Biologicals 93 (2026) 101873

Contents lists available at ScienceDirect

Biologicals

journal homepage: www.elsevier.com/locate/biologicals

Preparedness and response to emerging veterinary disease outbreaks – A meeting report

Francisco Reviriego-Gordejo [a], Dries Minne [b], Ivo Claassen [c], Jean-Charles Cavitte [d], Annemarie Bouma [e], Olivier Debaere [f], Max Bastian [g], Dónal Sammin [h], Ely Bénéré [i], Ron Bergevoet [j], Claude Saegerman [k], Jacqueline Poot [l], Olivier Espeisse [m], Jean-Christophe Audonnet [n], Sandra Manzanares-Laya [o], Frédéric Descamps [p,*]

[a] European Union Commission, Directorate-General for Health and Food Safety, Animal Health, Belgium
[b] European Union Commission, Directorate-General for Health and Food Safety, Veterinary Medicines, Belgium
[c] Head of Veterinary Medicines Division of the European Medicines Agency, the Netherlands
[d] European Union Commission, Directorate-General of Agriculture and Rural Development, Research and Innovation, Belgium
[e] Ministry of Agriculture, Fisheries, Food Security and Nature, the Netherlands
[f] Crisis Director, Ministry of Agriculture, France
[g] StIKo Vet, The Friedrich-Loeffler-Institut, Germany
[h] European Commission for the Control of Foot-and-Mouth Disease, Italy
[i] AnimalHealthEurope, Belgium
[j] Wageningen University & Research Centre, the Netherlands
[k] Research Unit of Epidemiology and Risk Analysis Applied to Veterinary Sciences (UREAR-ULiège), Fundamental and Applied Research for Animal and Health (FARAH) Center, Faculty of Veterinary Medicine, University of Liège, Sart-Tilman, Liège, Belgium
[l] Medicines Evaluation Board, the Netherlands
[m] Chairman of the International Alliance for Biological Standardization, France
[n] International Alliance for Biological Standardization, France
[o] P95 Clinical and Epidemiology Services, Leuven, Belgium
[p] Zoetis, Belgium

ARTICLE INFO

Keywords:
Emerging infectious diseases
Animal health
Preparedness
Vaccines
Regulation
One health

ABSTRACT

Emerging infectious diseases (EIDs) in animals are responsible for disruptive outbreaks in the agricultural sector. Animal health preparedness includes timely and effective vaccines, which face regulatory and economic constraints in the European Union (EU). The International Alliance for Biological Standardization hosted a meeting to address these challenges and promote discussion between different European stakeholders, with the aims of identifying current preparedness obstacles in the EU and sharing different experiences from Member States, while additionally sharing the veterinary vaccine industry perspective.

Preparedness must distinguish between expected events (usually slow-spreading diseases) and unexpected events (typically EIDs), for which the appropriate vaccination strategies remain uncertain. Key considerations include economic constraints, defining target diseases and species, and balancing the aim for ideal vaccines vs timely efficacious vaccines. Ultimately, decision-makers must address whether to react to outbreaks or proactively develop solutions in advance. Practical recommendations based on the derived discussion included the development of a collaborative framework for decision-making between different stakeholders, dedicated funds for EIDs, communication strategies with the general public, addressing logistical issues, and implementing regulatory advances to respond to emergency situations, applying pragmatic and risk-balanced approaches.

* Corresponding author.
E-mail addresses: REVIRIEGO-GORDEJO@ec.europa.eu (F. Reviriego-Gordejo), Dries.MINNE@ec.europa.eu (D. Minne), ivo.claassen@ema.europa.eu (I. Claassen), Jean-Charles.Cavitte@ec.europa.eu (J.-C. Cavitte), a.bouma@minlnv.nl (A. Bouma), olivier.debaere@agriculture.gouv.fr (O. Debaere), Max.Bastian@fli.de (M. Bastian), Donal.Sammin@fao.org (D. Sammin), ely.benere@zoetis.com (E. Bénéré), ron.bergevoet@wur.nl (R. Bergevoet), claude.saegerman@uliege.be (C. Saegerman), j.poot@cbg-meb.nl (J. Poot), olivier.espeisse@iabs.org (O. Espeisse), jean-christophe.audonnet@iabs.org (J.-C. Audonnet), sandra.manzanareslaya@p-95.com (S. Manzanares-Laya), frederic.descamps@zoetis.com (F. Descamps).

https://doi.org/10.1016/j.biologicals.2026.101873
Received 24 December 2025; Accepted 7 January 2026
Available online 13 January 2026

Abbreviations

AHS	African horse sickness
AI	Avian influenza
AMR	Antimicrobial resistance
ASF	African swine fever
BARDA	Biomedical Advanced Research and Development Authority
BTV	Bluetongue virus
CEPI	Coalition for Epidemic Preparedness Innovations
CSF	Classical swine fever
DR	Delegated regulations
EID	Emerging infectious diseases
EMA	European Medicines Agency
ERA	European Research Area
EU	European Union
EUPAHW	European Partnership on Animal Health & Welfare
FMD	Foot-and-mouth disease
GMO	Genetically modified organisms
GMP	Good Manufacturing Practice
HPAI	Highly pathogenic avian influenza
IABS	International Alliance for Biological Standardization
ICRAD	International Coordination of Research on infectious Animal Diseases
IR	Implementing regulations
MA	Marketing authorisations
MS	Member States
MSt	Multi-Strain
MUMS	Minor Use, Minor Species
NIVI	Nordisk Foundation Initiative for Vaccines and Immunity
R&D	Research and development
VAMF	Vaccine antigen master file
VMP	Veterinary medicinal products
VPTMF	Vaccine platform technology master file
WOAH	World Organisation for Animal Health

1. Introduction

Emerging infectious diseases (EIDs) 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 (HPAI), bluetongue virus (BTV), and epizootic haemorrhagic disease have had a profound effect on farmers and the food supply chain [1–5]. The trend continues with other emerging (or re-emerging) diseases like *peste des petits ruminants* and sheep and goat pox [6,7]. Proven strategies exist to help control the impact of emerging and re-EIDs, including surveillance, epidemiological modelling, animal movement control, biosecurity, and vaccination [8,9].

Appropriate vaccines are not always readily available, however, especially in emergency situations. Recognising 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, the International Alliance for Biological Standardization (IABS) organised a meeting on 25 and March 26, 2025 in Brussels, Belgium, with expert speakers from different EU stakeholders. The objectives of the meeting were to review the current legal, regulatory, epidemiological, and economic landscape in relation to preparedness and response to emerging veterinary disease outbreaks in the EU, to analyse the issues preventing (or delaying) access, availability, or use of relevant vaccines, to examine regulatory procedures, economic incentives and disincentives, surveillance policies, and legal and policy framework, with careful attention to barriers that must be addressed to expedite vaccine availability and improved EID control.

2. Opening remarks and survey results

Olivier Espeisse (Chairman of IABS-EU) opened the meeting with a warm welcome and presented the results of the survey that had been previously sent to all participants. This survey aimed to provide a sense of the expectations about the meeting and the conversation that would take place. The majority of respondents worked in the private or the academic sector (32 % and 28 %) or in non-governmental organisations (28 %), including IABS members, while a minority worked for governmental organisations (12 %). Most respondents expected to contribute to the recommendations and learn during the meeting. Many had a positive opinion on the veterinary medicinal products legislation (Regulation EU 2019/6), with only one negative opinion. Economic constraints were identified as the main challenge for vaccine development, along with legal and regulatory obstacles. The risk for investing in EID prevention is perceived as too high and the cost-benefit balance of investing is not favourable. Thus, it is easier to seek a temporary authorisation for use than investing in a permanent Marketing Authorisation (MA) [10]. Difficulty of access to the right challenge models for the disease of interest, limited availability of strains from outside the EU, and very complex and demanding evaluation processes were also mentioned. Survey participants shared other concerns, such as genetically modified organisms (GMOs) regulation, Good Manufacturing Practice (GMP) certification for facilities outside the EU, and lack of regulatory consistency among Member States (MSs). Several short- and long-term adaptations were suggested in the survey. Evaluation requirements include the adaptation of GMP and GMO legislation, reduced data requirements for inactivated vaccines that have a different safety profile, encouragement of autogenous vaccines in some situations, the prequalification concept that the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) has been practicing for foot-and-mouth disease (FMD), assessing EIDs vaccine efficacy in the post-marketing phase, vaccine banks, and improving the platform technology. Finally, improvement of economic incentives in zoonotic diseases prevention is required, as vaccinating animals protects public health.

3. Session I – review of current status and obstacles

3.1. Animal health legislation – vaccination

Francisco Reviriego-Gordejo (EU Commission, Directorate-General for Health and Food Safety, Animal Health) presented the EU's regulatory framework on vaccination in the context of animal health, primarily guided by Regulation (EU) 2016/429. This regulation addresses preparedness and response to both listed and emerging diseases within a dynamic epidemiological environment. The regulation targets 63 diseases considered of particular concern to the EU (Article 5). These are subject to EU-level intervention through disease preparedness, control, eradication, surveillance, and notification measures (Article 9).

Diseases and their respective animal species are classified into five categories (A–E) under Commission Implementing Regulation (EU) 2018/1882. Category A diseases are those for which the EU foresees immediate eradication through vaccination and are not normally present in the EU. Category B diseases are those for which eradication is compulsory throughout the EU, while it is optional for category C diseases. Category D groups those diseases that require specific measures to prevent from spreading through movements certifications between MSs or at entry into the EU. Finally, category E diseases require notification and surveillance within the EU.

The EU animal health legislation has evolved into delegated (DR) and implementing regulations (IR). The DR (EU) 2023/361 foresees dedicated measures for vaccination against category A diseases and two of the diseases in category B. This regulation is very explicit and detailed in terms of harmonised conditions, surveillance, recovery, and restrictions. The DR (EU) 2020/689 provides regulation on the eradication programmes for categories B and C diseases, including the approval of programmes and the granting of disease-free status. As regards vaccination, this regulation for categories B and C is more flexible than the regulation for category A. Finally, Articles 48–52 of the Regulation (EU) 2016/429 (only for category A diseases), Commission DR (EU) 2022/139, and Commission IR (EU) 2022/140 are the instruments to regulate vaccine banks, including their financial support. Vaccination in the EU is characterised by a large degree of freedom provided that certain preconditions are applied, such as designing sound strategies and applying risk-mitigation measures. Disease-specific conditions include carefully applying specific rules, such as implementing post-vaccination surveillance systems, applying movement prohibitions for animals and products in the vaccination zone, and recovering the previous animal health status. The allowed vaccination strategies can be divided into emergency (addressing an imminent risk) and preventive vaccination (addressing a non-imminent risk). Emergency vaccination can also be classified as suppressive, in which vaccinated animals from affected establishments will be killed, or protective, which aims to protect the animals surviving the epidemic. The trade of these animals and commodities can be done under certain risk-mitigation provisions to facilitate and enable a swift and safe trade, under certification and traceability.

Regarding decision-making, the MSs assess the disease risk (Annex II, DR 2023/361) and decide on vaccination strategies. A preliminary vaccination plan (Annex III) must be sent to other MSs and the Commission at least two days before starting vaccination. The official plan is submitted within two weeks of initiation. The Commission may adopt complementary measures (Article 71, Regulation 2016/429). MSs must implement disease-specific surveillance and risk mitigation (Annex XIII) and submit regular reports (Annexes V and VI).

The Commission manages EU vaccine banks (now known as *stockpiling*) under Article 48, ensuring adequate stock, biosecurity, and timely replacements (DR 2022/139). Vaccine banks include antigens and vaccines for FMD, classical swine fever (CSF), lumpy skin disease, *peste des petits ruminants*, and sheep and goat pox (IR 2022/140, Annex I), represented in Table 1. Access is prioritised for MSs and, secondarily, for third countries, based on urgency, national bank availability, and the presence of EU vaccination requirements. Product types, quantities, storage, and distribution conditions are regulated (Article 50), and details on vaccine stocks are classified (Article 51). National banks must meet EU standards and report updates to the Commission (Article 52), although some information (e.g., vaccine types) is publicly available.

In conclusion, the EU Animal Health Law offers a harmonised but adaptable framework for vaccination of certain diseases. It positions vaccination as a complementary tool within broader disease control efforts involving biosecurity, surveillance, and trade safeguards. The legislation is generally aligned with the World Organisation for Animal Health (WOAH) standards. Vaccine banks in the EU remain a critical investment in disease preparedness, though challenges such as trade impacts, stakeholder alignment, and resource needs persist.

3.2. Veterinary medicinal product legislation

Dries Minne (EU Commission, Directorate-General for Health and Food Safety, Veterinary Medicines) outlined the Veterinary Medicinal Products (VMP) legislation, specifically Regulation (EU) 2019/6, and its "toolbox" to address EIDs. One primary tool is the cascade, outlined in Articles 112–114, which allows veterinarians to use medicinal products outside the terms of their MA. This cascade is more flexible than previous legislation. For instance, in the first step of the cascade, veterinarians may now choose between the use of VMPs authorised in their own country for different species or indications, or the use of VMPs authorised in other MSs. Additional examples of this flexibility are evident in the third step, where products for human use and authorised in any EU MS may be used, and in the fourth step, where VMPs authorised in third countries for the same animal species and same indication can be used. However, the use of VMPs authorised in third countries is limited to non-immunological VMPs to avoid risks such as the potential introduction of new infectious agents in the EU. For food-producing animals, only substances allowed in accordance with Regulation (EC) 470/2009 may be used. Regarding autogenous vaccines, Article 2(3) defines them as useable within an epidemiologically linked unit, compared to the previous restriction to the same holding. Despite this broader scope, Article 94 requires autogenous vaccines to be manufactured according to GMP. Currently these GMP rules for autogenous vaccines are not harmonised. However, the Commission is developing an Implementing Regulation on harmonised GMP for autogenous vaccines. Also, Article 4 of the old directive allowed MSs to use non-inactivated immunologicals, which is no longer permitted.

Article 110(2) provides the possibility for MSs to allow the use of immunological VMPs not authorised in the EU during outbreaks of listed diseases (Article 5, Animal Health Law) or EIDs (Article 6), provided no EU-authorised VMPs are available. A recent example is related to BTV-3 prevention by vaccination, where MSs opted to authorise vaccines under development by European companies instead of using an existing South African vaccine. Article 110(3) further allows MSs to use previously authorised but currently unavailable immunological VMPs on a case-by-case basis for diseases present in the EU but not listed under Articles 5 or 6. Additionally, Article 116 provides the possibility for competent authorities to allow the use of VMPs authorised in another MS. On MAs, Article 25 permits MSs to grant MAs without full documentation on quality, efficacy, and safety in exceptional cases where immediate availability outweighs risks. These authorisations are valid for one year and must be reassessed annually. Article 23 allows MAs for limited markets with incomplete efficacy or safety data (although full quality data is required), which are valid for five years. A limited market may apply to rare diseases, diseases occurring in geographically restricted

Table 1
Biological products to be included in the European Union antigen, vaccine, and diagnostic reagent banks.

Name of category A disease	Biological product	Type and/or strain of biological product	Number of doses	Validity period of biological product
Foot-and-mouth disease	antigen	inactivated various strains representing all seven serotypes: O, A, Asia 1, C, SAT1, SAT2, SAT3	at least 1 000 000 and up to 5 000 000 for each selected antigen, depending on the priority	at least 60 months
Classical swine fever	vaccine	live attenuated	at least 1 000 000	at least 24 months
Infection with lumpy skin disease virus	vaccine	live attenuated or inactivated	at least 250 000	at least 20 months
Infection with *peste des petits ruminants* virus	vaccine	live attenuated or inactivated	at least 250 000	at least 20 months
Sheep pox and goat pox	vaccine	live attenuated or inactivated	at least 250 000	at least 20 months

diseases, or VMPs for minor species.

Standard MAs include provisions such as the Vaccine Antigen Master File (VAMF), a standalone dossier containing all quality data on the active substance. Additionally, the Vaccine Platform Technology Master File (VPTMF) groups common components, enabling faster development and authorisation of vaccines using a shared platform, especially valuable in EID situations. Certificates for both master files can be issued as part of a new MA application or as separate procedures. Lastly, data protection provisions are designed to encourage innovation. The standard protection period remains 10 years for a VMP authorised for one major specie. For VMPs authorised for a minor specie, data is protected for 14 years. An additional protection period of 1 year is granted for each additional major species and 4 years for each additional minor species. The total data protection is limited to 18 years.

3.3. Current regulatory framework for emergency preparedness

Ivo Claassen (Head of Veterinary Medicines Division of the European Medicines Agency) discussed the regulatory framework for responding to emergency animal disease outbreaks. The importance of emerging and re-emerging animal diseases is growing due to their serious impact on animal and human health, risk of zoonotic spillover, animal welfare, and economic consequences such as disruptions to food supply and trade. Ensuring the timely availability of safe, effective vaccines is essential in line with the One Health approach [11].

The European Medicines Agency (EMA) supports EID control by monitoring disease trends both in the EU and globally, and by engaging early with vaccine developers when outbreaks threaten. The agency works with the European Commission, European Food Safety Authority, and WOAH, and the response framework relies on Regulation (EU) 2019/6, which includes tools like MAs under exceptional circumstances, accelerated assessments, and Multi-Strain (MSt) dossier updates to include new strains over time. MAs applicants and stakeholders can interact with EMA through various channels such as *AskEMA* for early queries, the Innovation Task Force for development-stage guidance, scientific advice for later development, pre-submission meetings, and procedural or technical support via the EMA website. Small and medium-sized enterprises also have a dedicated office. MAs under exceptional circumstances may be granted when the benefits of immediate vaccine availability outweigh the risks posed by incomplete efficacy and safety data [12]. Eligibility can be assessed nationally or centrally, often allowing accelerated review. Past examples include three MAs under exceptional circumstances for avian influenza vaccines (2006–2008) and 11 for BTV vaccines (2008–2010), with approval times ranging from five to 11 months. More recent cases include vaccines for HPAI, porcine teschovirus (PTV3), and epizootic haemorrhagic disease, with the authorisation process taking between three and 24 months. In four of five recent procedures, the average time from validation to positive opinion was about 100 days. Previously discussed tools like the VAMF and VPTMF also offer fast and predictable responses [13–16]. Additional tools include MSt dossiers and novel therapies. MSt dossiers allow for a single MA application to include multiple antigens or strains, ideal for inactivated vaccines targeting highly variable pathogens that require frequent updates based on field conditions [17].

Regarding challenges in vaccine availability for EIDs, technical or scientific, regulatory, and economic are the main categories. Technical hurdles include pathogen complexity (e.g., African swine fever [ASF] virus), the need for broad protection across strains, access to high-containment labs (e.g., for FMD and HPAI vaccines), and the capacity to quickly scale up production. Regulatory challenges involve meeting authorisation requirements, maintaining relevant strains, updating strains in response to evolving outbreaks, and managing regulatory uncertainty. Ultimately, economic challenges include uncertain market returns, limited financial incentives, and the high cost of maintaining vaccine stockpiles.

In the future, innovations in veterinary vaccinology may include new vaccine platforms based on DNA, RNA, and vector-based prototypes, with a similar approach to the Coalition for Epidemic Preparedness Innovations (CEPI) model [18]. Finally, future developments also point to novel delivery systems like nanoparticles, new adjuvants, immunomodulators, and vaccines for parasitic diseases.

3.4. Ten years of EU funding of research on veterinary vaccine development

Jean-Charles Cavitte (EU Commission, Directorate-General of Agriculture and Rural Development, Research and Innovation) presented the EU's efforts and challenges in funding applied research on veterinary vaccines over the past decade. The principle that prevention is better (and potentially cheaper) than cure underpins this work. Controlling certain infectious diseases like ASF, Avian Influenza (AI), and vector-borne diseases is challenging without vaccination, as mass culling raises societal concerns. Vaccines support livestock farming, food supply, public health, and antimicrobial resistance (AMR) control [19,20]. However, despite their benefits, veterinary vaccines face several challenges. For instance, funding in both public and private sectors is limited (size of the animal health market is estimated to be 10–20 times smaller than the human one) [21–26] and the market for vaccines against regulated diseases is perceived as lacking. Other challenges include the specific logistical constraints (e.g., group vaccination, cost per unit), trade-related impacts of vaccination, and duplication of research across countries.

Past EU-funded collaborations have produced valuable outcomes. Under the Seventh Framework Programme (FP7), projects like CSFV_GoDIVA and PARAVAC led to the development of Suvaxyn® CSF Marker (a live marker vaccine for CSF) and Barbervax® (a vaccine against *Haemonchus contortus* in sheep, not available in the EU). Between 2014 and 2020, approximately €35 million was invested under Horizon 2020's Societal Challenge 2, focusing on agriculture, food, and the bioeconomy. The SAPHIR project delivered promising vaccine candidates for *Mycoplasma hyopneumoniae*, Bovine Respiratory Syncytial Virus, and Porcine Reproductive and Respiratory Syndrome Virus, as well as improved adjuvants [27]. Other projects launched during this period include PARAGONE (vaccines for animal parasites), PIGSs (Programme for Innovative Global Prevention of *Streptococcus suis*), DEFEND (Addressing the dual emerging threats of ASF and Lumpy Skin Disease in Europe), and VACDIVA (A safe Differentiating Infected from Vaccinated Animals vaccine for ASF control and eradication) [27–31]. These projects included active involvement from the pharmaceutical industry. The ICRAD – ERA NETwork funded 33 transnational small- and medium-sized projects [32]. Three focused on vaccine development or related technologies: Plant4Nemavax (plant-based nematode vaccines), NEOVACC (vaccine immunity in neonatal livestock), and NucNanoFish (nano-vaccines for fish).

Horizon Europe, the current research framework running from 2021 to 2027, has already committed over €20 million to vaccine research. Four key projects include REPRODIVAC (next-gen vaccines and diagnostics for livestock reproductive diseases) [33], SPIDVAC (vaccines and diagnostics for African horse sickness [AHS], *peste des petits ruminants*, and FMD) [34], VAX4ASF (ASF vaccine technologies) [35], and ASFaVIP (evaluating live attenuated ASF vaccines) [36]. Again, the pharmaceutical industry is closely involved. Additionally, the European Partnership on Animal Health & Welfare (EUPAHW), a Horizon Europe initiative, supports research and innovation across Europe [37,38]. This co-funded partnership, with a projected €360 million budget (50 % EU-funded), involves the pharmaceutical and diagnostic industries in its stakeholder committee and industry is expected to take part in certain EUPAHW projects selected through transnational joint calls. Areas of priority and their corresponding operational objectives and joint internal projects are represented in Table 2 and Fig. 1.

Despite these investments, several challenges hinder the effectiveness of EU-funded vaccine research. These include the lack of a

Table 2
Operational Objectives set by the European Partnership on Animal Health and Welfare according to priority area.

Priority area	Operational objectives
Surveillance/monitoring systems and risk assessment for animal health and welfare	**OO1.** Contribute to design and harmonise surveillance and monitoring systems for animal health and welfare. **OO2.** Contribute to adapt risk assessment and alert communication to the new needs in animal health and welfare.
Procedures, methodologies and tools to analyse animal health and welfare	**OO3.** To develop diagnostic procedures, methodologies and tools to support the surveillance of animal health. **OO4.** To develop procedures, methodologies and tools to support the monitoring of animal welfare.
Management and husbandry guidelines on farm including aquaculture, during transport and at slaughter	**OO5.** To develop guidelines and preventive tools to fight against animal infectious diseases on farm and during transport. **OO6.** To develop guidelines and prototype solutions that advance animal welfare on farm, during transport and at the end of life.
Treatments and vaccines	**OO7.** To develop new interventions and treatments, or improve existing ones, against specific priority animal infectious disease. **OO8.** To develop new vaccines or improve existing vaccines, including adjuvants and immune-modulators.
Integrated approach, including socioeconomic aspects of animal health and welfare	**OO9.** To develop an integrated approach on animal health and welfare including socioeconomic aspects.

Abbreviations: OO, operational objective.

monitoring system for tracking project outcomes, slow funding timelines, insufficient urgency mechanisms, limited resources for animal health research, fragmented public–private collaboration, and uncertainty around industry engagement. The example of CEPI in human health may serve as an example of possible ways to better support vaccine development for veterinary use.

3.5. Experience of Member States

The meeting continued with a discussion of the complexities and challenges surrounding vaccination campaigns against avian and other animal diseases in Europe, focusing primarily on the Netherlands, France, and Germany.

3.5.1. Experiences in the Netherlands with vaccination and emergency preparedness

Annemarie Bouma (Ministry of Agriculture, Fisheries, Food Security and Nature, LVVN, the Netherlands) presented the Dutch experience with vaccines and emergency preparedness. In the Netherlands, a BTV-3 incursion occurred in September 2023, resulting in thousands of infected herds. In 2024 also, and a few BTV-12 infections were detected. BTV is not a Category A disease, so, there is less involvement of the government. Nevertheless, the Ministry of LVVN was in close contact with vaccine manufacturers and the sectors (sheep and cattle farmers). Using Articles 25 and 110 of Regulation 2019/6, vaccines against BTV-3 became available for the 2024 season. However, the decision to vaccinate was left to the farmer sectors.

In 2022 the Netherlands was confronted with a high number of infections with HPAI H5. The outbreaks were controlled according to the compulsory EU measures, and some additional national measures. To reduce the number of outbreaks in the more distant future, a step-by-step approach was chosen to come to a large-scale vaccination programme. One of the steps was a pilot with vaccinated layer poultry against AI.

While authorities emphasised the importance of preparation, surveillance, and infrastructure, the disease or diseases they need to be prepared for is uncertain. Good collaboration with all stakeholders, including pharmaceutical companies is necessary, because to protect animals, vaccines will need to be developed. Because of competition, pharmaceutical industry cannot always be transparent, but some information on the process and timelines would be helpful.

3.5.2. Best practices in France experience with poultry vaccination, challenges and opportunities

Olivier Debaere (Crisis Director – Ministry of Agriculture, France) presented the French experience with poultry vaccination. In October 2023, France pioneered a large-scale vaccination campaign against

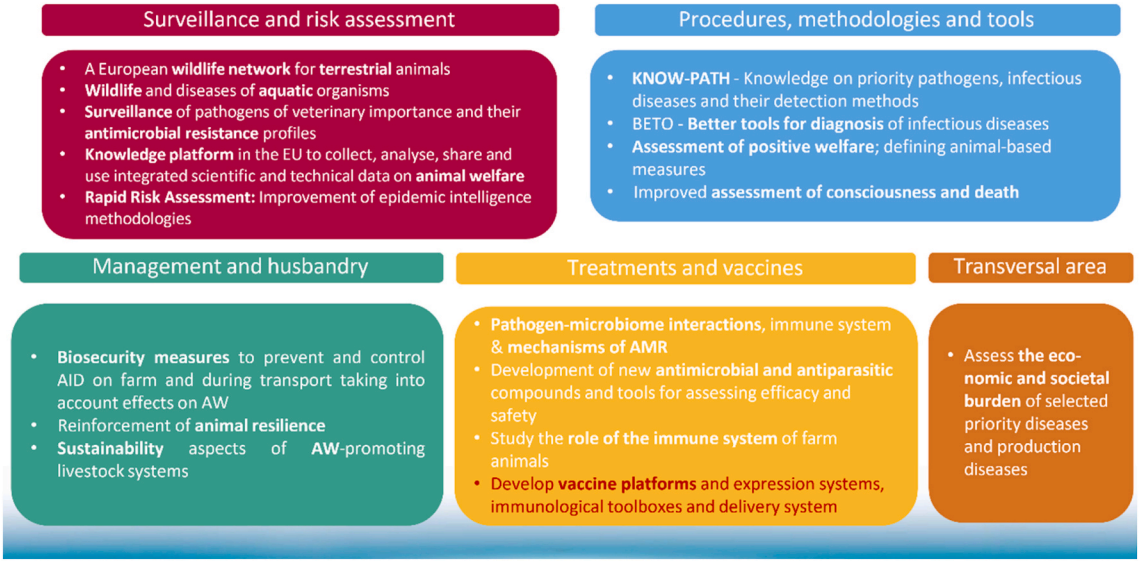

Fig. 1. Joint internal projects covering the Operational Objectives of the Strategic Research and Innovation Agenda of the European Partnership on Animal Health and Welfare.
Source: Jean-Charles Cavitte. 10 years of EU funding of research on veterinary vaccine development. IABS-EU Meeting on Preparedness and Response to Emerging Veterinary Disease Outbreaks Brussels, 25–26 March 2025

HPAI, vaccinating over 60 million ducks annually with two authorised vaccines. The decision followed severe outbreaks that affected thousands of farms and cost over €1.6 billion in compensation, leading to zoonotic risks, distress among breeders, societal disapproval of the mass killings, and an excessive burden on public finances. The French strategy emphasised public communication, legal and financial frameworks, international diplomacy to mitigate trade barriers, and thorough surveillance [39]. The first campaign significantly reduced the occurrence of outbreaks, prompting continued vaccination efforts with increasing financial contributions from farmers, up to 30 %. The expected number of outbreaks in France in 2023–2024 was estimated at 487 (95 % prediction interval (PI): 273–701), significantly higher than the observed number (n = 10), indicating a 95.9 % reduction attributable to vaccination [40]. In the second year of the campaign, from October 2024 to February 24, 2025, only 19 outbreaks were observed, suggesting continued success of vaccination.

3.5.3. *Make them available – the (bumpy) road to the BTV-3-vaccine*

Max Bastian (StIKo Vet, The Friedrich-Loeffler-Institut, Germany) described the different challenges Germany experienced with a sudden outbreak of BTV serotype 3 (BTV3) which started in the Netherlands in September of 2023 and reached Germany in October. Existing vaccines in Germany only targeted serotypes 1, 4, and 8, and no approved BTV3 vaccine was available in Europe. South African vaccines were either live (unsuitable) or not fully authorised, and efforts to authorise a new vaccine before the mid-year midge season faced bureaucratic delays [41]. National emergency approval, used successfully in 2008 for BTV8 [42], was initially dismissed due to legal and financial concerns.

Without available effective vaccines in Europe and facing regulatory delays and as a last resort, German authorities attempted to use an autogenous vaccine before the start of the midges season. Initially promising, the campaign was halted when live virus was detected in the vaccine. It caused illness (13 %) and deaths (0.9 %) in sheep and cattle and the vaccine was recalled after one week of delivery. Due to the prompt reaction of the manufacturer and the authorities the overall damage remained manageable. The situation highlighted regulatory hurdles, limited flexibility in vaccine approval processes, and the risks of emergency solutions. Eventually, authorised BTV3 vaccines became available under national approval. Unfortunately, when the vaccines finally became available the time window was too short before the start of the midges season to build up a reliable herd immunity. So, at least in the western part of Germany, BTV-3 caused a lot of problems in the dairy and beef industry and had devastating effects in sheep.

3.5.4. *What is happening outside the EU?*

Dónal Sammin (European Commission for the Control of Foot-and-Mouth Disease; EuFMD) explained that EuFMD has had a long history of preventing and controlling FMD in Europe, beginning in 1954 [43]. While its mandate has since expanded to include four additional animal diseases, FMD remains its core focus. The EuFMD now includes 39 member countries and supports emergency preparedness and risk reduction in regions neighbouring Europe through training, surveillance, and collaboration. Coordinated surveillance efforts exist in high-risk areas like the Thrace region between Bulgaria, Greece and Turkey, and engagement with 20 neighbouring countries in North Africa, the Near East, and the “South-East European Neighbourhood”, where FMD is endemic but there is periodic introduction of new viruses. EuFMD offers technical and laboratory support, facilitates the sharing of risk information, and helps countries manage outbreaks by enabling faster detection and response, including vaccine matching.

A global network of FMD reference laboratories provides global surveillance for FMD viruses, sharing genome sequencing data to track virus strains and vaccine matching data to inform vaccine decisions [44,45]. A SAT 2 virus was identified in Algeria in late 2023 —the closest match to this was a virus isolated in West Africa in 1991— illustrating that there are still significant gaps in our knowledge of circulating viruses. New incursions and long-distance virus movements underscore the need for robust surveillance and preparedness. In response to these risks, EuFMD has focused on vaccine security, ensuring the timely, sustained and uninterrupted availability of high-quality, effective vaccines. This led to the development of several decision-making tools, including those that support vaccine selection (PRAGMATIST) and stockpile planning (VADEMOS), while addressing challenges associated with how the Nagoya Protocol is being implemented.

A significant initiative by EuFMD, has been the development of a scheme for the Prequalification of Vaccines (PQv), modelled on a WHO/UNICEF scheme, and aimed at independently verifying that FMD vaccines comply with WOAH standards. This system supports regulators, vaccine purchasers, and producers, especially in low- and middle-income countries. After completion of a successful proof-of-concept stage, EuFMD has published an initial list of prequalified vaccines. EuFMD is now seeking funding and global or regional collaborating partners to progress to a second stage of this scheme. Such systems are key to Europe's preparedness and ability to respond quickly to EID threats.

3.5.5. *Perspective from the veterinary vaccine industry*

Ely Bénéré (AnimalHealthEurope, Belgium) discussed EIDs preparedness from the point of view of the pharmaceutical industry. The ongoing and increasing risk of EIDs, such as ASFV, BTV, HPAI, FMD, requires a rapid response, with a vital role for vaccination in prevention. Yet, timely access to authorised vaccines in Europe remains challenging. The example of the BTV3 outbreak highlights both progress and hurdles—vaccines were developed quickly, but only available in a limited scope under emergency provisions. An effective outbreak response is based on four pillars: rapid decision-making, fast vaccine development, expedited regulatory pathways, and flexible manufacturing capacity.

The pharmaceutical industry faces several constraints, including high costs, regulatory complexity, and uncertain returns on investment, which make proactive vaccine development for all potential threats unrealistic. Rapid action also requires early clarity from governments on vaccine strategies and use, and better alignment on registration pathways. Developing vaccines, even with reduced data requirements, is a complex and time-consuming process, requiring multiple steps, from isolating pathogens to clinical testing. In this context, advanced technologies offer speed but also come with cost and practical limitations.

Manufacturing EID vaccines poses its own challenges, including the need for high biosafety level facilities, long permit timelines, and limited flexibility due to shared production lines. Using contract manufacturers or non-EU sites adds cost and complexity due to import regulations. The regulatory pathways, while helpful, are seen as insufficient for true EID preparedness. A detailed analysis of provisions like exceptional circumstances, limited market, MSt vaccines, and vaccine platform technology, reveals that each has pros and cons, often falling short in terms of speed, predictability, or applicability to emergencies.

The pharmaceutical industry views an EU-wide MA as the ultimate goal, but the path is complicated and burdensome, involving overlapping processes and high costs, especially in times of non-use. While some fee incentives exist, they do not fully apply to emergency vaccines due to regulatory limitations. As EIDs ignore borders, vaccine development must be prioritised, with better regulatory tools and support. Currently, the industry bears most of the risk and cost, a model that is unsustainable going forward.

The session concluded with a call for stronger collaboration among EU countries, recognising that veterinary authorities often face similar issues in isolation, and that future disease preparedness requires coordinated, transparent, and timely responses, including readiness for situations where industry is not willing, not able or not interested to produce an emergency vaccine.

4. Session II – panel discussion

Jean-Christophe Audonnet (IABS, France) moderated this panel discussion, which was composed of the following panel members: **Francisco Reviriego-Gordejo** (EU Commission, Directorate-General for Health and Food Safety, Animal Health, Belgium); **Dries Minne** (EU Commission, Directorate-General for Health and Food Safety, Veterinary Medicines, Belgium); **Ivo Claassen** (Head of Veterinary Medicines Division of the European Medicines Agency, The Netherlands); **Jean-Charles Cavitte** (EU Commission, Directorate-General of Agriculture and Rural Development, Research and Innovation, Belgium); **Annemarie Bouma** (Ministry of Agriculture, Nature and Food Quality, The Netherlands); **Olivier Debaere** (Ministry of Agriculture, France); **Nancy De Briyne** (Federation of Veterinarians of Europe, Belgium); **Ely Bénéré** (AnimalHealthEurope, Belgium); **Dónal Sammin** (EuFMD, Italy); and **Max Bastian** (StIKo Vet, The Friedrich-Loeffler-Institut, Germany).

The discussion was structured in several topics.

4.1. Regulatory systems and innovation alignment

To ensure that the various regulatory and industrial tools work together to better address EIDs, tools must be coordinated across research and development (R&D), manufacturing, and regulations. While technologies advance, political, social, and communication challenges remain. Public understanding—especially regarding food animal vaccination—is limited and needs better communication. Regulatory tools alone will not be sufficient to solve the challenges in EID vaccine development. Tools must be used together. Regulatory streamlining (not more complexity) and prequalification of vaccine prototypes could help speed emergency deployment. Simplifying GMO regulations may also help streamline veterinary vaccine approval. Since GMO and veterinary vaccine safety requirements largely overlap, removing vaccines from redundant GMO legislation would reduce licensing delays.

In addition, EU regulatory bodies are not sufficiently aligned in supporting innovation. Lack of coordination among EMA, the European Directorate for the Quality of Medicines & HealthCare, and the European Commission sometimes creates obstacles, such as new efficacy requirements that may unintentionally hinder innovation.

Ultimately, EIDs are those not yet listed under EU or WOAH definitions in regulatory terms. However, the *emerging disease* term is also used informally for any disease without a vaccine, creating confusion and complicating regulatory discussions.

4.2. Vaccine development challenges and industry engagement

Vaccine producers need predictable market signals and reduced regulatory burden to start developing vaccines for emerging or existing diseases that currently have no market. The risk of financial loss is too high without market guarantees. Outbreak unpredictability, high costs, and long timelines deter investment. For instance, certain diseases disappear before products are launched, making long-term investment unattractive compared to chronic disease markets.

Having a vaccine is not sufficient to ensure its successful use. Communication, public trust, education, and proper coordination are also essential. Misunderstanding about vaccine safety (e.g., meat safety) can fuel hesitancy, and public and political support fluctuates. Vaccination campaigns (e.g., for AI) can lose momentum due to scepticism, unlike vaccination for BTV, which had more stable support.

4.3. Public–private funding models and market incentives

To prepare and develop future vaccines for EIDs, public–private models are essential. Industry alone cannot absorb all the risks, thus a CEPI-like model could provide needed stability and investment in prototypes. Establishing such a model would require political will, EU coordination, and solutions to issues like access to pathogens. The Commission could support this outside of competitive calls, and a veterinary Innovative Health Initiative-equivalent could be developed.

Industry must take the initiative, starting with lighter partnership models (e.g., co-programmed in Horizon Europe). Veterinary R&D is supported by push-funding, however, market incentive mechanisms are almost non-existent. Human health sectors are trying to develop such mechanisms (e.g., through the European Research Area [ERA]), and similar models could be considered in veterinary fields. Finally, the livestock sector's link to AMR in public health justifies more investment. However, prior proposals to increase their funding contribution have not been successful.

4.4. Investment strategy and R&D effectiveness

The veterinary industry is probably not capable of absorbing large sums, such as the €200 million for ASF vaccine development. There is scepticism about the capacity of the sector, including large pharmaceutical companies, to efficiently use very large budgets and expectations should be managed accordingly. Debate exists regarding the stage of research at which investment should be focused on, as some stakeholders are in favour of basic research, while others want near-market innovations. Better alignment with funding capabilities and project goals is needed.

R&D in the veterinary vaccine sector is effective, although not always visible. EU projects have yielded important outcomes. However, diseases like ASF remain unsolved despite heavy investment, demonstrating the limits of R&D under current models. The VPTMF could greatly accelerate virus vaccine rollout by allowing early regulatory evaluation. However, this is less applicable to bacterial diseases.

4.5. National vs EU-wide approaches

National vaccination plans, including EIDs such as the Rift Valley Fever, would be useful. Aligned with AMR strategies and a flexible approach, these plans could improve preparedness and vaccine uptake for EIDs. Although EU-wide centralised authorisations are more efficient, both national and centralised regulatory approval routes have roles: centralised procedures suit large-scale EIDs, while national approaches are better for small, localised outbreaks.

5. Session III – review of remedies

5.1. Economic aspects of vaccination – analysis from the situation in The Netherlands

Ron Bergevoet (Wageningen University & Research Centre, The Netherlands) analysed the economic aspects of the Dutch vaccination experience. The case was made that we cannot afford to wait for a disease outbreak to do socioeconomic analysis. Key considerations, especially regarding vaccination strategies, can and should be addressed in advance. Drawing on experiences from the Netherlands, the severe economic impact of outbreaks like FMD was discussed, with the example of a German incident with water buffaloes that have been estimated to cost between €100 million and €1 billion. When comparing strategies of vaccination versus culling, vaccination may reduce direct costs by avoiding large-scale culling, but it introduces higher tracing, monitoring, and administrative costs.

Furthermore, a zone with vaccinated animals is only declared free of FMD three months after the last vaccinated animal is slaughtered. Finally, logistics become complex due to the need to separate vaccinated from non-vaccinated products. This disrupts value chains and lowers revenues, particularly in export markets where countries may refuse vaccinated animal products. Nevertheless, it should be kept in mind that the economic losses are not solely due to vaccination, but to the outbreak itself.

Ultimately, the decision to vaccinate should factor in logistics, costs, trade implications, and stakeholder cooperation. While vaccination supports animal welfare and health, it requires thorough preparation, clear agreements, and effective communication during non-crisis periods to be successful when an outbreak does occur.

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

Claude Saegerman (University of Liège, Belgium) described the drivers involved in EIDs. While pandemics are extremely costly, prevention costs represent just a small fraction [46], making a strong case for proactive strategies. Drivers of disease emergence, such as land use, climate change, urbanisation, and trade, often interact, increasing complexity and requiring a One Health perspective that includes humans, animals, and the environment [47–49].

Current studies in animal health are limited in number and scope, often failing to account for uncertainties or to use comprehensive, traceable methods. A new methodology was developed, using multi-criteria decision analysis [50–53], to prioritise diseases based on key drivers, incorporating expert input, sensitivity analysis, and clustering. This method was tested across around 30 diseases, including influenza, AHS, and FMD. The methodology evaluates 50 drivers in eight domains, such as wildlife interface, climate change, monitoring capability, and trade, and applies a scoring system to assess the likelihood of emergence.

Results showed that porcine epidemic diarrhoea, FMD, low-pathogenic AI, and AHS ranked highest, and some other diseases like HPAI, sheep and goats' pox and lumpy skin disease ranked high in terms of emergence potential, aligning well for some of these diseases with current real-EU outbreaks, indirectly validating the method. Sensitivity analysis demonstrated the method's robustness, even when experts or domains were removed from the model. This methodology is not only effective and quick to apply but can be updated regularly to reflect changing drivers. Artificial intelligence can be used to enhance data assessment and expert elicitation when evidence-based data is limited. Ultimately, a balance needs to be found between risk, cost, and benefit when addressing EID threats.

5.3. Regulatory and technological responses

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

Jacqueline Poot (Medicines Evaluation Board, The Netherlands) provided an overview of the regulatory process surrounding the BTV-3 outbreak in the Netherlands in 2023, focusing on the rapid development and approval of vaccines under Article 110.2. Initial discussions between the Ministry and vaccine manufacturers led to pre-submission meetings where minimum regulatory requirements and timelines were established. A rolling submission process allowed the authorities to begin assessing data early, and three dossiers were submitted between March and April 2024. The assessment process, including back-and-forth exchanges, ranged from five and a half to two and a half weeks, with quicker reviews for more complete submissions. Final decisions by the national committee and the Minister took about 10 days, resulting in a notably fast approval process. No fees were charged, reflecting the emergency nature of the procedure.

All approved vaccines were based on existing BTV platforms with similar components, which simplified the assessment. Two vaccines used the outbreak strain, while one did not, raising questions about cross-strain protection. Differences were also present in how potency was measured—either through antigen titres before inactivation or ELISA-based quantification. While both were acceptable under the guidelines, the former introduced more uncertainty regarding potency. The minimum accepted data in dossiers included validated inactivation methods, limited or no stability data, no consistency batches, and minimal safety and efficacy data, often borrowed from similar vaccines. For efficacy, only challenge studies in sheep were required, with no data on cattle or long-term immunity, although such information becomes more important as the outbreak progresses.

Communication during the process was centralised and efficient, and the assessment was pragmatic, with a clear focus on benefit-risk balance. While assessment speed likely cannot be improved further, development timelines might be shortened by preparing vaccine strain banks in advance, although challenges like financial feasibility, the need for challenge studies, and limited data on immunogenicity remain. Preliminary research by the Friedrich Loeffler Institute indicated that booster doses improved neutralising antibody levels in vaccinated animals, hinting that serology might someday replace challenge trials as a quicker measure of efficacy. However, more research is needed to confirm whether antibody titres reliably correlate with protection and to search for alternative evaluation methods that could accelerate vaccine readiness in future outbreaks.

5.3.2. Perspective from the veterinary vaccine industry

Ely Bénéré (AnimalHealthEurope, Belgium) discussed the possible solutions to improve EU preparedness from the point of view of the pharmaceutical industry. To improve vaccine preparedness, proactive collaboration between public and private sectors is important. Public authorities should launch tenders for ready-to-use vaccine antigen banks and provide funding to support research, partnerships, and increased manufacturing capacity. Secondly, regulatory and legal requirements must be adapted to better support vaccine development for EIDs. Proactive EU-wide vaccine registration is a better way forward than relying on emergency-use authorisations like Article 110. The challenges of cost, regulatory burden, and limited return on investment must be shared across stakeholders.

A pragmatic approach to benefit-risk assessments must be adopted, establishing a defined list of EID agents recognised as critical, allowing regulatory incentives to be applied more consistently. Broader and more predictable eligibility criteria for reduced-data MAs are needed, similar to models used in the U.S., and fewer restrictions on the types of threats covered. For example, to speed up the process, serology could be accepted as a reasonable indicator of efficacy, and reduced quality-related data requirements should be automatically allowed for EID vaccines.

To further accelerate vaccine availability, default shortened regulatory timelines and reintroducing fee incentives may be considered. Finally, minimising post-authorisation burdens would be helpful, such as simplified licence renewal in the absence of product use, and maintenance of licences without the need for new data, unless the vaccine is marketed. Better collaboration with regulators, harmonising labelling and assessment requirements, and recognising approvals from third countries are needed to reduce duplication.

A specific proposal for BTV vaccines was discussed. Currently, the emergence of new BTV serotypes triggers emergency responses that burden industry with urgent development and regulatory requirements. Despite extensive knowledge and similar vaccine technologies, no fast-track centralised approvals exist. Modification of the exceptional circumstances guideline was proposed to allow centralised submission of new inactivated BTV vaccines based on approved MSt dossiers, using the same manufacturing process and composition, with the only change being the new serotype. Data requirements would be minimised, focusing on antigen qualification, inactivation validation, and estimating a minimum antigen content for the corresponding vaccine to provide reasonable expectation of efficacy. No new potency, safety, or efficacy data would initially be required, although with a commitment of post-marketing data collection once the vaccine is used.

This would come with some risks, such as uncertain efficacy for initial batches and applicability only to monovalent vaccines, but the benefit-risk balance would remain favourable given the urgency and existing knowledge. Finally, regulatory authorities could explore this concept further, especially the possibility of replacing potency assays

with antigen content or immune response as a proxy for protection. The overarching message was that more flexibility and pragmatism from regulators would incentivise greater industry investment in EID vaccine development.

6. Session IV – panel discussion

Frédéric Descamps (Zoetis, Belgium) moderated this panel discussion, which was composed of the following panel members: **Ron Bergevoet** (Wageningen University and Research Centre, The Netherlands); **Claude Saegerman** (University of Liège, Belgium); **Jacqueline Poot** (Medicines Evaluation Board, The Netherlands); **Ivo Claassen** (Head of Veterinary Medicines Division of the European Medicines Agency, The Netherlands); **Ely Bénéré** (AnimalHealthEurope, Belgium); and **Martin Beer** (Friedrich-Loeffler-Institut, Germany, remotely).

The discussion was structured in several topics.

6.1. Crisis response vs. regulatory flexibility and preparedness

To ensure a shift from outbreak response to preparedness within a regulatory framework, tools like the VPTMF and MSt dossiers should be used proactively, with regulatory adjustments and prior investment. Currently, preparedness strategies are bound to crisis-only scenarios. Exceptional circumstances and limited market rules may support preparedness strategies, however, this should be done through changes in the regulation or a more pragmatic interpretation of it. Additionally, reduced data requirements for antigens in advance of outbreaks can be used if scientific support exists (e.g., serological correlates) and regulators are open to flexible pathways.

Disease prioritisation based on scientific drivers is key, and the list of diseases should evolve regularly to stay relevant. EU-level coordination is ideal as a starting point, but national specifics still matter. The risk prioritisation tool based on key drivers in Belgium has the potential to impact on preparedness, as it is effective and methodologically sound, offering a robust framework for risk anticipation. Another tool has been created, the D2R2 tool, to regularly score diseases on impact, which informs government decisions but requires continuous resourcing.

The balance between acting with urgency and using evidence on the decision to vaccinate (e.g., for FMD) is delicate. It is required to act quickly without complete data, and waiting too long undermines the vaccine effectiveness. It is useful to have discussions with the industry before emergency crises, but the real-world decisions remain critical. There is a window between detection and vaccination, which must be used wisely for manufacturing and logistics readiness. In any event, epidemiological models assessing whether vaccination has an additional benefit already exist to assist in preparedness. For that purpose, not all data are necessary, but the vital information is (e.g., density, occurrence). The problem is related to diseases which have not been in the territory for decades, for which there is no preparedness.

Examples of regulatory flexibility are the recent Article 25 approvals without final product potency tests, which have shown to be pragmatic approaches and are already being applied. Emergency-use vaccine guidelines should formally accept no potency test, especially for known inactivated vaccines (like BTV), to support rapid, predictable emergency responses.

6.2. Regulatory challenges and recommendations

The legal definition of exceptional circumstances is so limited because the regulation specifically limits it to public or animal health, not economic reasons, per strict legal interpretation. The debate about whether regulation could be interpreted more flexibly or pragmatically remains. It has been suggested that the intent and benefit-risk balance can allow broader interpretation, however, this is sensitive and legally contested. The EU Commission and its legal service (i.e., not the EMA or the Committee for VMP) is the final authority that decides how regulation is interpreted or changed.

A revision of vaccination regulations might be needed, especially for diseases like BTV, given inconsistencies and hurdles, such as a middle ground between emergency use and Article 110. It should allow quick decisions with clear EU-wide protocols and post-vaccination requirements for consistency and ethical clarity. Article 110 is being overused as the first resort (instead of last resort) due to shortcomings in other regulatory mechanisms. The regulatory framework needs updating to reflect predictable outbreak patterns (e.g., new BTV strains), similar to the flu model in human health. However, field data from vaccine use under Article 110 can inform the formal vaccine authorisation process, as it offers real-world insights that should contribute to centralised regulatory decisions.

6.3. Technological readiness and industry incentives

Technical complexity, high cost, and existing reliable production methods discourage switching to less-established technologies, such as *plug-and-play* platforms for new serotypes. Additionally, regulatory difficulties are not the only reason companies hesitate to develop vaccines. Business decisions often depend on risk and return on investment. In some cases (like BTV3 or AI), companies have quickly developed vaccines, indicating other factors are at play. Incentives are needed to encourage industry to develop vaccines before emergencies occur. Tools like the prioritisation framework are useful, but without commercial incentives or streamlined processes, companies may not act preemptively.

6.4. Vaccination policies and economic impact

Vaccinated animals are often culled after an outbreak. Trade rules, regulatory inconsistencies, and economic pressures lead to early slaughter, even though culling is not always necessary. The interpretation on whether current EU regulation allows vaccinated animals to live is varied. Past frameworks allowed it, but current practice tends toward caution, favouring culling. The issue on who should pay for the economic losses if vaccinated animals are removed should be addressed during non-emergency period planning, possibly through shared funding or insurance schemes.

7. Conclusions and recommendations

As closing remarks, Jean-Christophe Audonnet outlined the conclusions and recommendations derived from the presentations and discussions that took place over the meeting, as key learnings for improved preparedness against EID in animals.

7.1. Conclusions

Emerging diseases is defined by the WOAH as the *new occurrence in an animal of a disease, infection or infestation, causing a significant impact on animal or public health resulting from a change of a known pathogenic agent or its spread to a new geographic area or species; or a previously unrecognised pathogenic agent or disease diagnosed for the first time* [54].

Preparedness must differentiate between *expected events* (typically slower-spreading diseases) and *unexpected events* (most EIDs). Expected events allow for planned responses using established solutions, whereas unexpected events demand the best vaccination strategy and scientific knowledge to develop immunogens. The feasibility of developing universal vaccines remains an open question. Considerations include defining target diseases and species, and striking a balance between designing the “ideal” vaccine versus rapidly producing an “efficacious enough” one. Key decisions revolve around whether preparedness should aim to be *ready to react* (responding to outbreaks) or *ready to act* (preparing solutions in advance).

7.2. Recommendations

7.2.1. Development of a collective decision matrix

A comprehensive, collaborative framework involving regulators, industry stakeholders, veterinarians, and surveillance systems is needed to guide preparedness based on disease severity, drivers of emergence, and economic implications. This matrix must also consider manufacturing feasibility and vaccine registrability under a "Pre-authorised Vaccine Concept". Policies should align with WOAH standards and EU Animal Health Law, and foster stronger connections between Chief Veterinary Officers and regulatory bodies.

7.2.2. Dedicated R&D funding for EIDs

There is currently no EU-wide emergency fund for veterinary vaccine R&D, and financial incentives are essential to encourage industrial investment in EID vaccines. Vaccine development for EIDs involves multiple uncertainties (scale, impact, feasibility), making return on investment difficult to predict. At present, industry bears the financial risk, which is unsustainable. The establishment of a dedicated funding mechanism for animal health similar to CEPI, Biomedical Advanced Research and Development Authority (BARDA), or Novo Nordisk Foundation Initiative for Vaccines and Immunity (NIVI) was advocated, thus aligning with the One Health approach due to overlaps in animal and human pathogens. Although such initiatives require substantial budgets, they are small compared to the potential economic losses of uncontained EIDs.

7.2.3. Addressing societal, logistical, and political issues

Vaccines for EIDs should be considered preventive insurance rather than emergency fixes. Emerging societal and political concerns, such as animal welfare and 3Rs policies (Reduce, Refine, Replace), food security, and vaccine hesitancy must be integrated into preparedness strategies. Critical external timelines (e.g., political, communication, logistical, diplomatic) must be factored alongside scientific and regulatory efforts. A strong, transparent communication strategy rooted in science is vital to build public trust and ensure vaccination campaigns succeed.

7.2.4. Regulatory enhancements

Although a regulatory framework exists, gaps remain in enabling proactive EID responses. The current system often leads to increased reliance on unapproved or autogenous vaccines, raising safety concerns. In this sense, encouragement of licensed vaccine development is necessary to minimise reliance on emergency permits or off-label use, and an EU-wide authorisation mechanism could improve vaccine availability during both calm and crisis periods.

Regulatory guidelines, especially from CVMP, should be updated to address emergency and proactive use cases, applying pragmatic, risk-balanced approaches. Proposals include adapting guidelines for specific serotype updates (e.g., inactivated BTV vaccines) or using the human influenza model as a regulatory benchmark. Existing "exceptional circumstances" policies should be reviewed and potentially applied in non-crisis times to enhance readiness. Similarly, establishing an evolving EU-wide list of "priority" EIDs could reduce regulatory burdens for critical vaccines, much like the historical MUMS (Minor Use, Minor Species) list.

Closer collaboration across EU regulatory bodies would streamline approval processes and improve access to critical vaccines. The complexity added by overlapping regulations (e.g., Nagoya Protocol, GMOs, biosafety, training) should be minimised and duplicative requirements (e.g., between ERA and Directive 2001/18) should be removed. Also, while autogenous vaccines have a role for local, low-scale use, they should not be the primary response for viral EIDs due to lower quality standards.

Finally, preparedness can also benefit from assessing and pre-qualifying vaccines already in use in countries where specific EIDs are endemic. Supporting manufacturers in low-to middle-income countries to improve vaccine quality can bolster global and European preparedness.

CRediT authorship contribution statement

Francisco Reviriego-Gordejo: Conceptualization, Investigation, Writing – review & editing. **Dries Minne:** Conceptualization, Investigation, Writing – review & editing. **Ivo Claassen:** Conceptualization, Investigation, Writing – review & editing. **Jean-Charles Cavitte:** Conceptualization, Investigation, Writing – review & editing. **Annemarie Bouma:** Conceptualization, Investigation, Writing – review & editing. **Olivier Debaere:** Conceptualization, Investigation, Writing – review & editing. **Max Bastian:** Conceptualization, Writing – review & editing. **Dónal Sammin:** Conceptualization, Investigation, Writing – review & editing. **Ely Bénéré:** Conceptualization, Investigation, Writing – review & editing. **Ron Bergevoet:** Conceptualization, Investigation, Writing – review & editing. **Claude Saegerman:** Conceptualization, Investigation, Writing – review & editing. **Jacqueline Poot:** Conceptualization, Investigation, Writing – review & editing. **Olivier Espeisse:** Conceptualization, Project administration, Writing – review & editing. **Jean-Christophe Audonnet:** Conceptualization, Project administration, Writing – review & editing. **Sandra Manzanares-Laya:** Writing – original draft, Writing – review & editing, Validation. **Frédéric Descamps:** Conceptualization, Investigation, Writing – review & editing.

Disclaimer

This meeting report reflects the authors' view and do not necessarily reflect the views or policies of their organisations.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the scientific writer used the tool Fireflies to support in notetaking during the meeting and ChatGPT to support in the summary of some parts of the text. After using these tools, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Funding

The meeting "Preparedness and response to emerging veterinary disease outbreaks" was organised by IABS-EU with financial support from Ceva, Actors4Health and Zoetis. This meeting report is funded by IABS-EU.

Declaration of competing interest

FRG, DM, IC, AB, OD, DS, RB, CS, and JP declare no conflicts of interest.

JCC performed programming calls for selection of EU-funded research projects in veterinary vaccine development, without a financial interest. MB received support from IABS-EU for travelling to this meeting. EB is an employee of Zoetis (manufacturer of veterinary vaccines), holds stock/stock options in Zoetis and is the Vice-Chairman of AnimalHealthEurope's Regulatory Procedures working Party since 2025. OE received consulting fees from the World Egg Organisation and CEVA Santé Animale, and received support from the World Egg Organisation for attending meetings or travel. JCA received consulting fees from Boehringer Ingelheim, CEVA Santé Animale, Virbac S.A., Fab'entech S.A., IABS-EU, and Substipharm, received support from IABS-EU for attending meetings and/or travel, and holds stock/stock options in Sanofi. SML is an employee of P95, and P95 received consulting fees from IABS-EU. FD is an employee of Zoetis (manufacturer of veterinary vaccines), holds stock/stock options in Zoetis, and is the Chairman of

AnimalHealthEurope's Biological Working Party since 2019.

Acknowledgements

The authors wish to gratefully thank IABS-EU, CEVA, Actors4Health and Zoetis for funding the meeting, and the moderators, speakers, and panellists for their participation and for providing valuable discussions at the meeting. The authors acknowledge Marlène Louis and Madinina Cox from the IABS Secretariat for their support in the organisation of the event and Marc Baay from P95 Clinical & Epidemiology Services for scientific writing support.

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