired from industry and provides scientific and technical consulting support.

Biosketch

Dr. Max Bastian

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EDUCATION:

· **10/1993 – 07/1999 –** Studies of Veterinary Medicine, University of Veterinary Medicine, Hannover
· **01/2000 – 02/ 2004 –** PhD thesis (Doktorarbeit), Swiss Tropical Institute, Basel, and University of Veterinary Medicine, Hannover
· **03/2015 –** Veterinary specialist for microbiology (Fachtierarzt)

PROFESSIONAL EXPERIENCE:

· **03/2004 – 12/2008 –** Postdoctoral Fellow, Institute for Clinical Microbiology, Immunolgy and Hygiene, Erlangen University and Institute for Medical Microbiology, Ulm University
· **01/2009 – 09/2015 –** Group Leader, Department of Veterinary Medicine, Paul-Ehrlich-Institute, Langen
· **Since 09/2015 –** CEO of the Standing Committee on Veterinary Vaccines at the Friedrich-Loeffler-Institut

Abstract

Max Bastian

Make them available – a bumpy road to the BTV-3-vaccine

Introduction: In Germany, the begin of the BTV-3-epidemic in September 2023 in The Netherlands was observed with great concern. Immediately, considerations started how a suitable BTV-3-vaccine could be made available before the next midges-season. It was unclear, how a timely marketing authorization or approval could be achieved.

Experiences with the autogenous BTV-3 vaccine: There was reason to expect that a vaccine would only become available by the end of 2024. To bridge the time and as there was danger in delay, the use of an autogenous BTV-3-vaccine was envisaged. Infected midges represent a confirmed epidemiological link. So, BTV restriction zones were defined as epidemiological units. Affected Federal States allowed the use of the autogenous vaccine, explicitly supported by StIKo Vet. As a precautionary measure, the first doses were applied by public veterinary institutions. Vaccinated sheep and cattle were closely monitored over fourteen days and showed no adverse reactions. Field vaccinations were commenced. One week after delivery of the vaccine to practioners had begun, one of the preemptively vaccinated herds showed signs of bluetongue disease. Infection with BTV-3 was confirmed by the state laboratory. There was no natural transmission in April, but it could later be confirmed that the vaccine contained active virus. Immediately the delivery was stopped and the recall initiated. During the one week between delivery and recall over ten thousand doses had been administered, thirteen percent of the vaccinated animals became ill and about one hundred animals died. Due to the very rapid reaction of veterinarians, authorities and the manufacturer greater harm could be avoided. However, the concept of using an autogenous vaccine against BTV-3 had to be abandoned.

Abstract

Max Bastian

The use of three, non-authorised BTV-3 vaccines is approved: Beginning of June, 2024, the Federal Ministry approved the use of three non-authorised BTV-3-vaccines. This was a gamechanger! There are differences, but all vaccines are safe and at least prevent severe disease. However, the voluntary vaccination does not result in sufficient vaccination coverage to prevent virus spread. In addition, there was not enough time to build up a reliable herd immunity. Despite all efforts, BTV-3 hit Germany with full force at the end of July. In the meantime, 29% of all cattle and 56% of all sheep have been vaccinated. Virus season is expected to start in June, but this year animal owners can protect their animals.

Biosketch

Ely Bénéré, DVM, PhD

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Ely Bénéré graduated from the University of Ghent (Belgium) with a degree in Veterinary Medicine and obtained a PhD in Biomedical Science in 2011.

She then moved to the animal health pharmaceutical industry and has 13 years of experience in Regulatory Affairs. She is currently working as Associate Director Regulatory Affairs at Zoetis, focusing on the development and registration of livestock biological products.

Ely is also part of the Regulatory Procedures Working Group of AnimalHealthEurope and has made significant contributions through this trade association by working closely with industry stakeholders and regulatory bodies, driving progress and implementing best regulatory practices.

Abstract

Ely Bénéré

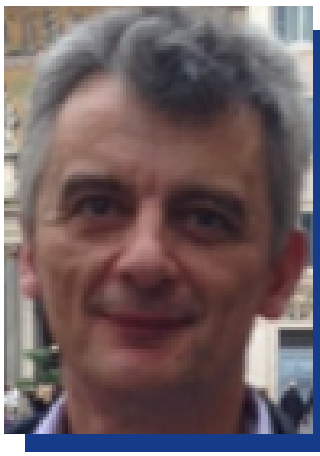
Point of view of EU Pharmaceutical Industry on the preparedness and response to emerging disease outbreaks.

The presentation of the EU pharmaceutical industry will consist of 2 sessions.

In the first session, industry will present its views on the status and the perceived obstacles for developing, licensing (or otherwise gaining authorization for use), and supplying adequate quantities of vaccines for emerging veterinary diseases "in the hurry". In this discussion, particular attention will be given to the specifics of the veterinary vaccine industry for emerging infectious disease (EID) vaccine's investment decisions and manufacturing capabilities. The pros and cons of regulatory pathways described in Regulation 2019/6 (i.e. exceptional use, vaccine Platform Technology Master File and Multi-Strain dossier concepts) will be reviewed, considering recent experiences with Bluetongue virus serotype 3, Highly pathogenic Avian Influenza and other EID's outbreaks. The benefits and drawbacks of national versus European approval approaches will also be discussed.

In the second session, industry will provide its perspective and suggestions for possible improvements. In high level terms, it will be proposed that the concept of platform technologies is expanded, that the risk/benefit approach for vaccines against EIDs is reconsidered and that opportunities for "pre-approval discussions/processes" with authorities to accelerate vaccine approval for emergency use are maximized. Especially for BTV vaccines, industry will provide concrete suggestions for new incentives towards (early) vaccine development. The suggestions will include a range of proposals, either short-term and long-term, ranging from the need for new or revised technical guidelines, to more ambitious proposals requiring changes in the current legislation.

Biosketch



Ron Bergevoet

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Ron Bergevoet PhD DVM is a veterinarian and economist and has more than 20 years of professional experience in the analysis of European and Dutch policies in the area of animal health and disease control, animal welfare, and agriculture policy. He is one of the key researchers working for Wageningen Social & Economic Research and participated in various national, European and international economical and evaluation studies on agricultural policy, animal health, animal welfare and animal transport.

Abstract

1/2

Ron Bergevoet

Economic aspects of vaccination – Analysis from the situation in The Netherlands

Background: This presentation addresses the economic aspects of vaccination (versus no vaccination)in case of an outbreak of an Emerging Infectious Disease (EID). This will be illustrated by FMD as an example.

Vaccination can be an effective tool in the prevention, control and eradication of an emerging infectious disease and contribute to limiting the effects of an outbreak. Besides epidemiological, animal welfare and social aspects, policy makers have to take into account economic aspects into consideration when they are faced with the choice on whether to vaccinate or not to vaccinate.
In case of an outbreak of an EID losses occur at farm, sector (joint livestock farmers) and national economy levels. When evaluating the losses or costs of an epidemic different components can be distinguished:

- **Direct costs related to the control of the epidemic**

These include the costs for the infrastructure for the control of the epidemic, the cost associated with culling and destroying of infected and contact animals, the costs associated with destruction of feed and milk on detected farms, and the compensation and vaccination costs.

- **Cost related to trade restrictions**

An epidemic of FMD will result in trade restrictions that are related to the epidemic per se and do not depend on the specific characteristics of the control strategy chosen. However the duration of these restrictions can be affected by the strategy chosen.

- **Ripple effects**

The effects from outbreaks of FMD that are felt upstream and downstream along the livestock value chain-breeding, feed production, input supply, slaughter, processing, final sale and consumption.

- **Spill-over effects**

The effects from outbreaks of FMD on tourism and other services. Since other than typical agricultural production is becoming more important for the rural economy these spill-over effect are likely to become a large part of the total epidemic costs.

Abstract

Ron Bergevoet

Differences in these costs that occur when applying control strategies with and without vaccination will be discussed. Typical costs related to vaccination are highlighted.

Generalizing the findings of the results presented in this presentation to other countries should be done with great care although the presented approach can be used by other countries to get insight into the ranking of optional control strategies.

Conclusions: An economic analysis should be part of the policy assessment when vaccination is considered in the control of an EID.

Literature: Bergevoet, R. H. M., & van Asseldonk, M. A. P. M. (2014). Economics of eradicating Foot-and-Mouth disease epidemics with alternative control strategies. Archivos de Medicina Veterinaria, 46(3), 381-388. https://doi.org/10.4067/S0301-732X2014000300006

Biosketch

Annemarie Bouma, DVM, PhD

Policy officer
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Ministry of Agriculture, Fisheries, Food Security, and Nature, the Hague

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Annemarie Bouma graduated as biologist and as veterinarian. She did a PhD in 1997 on the epidemiology of Aujeszky's disease. From 2002-2015 she worked as associate professor at the Faculty of Veterinary Medicine. Since 2011 she is working at the ministry of Agriculture, Fisheries, Food Security and Nature, in the Hague. As policy officer she is involved in the prevention and control of various infectious animal diseases, like avian influenza, African swine fever, SARS-CoV-2 in mink, and bluetongue. She also participates in issues regarding European legislation and WAOH. Currently she is working on a plan to come to a vaccination programme against HPAI in the Netherlands.

Abstract

Annemarie Bouma

Experiences in the Netherlands
Review of current status and obstacles

Introduction: The Netherlands has experience with outbreaks of many animal diseases, including zoonoses. The most recent experience was with bluetongue virus 3 and 12, and with highly pathogenic avian influenza.
BTV3, a vector-borne disease, cannot be controlled by measures we are used to e.g. for HPAI or FMD. The Netherlands sees vaccination as only effective tool to control this disease and reduce the impact. With respect to HPAI the Netherlands would like to come to a more sustainable solution to combat the continuous threat of infection from wild bird populations.

Issues: For BTV-3 the main challenge was the availability of suitable vaccines. The role of the Dutch government in development, production and marketing of BT vaccines is limited. We had ample discussions with pharmaceutical companies about a quick production of vaccines. And they did: in April 2024 vaccines were brought on the market. Another challenge was to evaluate the vaccines quickly, with limited data about the efficacy.
For HPAI there are other challenges now we have promising vector vaccines. One vaccine has EU market access, but vaccination of poultry results in the implementation of in intensive surveillance programme, together with high costs and effective infrastructure. Another issue is the trade of products of vaccinated poultry within the EU and to third countries. So far, many third countries seem reluctant in importing products from vaccinated poultry. There is a long way to go.

Lessons learned: When the problem is large, we can manage the rapid production of vaccines against certain diseases. However, it is difficult to predict which disease will be next. BTV12 is in the Netherlands, but we do not know how this virus will spread this season. So far, we have not received messages that manufacturers are working on a vaccine. Another challenge are certain platform vaccines, that are yet not authorised in the EU. For HPAI the challenge is suitable vaccines that work against all variants of H5 (or H7), a cost-effective surveillance programme, and trade issues. We will continue promoting vaccination as one of the measures to reduce the number of infections and their impact.

Biosketch

Jean-Charles Cavitte

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European Commission, Directorate-General
Agriculture and Rural Development

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Jean-Charles Cavitte holds a doctorate in veterinary medicine from "École Nationale Vétérinaire d'Alfort" and a subsequent specialisation at the French national school of veterinary services. He is senior research policy officer at the European Commission, in Directorate-General for Agriculture and Rural Development (DG AGRI).
After having led the food safety department in the French regional veterinary service, Dr Cavitte joined the European Commission in 1994. He started as a veterinary inspector in the Food and Veterinary Office, where he led the BSE team until he moved to veterinary legislation in DG Health and Consumer Protection at the end of 1999. He was in particular in charge of the revision of the EU zoonoses legislation, i.e. the Directive on zoonosis monitoring and the Regulation on Salmonella control, as well as the EU reference laboratories on microbiological food safety.

At the end of 2005, he moved to DG Research and Innovation, where he was responsible for defining orientations and supervising EU funded research projects in the domain of animal production and food safety. Jean-Charles Cavitte joined DG Agriculture and Rural Development in May 2014, in the "Research and Innovation" Unit. He is in charge of policy development and research programming in the animal sector; from animal health, including zoonoses and AMR, and animal welfare, to animal breeding, feeding and husbandry, as well as livestock production systems. He is also working on strengthening the European Research Area and international cooperation in the domain and is the contact person for the Horizon Europe Partnership on Animal Health and Welfare.

Abstract

Jean-Charles Cavitte

Ten years of EU funded research on vaccine development

The EU has been funding research on vaccinology and veterinary vaccine development during successive Framework Programmes. Around 35 million euros under H2020 (2014-2020) and over 20 million euros so far under Horizon Europe (2021-2027) were committed in vaccine development and related activities (diagnostics, vaccination). The projects targeted mainly epizootic animal diseases that are regulated at EU level, where vaccination is often not the default control option. Endemic diseases, zoonotic or not, viral, bacterial or parasitic, were also targeted. In spite of those continuous efforts to finance vaccine development, there are challenges that require reflection: the need to measure the true impact of the EU funded research on veterinary vaccines once EU funding ends, the lack of flexible financing systems to address urgent research needs in the veterinary domain.

While overall progress has been made in funding of veterinary vaccine development through public and private sources, overcoming many hurdles impede delivering on its full potential. To name some: (a) the lack of funding capacity, in both the public or private sectors, and their limited interconnections (b) the diversity of animal species and pathogens, (c) the perceived lack of market for certain diseases, (d) the consequence of vaccination on trade in animals and products, (e) the specific constraints for veterinary vaccines, (f) the harsh competition in the private sector, (g) the potential duplication of research efforts in EU countries. Furthermore, there is a need to strengthen the prioritisation and coordination of research at both European and global levels.

Under Horizon Europe, a co-funded European partnership on animal health and welfare (EUPAHW) has been launched in 2024. With a planned total budget of 360 million euro for a period of 7 to 10 years, the EUPAHW includes among its objectives the development of veterinary vaccines, next to prevention, surveillance, detection and other measures to address animal infectious diseases. While this is not a public-private partnership, significant interaction with industry is expected. The activities of the EUPAHW may not aim at reaching the highest Technology Readiness Levels, though basic and applied research will certainly contribute to vaccine development, and it has initiated work on vaccine technology platforms. The partnership may have the capacity to react to urgent needs faster than the procedures in place for initiating projects under Horizon Europe. The potential international development of EUPAHW activities would need commitments from additional partners.

Abstract

Jean-Charles Cavitte

While not all hurdles to deliver on the full potential of public funding can be addressed through the EUPAHW, it should provide new opportunities and capacity building that classical collaborative projects are not able to cover. At a time where One Health is increasingly put forward, lessons for a more efficient enabling environment for veterinary vaccine development could certainly be learned from the medical domain.

Biosketch

Dr Ivo Claassen

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European Medicines Agency

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Ivo has over 35 years of experience in multiple roles in vaccine production, QC/QA, R&D and regulatory affairs, both for human and veterinary vaccines. He has worked internationally on capacity building for veterinary infectious disease management. A large part of his career he has worked on vaccines that were designed specifically to be used only during emergency situations. He joined the European Medicines Agency in 2018 as the head of the Veterinary Medicines Division where he worked with his team on the implementation of the Veterinary Medicines Regulation. Since 2021 he is the deputy Executive Director of EMA.

Abstract

Olivier Debaere

France experience with poultry HPAI vaccination

Since 2015, France has experienced 5 epizootic waves of HPAI, with a total of almost 3,000 infected farms, leading to the slaughter of over 40 million poultry.

This situation has become totally unbearable because of the risk to public health, the distress of farmers and the exhaustion of human and financial resources.
For these reasons, the option of a strategy of preventive vaccination of ducks was considered to slow the spread of the virus.

The first ducks were vaccinated on 1 October 2023. Vaccination is compulsory for all farms with more than 250 meat ducks. More than 61 million ducks were vaccinated against HPAI between 1 October 2023 and 30 September 2024. Two inactivated vaccines are used: the VOLVAC vaccine produced by Boerhinger Ingelheim and the RESPONS vaccine produced by CEVA. These DIVA vaccines are effective against the 2.3.4.4.b H5N1 clade.

In accordance with WOAH standards and EU regulation 2023/361, a system of active and passive surveillance of vaccinated birds has been put in place to verify the absence of viral circulation.

Given the success of the first campaign, with only 10 outbreaks of HPAI during the 2023/2024 season, the vaccination strategy has been be renewed since 1st October 2024.

Biosketch

Nancy De Briyne, DVM

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Mrs. Nancy De Briyne, DVM, EBVS® European Veterinary Specialist in Animal Welfare Science, Ethics and Law, Executive Director FVE. Nancy De Briyne studied veterinary medicine in Ghent (Belgium), graduating in 1996. After working as a veterinary practitioner in Belgium and the UK, she works since 2000 for the Federation of Veterinarians of Europe (FVE) being currently Executive Director of the FVE.

Her overall role within FVE is to follow the strategy, oversee operations, and ensure the organisation's goals and objectives are achieved. More specifically, she follows closely all dossiers in relation to veterinary medicines, AMR, animal health and welfare, and the status of the veterinary profession.

In respect to medicines, she published papers on antimicrobials, antibiotic sensitivity testing and adverse events of medicines. She has been a member of the Management Board of the European Medicines Agency representing the veterinary profession for 6 years [2016-2022].

She is also a diplomate of the European College of Animal Welfare and Behavioural medicine, subspecialty Animal Welfare Science, Ethics and Law, and is a member of the EU Platform on Animal Welfare.

Research profile: https://www.researchgate.net/profile/Nancy_De_Briyne

Biosketch

Sjaak de Wit
DVM, PhD, EVBS®

European Specialist in Poultry Veterinary Science

President of the World Veterinary Poultry Association

Sjaak gained his veterinary qualification at the University of Utrecht in 1989 and completed a PhD degree concerning diagnosis and transmission of infectious bronchitis virus, in 1997 at the University of Utrecht. He is senior researcher at Royal GD and professor integrated Poultry Health at the veterinary faculty of the University of Utrecht. In 2008 he was one of the founding officers of the European College of Poultry Veterinary Science. Since 2023, he is president of the World Veterinary Poultry Association.

He has been actively involved in applied and fundamental research related to the diagnosis and control of poultry diseases, especially viral diseases as infectious bronchitis virus, infectious bursal disease, Newcastle Disease, and Avian Influenza.

Biosketch

Frédéric Descamps

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Frédéric Descamps graduated as Veterinarian from the Faculty of Liège, Belgium, and obtained his PhD on the pathogenesis and immunology of Microsporum canis in cats in the same faculty. He has been working in the field of Veterinary Regulatory Affairs since 2003, first in the public sector where he has been acting as Senior Assessor at the Belgian Medicine Agency and as Belgian alternate CVMP member at the European Medicines Agency. Then he moved to the Veterinary pharmaceutical Industry in 2011. He is now Senior Director of Regulatory Affairs at Zoetis. He is also Chair of the Biological Working Party of AnimalHealthEurope. His primary responsibility is to develop new biological products (vaccines in particular) and maintain existing products on the market.

Biosketch

Olivier Espeisse

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Olivier Espeisse (DVM, Maisons-Alfort, and MBA, Bowling Green State University) practiced dairy veterinary medicine in Normandy before moving to the veterinary pharmaceutical industry, where he has been particularly involved in association work at global and European level. He is a member of the IABS VBC.

Biosketch

Miia Jakava-Viljanen

DVM, PhD, Specialist in Animal Disease
Chair, Veterinary Biologicals Committee
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Following positions at the Helsinki University in Finland in teaching microbiology, immunology and epidemiology, and research, as a veterinarian, Dr Miia Jakava-Viljanen joined the Finnish Food Authority as Head of Section involved in virology, epidemiology and veterinary vaccines, and batch release and testing of vaccines.

She subsequently moved into the policy area, assuming the post of Government Counsellor at the Ministry of Agriculture and Forestry of Finland worked with Animal Health and Welfare legislation, rabies, pet movement, bee health, animals used for scientific purposes (3Rs), EU co-financed programs, funding for research projects and collaboration with Russia.

Seconded to the European Commission, she was involved in the implementation of the EU legislation on Animal Health and participated to the work on EU climate change. She joined the European Medicines Agency in 2014 - 2019 as National Expert where she was responsible to provide consultation and expertise specifically in the area of veterinary biologicals, immunological medicines and emerging therapies, EU legislation and policy as scientific/content lead. Currently she is working at the Finnish Food Authority.

She is an expert of EDQM European Pharmacopoeia Group 15V (vaccines and sera) since 2002. She joined IABS in 2019 and is a member of the executive board and the Chair of the Veterinary Biologicals Committee. She is organizing IABS meetings focusing on the veterinary field.

Biosketch

Carmen Jungbäck, Dr

Board Member Vice-Chair
IABS-EU

Germany

Dr Carmen Jungbäck graduated from the Tierärztliche Hochschule, Hannover with a degree in Veterinary Medicine. In 1981, after a few years as an animal surgeon she joined the Paul-Ehrlich-Institut, (Federal Agency for Sera and Vaccines), Langen, Germany, where she was Head of the section Veterinary Virology 1 until retirement in 2016. The section's area of activities comprises vaccine licensing and testing, with special expertise in viral vaccines for poultry. In this context, the practical testing of vaccines during licensing and for official batch release is one of the major responsibilities.

She was also member of a number of advisory boards to the EDQM-OMCL Network, Ph.Eur Group 15V and CVMP-IWP and JEG3R at EMA dealing with IVMPs under various aspects.

At IABS she is member of the board and Chair of the Veterinary Biologicals Committee and Vice-President of IABS - EU. She is organizing IABS meetings focusing on the veterinary field. As member of IABS-EU she is involved in the IMI projects (ZAPI and Vac2Vac).

Biosketch

Gábor Kulcsár, DVM, PhD

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Gábor Kulcsár graduated at the University of Veterinary Medicine in Budapest in 1993. He specialized as a veterinary microbiologist and he earned his PhD from the same university.

He has been working on the field of authorization and control of veterinary immunologicals since 1994. He was appointed as the head of the Hungarian regulatory agency in 2008. Among other national and international memberships he is the Hungarian member of the CVMP at the European Medicines Agency and the chairperson of the Standing Committee on Prequalification of Vaccines against FAST diseases at the FAO EuFMD.

Biosketch

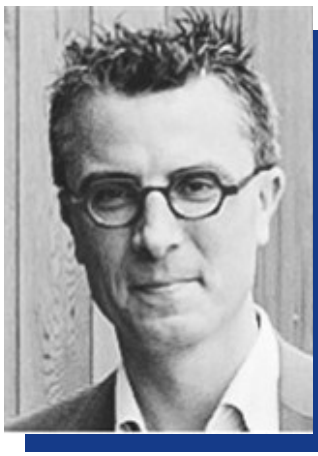
David Mackay

Advisor to the Board

UK

David qualified as a veterinary surgeon and worked in general veterinary practice before obtaining postgraduate degrees in immunology from the Universities of Birmingham and London. He then embarked on a research career in exotic viral diseases of livestock culminating as Head of the Pirbright Laboratory of the Institute for Animal Health.David subsequently moved into the regulatory area, assuming the posts of Head of Immunologicals and then Director of Licensing at the Veterinary Medicines Directorate in the UK before moving to the European Medicines Agency as Head of Veterinary Medicines. During his career he has published widely on epizootic diseases of livestock and on regulatory issues, particularly in relation to veterinary vaccines. David retired from the EMA in 2018 and now provides independent advice to governmental and non-governmental bodies in relation to regulation and use of veterinary medicines.

Biosketch



Dries Minne

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Dries graduated as a pharmacist at Ghent University and holds an additional degree of Master in Business Planning. He started working in the pharmaceutical company Pfizer as regulatory affairs officer for human medicinal products in 2003. In 2004 he made the shift to the Belgian Federal Agency on Medicines, where he started working as project manager for veterinary medicinal products. In 2010 Dries was appointed as the head of the veterinary division within the Federal Agency on Medicines and Health Products (FAMHP). In his role as Head of the veterinary division of the FAMHP, Dries was the Belgian delegate in the council working party on veterinary medicines, the Standing committee, the pharmaceutical committee, CMDv, QRD and NtA. In May 2022 Dries joined the European Commission as policy officer for veterinary medicinal products.

Abstract

Dries Minne

Ten years of EU funded research on vaccine development

The EU has been funding research on vaccinology and veterinary vaccine development during successive Framework Programmes. Around 35 million euros under H2020 (2014-2020) and over 20 million euros so far under Horizon Europe (2021-2027) were committed in vaccine development and related activities (diagnostics, vaccination). The projects targeted mainly epizootic animal diseases that are regulated at EU level, where vaccination is often not the default control option. Endemic diseases, zoonotic or not, viral, bacterial or parasitic, were also targeted. In spite of those continuous efforts to finance vaccine development, there are challenges that require reflection: the need to measure the true impact of the EU funded research on veterinary vaccines once EU funding ends, the lack of flexible financing systems to address urgent research needs in the veterinary domain.

While overall progress has been made in funding of veterinary vaccine development through public and private sources, overcoming many hurdles impede delivering on its full potential. To name some: (a) the lack of funding capacity, in both the public or private sectors, and their limited interconnections (b) the diversity of animal species and pathogens, (c) the perceived lack of market for certain diseases, (d) the consequence of vaccination on trade in animals and products, (e) the specific constraints for veterinary vaccines, (f) the harsh competition in the private sector, (g) the potential duplication of research efforts in EU countries. Furthermore, there is a need to strengthen the prioritisation and coordination of research at both European and global levels.

Under Horizon Europe, a co-funded European partnership on animal health and welfare (EUPAHW) has been launched in 2024. With a planned total budget of 360 million euro for a period of 7 to 10 years, the EUPAHW includes among its objectives the development of veterinary vaccines, next to prevention, surveillance, detection and other measures to address animal infectious diseases. While this is not a public-private partnership, significant interaction with industry is expected.

Abstract

Dries Minne

The activities of the EUPAHW may not aim at reaching the highest Technology Readiness Levels, though basic and applied research will certainly contribute to vaccine development, and it has initiated work on vaccine technology platforms. The partnership may have the capacity to react to urgent needs faster than the procedures in place for initiating projects under Horizon Europe. The potential international development of EUPAHW activities would need commitments from additional partners.

While not all hurdles to deliver on the full potential of public funding can be addressed through the EUPAHW, it should provide new opportunities and capacity building that classical collaborative projects are not able to cover. At a time where One Health is increasingly put forward, lessons for a more efficient enabling environment for veterinary vaccine development could certainly be learned from the medical domain.

Biosketch

Jacqueline Poot, DVM PhD

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Jacqueline graduated as a farm animal vet from Utrecht University and has worked in farm animal and companion animal practice.
Her PhD work was focused on Canine Leishmaniasis disease models and vaccination. She was a diplomate of the European college of Veterinary Parasitologists.

Jacqueline was a project leader in the biological R&D of a large pharmaceutical company for 12 years. Subsequently she joined the immunology department of a medical faculty as a lecturer and researcher before returning to the veterinary field by joining a large CRO in the mixed role of veterinarian/parasitologist.
In 2013 Jacqueline joined the veterinary department of the Dutch regulatory authority as an assessor. she is currently positioned at the CBG-MEB in the role of senior assessor and European representative.

Since 2015 Jacqueline is an active member of the CVMP Immunologicals Working Party. In 2017 she became a member of the CVMP Scientific Advice Working Party and was nominated alternate CVMP member. Since 2020 she is CVMP member for the Netherlands and in 2021 she was elected chair of the Novel Therapies & technologies Working Party.

Abstract

Jacqueline Poot

A regulatory perspective on authorisation under exceptional circumstances, the BTV-3/NET2023 case

Soon after the first BTV 3 cases appeared in the Netherlands in September 2024 it became clear that a vaccine was desperately needed in order to save the sheep population from being decimated by the BTV 3 outbreak and to prevent significant losses in cattle. The CBG-MEB veterinary unit was asked by the Dutch Ministry of Agriculture to evaluate BTV vaccines available outside the EU, but none were found suitable. In March and April 2024 data were provided by three manufacturers that had requested authorisation for use in accordance with Art.110(2) of the regulation 2019/6. The data were assessed within 2.5 to 5.5 weeks depending on the level of completeness of the dossier at the first submission. Generally this was achieved by using a 'rolling' submission. The reduced data requirements as identified in the IWP Guideline on authorization of IVMPs in exceptional circumstances were taken as the basis for the assessment and a pragmatic approach was taken. Where possible, details concerning the minimum data considered necessary will be highlighted. A pragmatic approach was also taken for the initial packaging and labelling in order to not delay the marketing process. Overall, this approach meant that vaccines were on the market in the Netherlands within 2 months from the first request for authorisation for use.

Biosketch

Francisco Javier Reviriego Gordejo, PhD

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Dr Francisco Javier REVIRIEGO GORDEJO obtained his PhD (1999) in Veterinary Epidemiology and his degree (1988) in Veterinary Science from the Universidad Complutense de Madrid. He holds a postgraduate diploma (2000) in Statistics and Design in Health Sciences from Universidad Autonoma de Barcelona.

He worked as Official vet for the Autonomous Region of Castilla y Leon (1990-2001) implementing eradication programmes, heading the Animal Health Laboratory of Avila and before worked as a veterinarian for pig farmers.

He joined the European Commission in 2001 as a Legislative Veterinary Officer. In 2005 was Head of Sector Epidemiology and Eradication, since 2008 to 2016 was as Head of the Sector Disease Control and Identification, later Adviser to the Director on Crisis management in Food, Animals and Plants and since2021 is Head of Unit for Animal Health in DG SANTE.

In addition to his work at DG SANTE, Dr Reviriego Gordejo participated in a number of World Organisation for Animal Health (WOAH) ad hoc groups.

Biosketch

Claude Saegerman

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DVM, MSc, PhD, Dipl. ECVPH, Claude Saegerman is a full professor in Epidemiology, Quantitative Risk Assessment and Biosecurity. He is director of the Research Unit Epidemiology and Risk Analysis applied to veterinary sciences in the Faculty of Veterinary Medicine, University of Liège, Belgium. He is member of several scientific committees, member of the Emerging Risks Exchange Network of EFSA, President of the veterinary section of the Royal Academy of Medicine of Belgium and elected member of the Council of the World Animal Biosecurity Association.

Abstract

Claude Saegerman

Drivers of emergence of infectious animal diseases: what are the challenges?

Background: During the past decade, livestock diseases have (re-)emerged in areas where they had been previously eradicated or never been recorded before (e.g. BTV, EHD, FMD). Livestock diseases spread irrespective of borders, and therefore, reliable methods are required to help decision-makers to identify potential threats and try stopping their (re-)emergence. How to anticipate these (re-)emergences? What are the challenges? Some options of responses are possible, e.g. multidisciplinary and evidence-based method for prioritizing livestock diseases of food-producing animals and zoonoses, multi-criteria decision analysis of drivers of emergence of infectious animal diseases, scenario analysis and preparedness, epidemiological surveillance, biosecurity to increase the resilience of farms and points of entry at country level, contingency plan, crash test, awareness, training and dissemination, etc. The focus of this presentation is about the drivers. A driver was defined as a factor that has the potential to directly or indirectly precipitate ("drive") or lead to the emergence or increasing incidence of infectious animal diseases.

Materials & methods: Ranking methods and multi-criteria decision analysis, in addition to clustering and sensitivity analyses, are cost-effective tools for such purpose and were applied to prioritize a list of selected diseases (N = 32 including 8 zoonoses) based on the opinion of 62 experts in accordance with 50 drivers-related criteria.

Results: Diseases appearing in the upper ranking were porcine epidemic diarrhoea, foot-and-mouth disease, low pathogenic avian influenza, African horse sickness and highly pathogenic avian influenza.

Abstract

Claude Saegerman

Conclusion and significance: As there is still limited scientific knowledge on the topic, expert elicitation of knowledge and multi-criteria decision analysis, in addition to clustering and sensitivity analyses, are very important to prioritize emerging infectious animal diseases including zoonoses based on their drivers. In addition, gap analysis permitted to identify the most important drivers that need more knowledge, information or surveillance. The follow up of the most important drivers could permit us to predict which emerging infectious diseases have more chance to appear, and by the way to be more prompt to anticipate its (re-)emergence and the response (e.g. vaccine development and/or its production in due time with sufficient quantity). The most important challenge should be the means to elicit independent and representative experts regularly in order to update information on drivers and also, to anticipate the response against the top of emerging animal diseases. The present methodology could be applied to other emerging animal diseases.

Biosketch

Dónal Sammin, Dr.

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Dónal Sammin is the Executive Secretary of the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) since 2023 and is based at FAO headquarters in Rome. Prior to joining EuFMD, Dónal spent most of his professional career working for the laboratory services of the Irish Government's Department of Agriculture, Food, and the Marine (DAFM) – in field and laboratory investigation of diseases of food-producing animals and in applied veterinary research. In 2015, he was appointed Head of DAFM Laboratories leading a team of 340 people, engaged in animal health, food safety and plant health related work.

Abstract

Dónal Sammin

What is happening outside the European Union?

The European Commission for the Control of Foot-and-Mouth Disease (EuFMD) was established under the auspices of the Food and Agricultural Organisation (FAO) in 1954 to promote national and international action for the prevention and control of FMD. Today EuFMD has 39 member nations, including the EU27 and its mandate has been extended to include FMD and similar transboundary animal diseases (FAST diseases[1]). Thirty-six members are FMD-free without vaccination whereas FMD is endemic in Türkiye, Israel and Georgia and these countries use vaccination on a routine basis to control the spread of the disease. Broadly speaking, the activities of EuFMD are aimed at ensuring the preparedness of member nations and reducing risk in neighbouring regions. Therefore, EuFMD works closely with non-member countries in North Africa, the Near East, and "the South-East European Neighbourhood (SEEN)" in capacity development, surveillance and risk information sharing.

EuFMD supports reference laboratories in undertaking virus surveillance in the European neighbourhood and in recent years, this has resulted in the identification of several new FMD viruses. Phyllogenetic analyses have shown that these new viral introductions reflect long-distance transmission from other regions, including South Asia, East Africa and West Africa.Of particular note amongst these introductions were two SAT-2 type viruses – a SAT2 topotype XIV virus that was introduced from East Africa into the near East in 2022 eventually spreading through Anatolia (Türkiye) in 2023 and a SAT2 topotype V virus introduced from West Africa into Algeria in late 2023.

In 2020, EuFMD was tasked by its member nations with addressing different aspects of vaccine security for member nations. A multi-stakeholder platform was convened to provide a forum where vaccine bank managers, vaccine manufacturers, regulators, and policy- and decision-makers could discuss challenges and potential solutions. A paper was published highlighting the implications of the Nagoya Protocol for the timely availability of vaccines against new and emerging FMD strains. User-friendly tools were developed in collaboration with The Pirbright Institute - to assess the supply and demand of vaccines (VADEMOS); to assist vaccine bank managers in selecting the most appropriate antigens (PRAGMATIST) and to make all of the data held by the global network of FMD reference laboratories readily available (Open FMD).

[1] FAST diseases = Lumpy Skin Disease, Sheep Pox and Goat Pox, Rift Valley Fever, Peste de Petits Ruminants

Abstract

Dónal Sammin

2/2

In addition, EuFMD developed a system for the prequalification of vaccines (PQv) following the same principles as those used by the World Health Organisation in the prequalification scheme they operate for human vaccines but adapted for the different infrastructure, legislation and resources available in the veterinary domain. The "proof of concept" phase of this project has been completed with the publication on the EuFMD webpages of a list of prequalified vaccines[i]. The listed vaccines have been shown to comply with minimum international standards as defined in the WOAH Terrestrial Manual based on independent expert evaluation of data provided by the manufacturers.This represents the first time that a system has been used to independently assure the quality of veterinary vaccines and to make the outcome publicly available. PQv is not a regulatory procedure but it can help national authorities as the public summary report may be useful in reaching a national decision on authorisation. Further developing the PQv concept and extending its scope to cover other transboundary animal diseases has the potential to provide the EU with a valuable source of information when preparing and responding to diseases for which effective and high-quality vaccines already exist in other regions of the world.

[1] FAO website: The PQv list. [1] FAST diseases = Lumpy Skin Disease, Sheep Pox and Goat Pox, Rift Valley Fever, Peste de Petits Ruminants (accessed 13/03/25).