Partnership on Animal Health and Welfare (PAHW)

Version 8 May 2020

Preamble

The present document is an updated version of the first fiche prepared by the European Commission in 2019 and reflects the comments received from Member States and other stakeholders in the context of ad hoc consultations. It was prepared jointly mainly by DG AGRI as the lead DG and by the SCAR Collaborative Working Group on Animal Health and Welfare Research¹ supported by experts and in consultation with the animal health industry (AnimalHealth Europe² and Diagnostics for Animals³) and other Commission Services.

The document follows the template provided by DG RTD, in order to facilitate further discussion within and outside the European Commission.

The present candidate partnership is proposed to be published in the Horizon Europe 2023-2024 work programme. The present document reflects the currently agreed vision, objectives, estimated impact and governing model of this candidate partnership. It will evolve after further discussion with potential partners on the governance model, indicative resources by interested partners, the SRIA/roadmap, and its probable links with other candidate partnerships that are also still under preparation and have complementary scope.

While the format proposed is Co-Funded partnership, due to the further integration intended between key public research entities, this may evolve depending on the outcome of discussions on the modus operandi with the different potential partners.

AnimalHealth Europe supports in general the approach to future R&D options for animal health and welfare as outlined in this version of the proposal and awaits further details on planned activities before deciding on any precise commitment.

1 General information

1.1 Draft title of the European Partnerships

Partnership on Animal Health and Welfare (PAHW)

1.2 Lead entity (main contact)

Contact at this stage: Hein IMBERECHTS (Sciensano, Belgium) T + 32 2 379 04 26 • M + 32 477 911 050 Hein.Imberechts@sciensano.be

¹ https://www.scar-cwg-ahw.org/

² Association representing manufacturers of animal medicines, vaccines and other animal health products in Europe; https://www.animalhealtheurope.eu/

³ Federation of Manufacturers of Animal Health Diagnostics; https://diagnosticsforanimals.com/

1.3 Commission services (main contact)

Directorate-General for Agriculture and Rural Development (DG AGRI): Jean-Charles CAVITTE

Directorate-General for Research and Innovation (DG RTD): Miguel LIZASO

&

Directorate-General for Health and Consumer Protection (DG SANTE): Luis VIVAS-ALEGRE

1.4 Summary (max 500 characters)

Through a coordinated public-public and public-private collaboration of actors, the European Partnership "Animal Health & Welfare"⁴ will help reduce socio-economic and environmental impact of animal infectious diseases, improve animal welfare, protect the economic viability of farms and produce safe food. Additionally, since many animal infectious diseases and resistant microorganisms are known to cross the borders between animals, humans and the environment (for instance via wildlife vectors and contributing to antimicrobial resistance), a successful EU Partnership on animal health and welfare will also be beneficial for public health. The partnership will foster generation of key knowledge, reinforce preparedness against upcoming and emerging threats for both animals and humans, promote and strengthen animal welfare, generate innovative methodologies and products, and support evidenced based policy making.

2 Context, objectives, expected impacts

2.1 Context and problem definition

Animal health and animal welfare constitute a Global Public Good⁵, whose preservation is the mission of the proposed "Animal Health & Welfare" partnership. The creation of such a partnership is timely, for never before has the need for such an initiative been so pressing and the opportunity of achieving significant and durable progress been so favourable. The challenges at hand and the mobilisation of the means with which they may be tackled will require a systemic, crosscutting, interdisciplinary and coordinated approach at the transnational level.

Global change, whose pace has quickened in recent decades, has far-reaching climatic, economic, sociological and environmental ramifications. Animal populations, whether domestic or wild, terrestrial or aquatic, that lie at the heart of ecosystems, along with plants, air and water, are confronted with new and more complex challenges, whether in relation to climate change, ecological transformation, increasing efficiency of animal farming and husbandry practices or increased trade to meet the growing demands of developing societies. Similarly, the increase in deforestation, human activities and urbanisation exerts an acute impact on biodiversity and the balance of natural ecosystems, including wildlife. As humans, animals and ecosystems are closely interconnected, these changes transform the interactions between pathogens, vectors and hosts in multiple and complex ways. These changes have a profound impact on animal health. In recent decades, there has been a surge in the emergence or re-emergence of endemic or epidemic animal diseases, with serious consequences not only

⁴ For the purpose of this partnership, animals mean farmed/managed animals, whether terrestrial or aquatic, including bees, as well as companion animals and wildlife when there is a potential threat to public or animal health.

⁵ http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Key_Documents/ANIMAL-HEALTH-EN-FINAL.pdf

for the sustainability of livestock farming, but also for public health, as a significant number of infectious agents affecting animals have zoonotic potential, with or without showing disease in the animal host. Moreover, the societal demand for animal welfare develops apace with increasing concern for sustainable development. Scientific work on animal welfare evolves and a better understanding of animal welfare and welfare needs of animals will lead to an adaptation of housing systems and management practices; this will contribute to respond to the societal and political demand in this field. The demand is legitimised not only from the ethical standpoint, but also for the role that animal well-being plays in resilience to pathogenic challenges and diminution in animal morbidity and mortality. Better animal welfare will further legitimate future livestock production, giving a "license to produce" to livestock farmers. Finally, the irrational or excessive use of chemicals, particularly pharmaceuticals, including antibiotics, in animal production has contributed to the emergence of antimicrobial resistance in pathogens zoonotic agents and the commensal flora and their potential vectors, which is now a source of therapeutic deadlock, with grave consequences for animal and public health. These therapeutic deadlocks appear also in other domains, e.g. resistance against anti-parasitic treatments. This, at a time when many endemic animal health and welfare issues are still awaiting effective and socially acceptable solutions.

Nonetheless, **new opportunities exist** – in the form of emerging disciplines and technologies – to not only withstand emerging diseases but also to make inroads against entrenched diseases (see below).

The main motivations for establishing the partnership on "Animals, Health and Welfare" (PAHW) are that the socio-economic and environmental impacts of animal infectious diseases (AID) and the challenges for both the science and management are so vast that they cannot be met by individual Member States or regions, nor by single or small groups of actors and stakeholders. An international constellation of specialities/disciplines, of private and public sectors, at the whole EU level and beyond is required. A partnership to sustain ambitious and integrated research efforts to support innovation in the control of AID is needed to address the intensifying global threats to animal health and seize the opportunities provided by unprecedented developing technologies. The feasibility of such an endeavour is ensured by the existing historical cooperation among public research programmes of the EU Member States.

2.1.1 Main reasons for addressing animal health and welfare

- The livestock sector plays a major economic role in agriculture, accounting for 168 billion annually, 45% of total EU agricultural activities, creating 4 million jobs⁶, while linked sectors (milk and meat processing, feed for livestock) have an annual turnover of approximately €400 billion⁷.
- Over 20% of animal production loss is still linked to animal diseases worldwide⁸.
 Reducing the burden of diseases would improve use of natural resources, which is all the more important since by 2050 the world's population will have reached nearly 10 billion people. The likely increase in animal production will create new challenges, including those for disease prevention and control.
- Many AID are transboundary in nature and an increasing number of **exotic diseases** are reaching Europe due to international trade, climate change, travel, etc. (e.g.

⁶ Animal Task Force, "<u>Why is European animal production important today? Facts and figures</u>", 2017.

⁷ European Court of Auditors. Audit report 31/2018: Animal welfare in the EU: closing the gap between ambitious goals and practical implementation.

⁸ http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Key_Documents/ANIMAL-HEALTH-EN-FINAL.pdf

COVID-19). Indeed, climate change increases the risk of emergence and spread of exotic vector-borne diseases (e.g. Blue Tongue, West Nile Fever, Lumpy Skin Disease, etc.). International coordinated action is therefore important.

- Emerging infectious diseases: novel pathogens, whether bacteria, parasites, fungi, viruses or prions, arise as a result of the exacerbation of drivers of emergence, such as globalisation and climate change. Activities that move infected individuals or contaminated fomites, or change the range of vectors or wildlife reservoirs result in spread and establishment of emerging infections. The rate of emergence of novel pathogens is increasing due to several factors, for example, human population expansion into wildlife refuges bringing people and livestock in contact with wildlife reservoirs of potential pathogenic microorganisms. It seems that biodiversity could act as a shield in this area. Likewise, the speed of spread is accelerating as a result of growth of trade and travel.⁹ Therefore, improved preparedness for and response to emerging infectious diseases will be more and more critical.
- Large epidemics (e.g. foot and mouth disease -FMD, bovine spongiform encephalopathy -BSE, classical swine fever -CSF, highly pathogenic avian influenza -HPAI, and more recently African swine fever -ASF) lead to costs in the hundreds of millions (FMD, HPAI, ASF), sometime billions of Euros (BSE). Also, many infectious diseases are endemic and less 'visible', yet extremely costly, mainly to farmers but also to society. For instance, worldwide, the annual costs inflicted by coccidiosis, a common AID in commercial poultry, have been estimated at 2 billion \in^{10} . Similarly, the economic impact of necrotic enteritis is estimated at US\$ 2 billion year through mortalities and poor performance and the cost of prevention and treatment¹¹. In 2004, costs associated with 34 endemic livestock diseases in Great Britain were estimated¹², where the assessment included impact on human health and animal welfare. Bovine mastitis had the highest cost for cattle diseases, between 137 and 244 £ million, followed by lameness and bovine viral diarrhoea. For the period 2014-2020, more than 1 billion EUR were allocated by the EU to fund animal health measures in the Member States, from emergency measures to programmes for the eradication, control and surveillance of animal diseases and zoonoses. In addition, diseased animals are treated with antibiotics, leading to increased resistance, further therapy failure in the population and additional costs.
- Beyond direct costs/losses, AID can lead to major crises disturbing trade and jeopardising consumer confidence. At the time of the BSE crisis, a serious drop in meat consumption occurred, obliging EU and national authorities to implement costly market support measures. Under the current ASF situation, exports of pork are banned from countries/regions where ASF occurs, seriously threatening the pig farming sector in those countries/regions.
- In a One Health perspective, certain AID have an impact on public health.
 Zoonoses are diseases transmissible between animals and humans, directly or indirectly (e.g. food-borne and vector-borne zoonoses). The majority of emerging

⁹ Jones et al, Nature Vol 451|21 February 2008 ; doi:10.1038/nature06536 ;

¹⁰ H.W. Peek & W.J.M. Landman (2011) Coccidiosis in poultry: anticoccidial products, vaccines and other prevention strategies, Veterinary Quarterly, 31:3, 143-161, DOI: 10.1080/01652176.2011.605247

¹¹ Shojadoost, B., Vince, A.R. & Prescott, J.F. The successful experimental induction of necrotic enteritis in chickens by Clostridium perfringens: a critical review. Vet Res 43, 74 (2012). https://doi.org/10.1186/1297-9716-43-74

¹² R. Bennett et al, Journal of Agricultural Economics Volume 56, Number 1, March 2005 ;Pages 135-144

AID are zoonotic¹³. At global level, a study conducted by ILRI¹⁴ found that 56 zoonoses were responsible for an estimated 2.5 billion illnesses and 2.7 million deaths per year. EFSA has estimated that the overall economic burden of human salmonellosis could be as high as \notin 3 billion a year.

Antimicrobial resistance (AMR) arising from antimicrobial usage (AMU) is another public health threat partly arising from veterinary AMU. By reducing the effectiveness of antimicrobial treatment, AMR in bacterial or parasite populations threatens the control of both animal and human infectious diseases. AMR is responsible for an estimated 33,000 human deaths per year in the EU¹⁵. It is also estimated that AMR costs the EU 1.5 billion EUR per year in healthcare costs and human productivity losses¹⁶. While the relative contribution of veterinary AMU to the burden of AMR in humans as compared with other sources (e.g. AMU in the medical sector, the environment) is not known with certainty, there is a clear relation between AMU in animals and AMR notably in pathogens from food-borne cases. Sales of antibiotics for use in animals in Europe decreased by 32% between 2011 and 2017 (although the situation remains contrasting among countries¹⁷. Many countries have implemented action plans based on recommendations of international organisations (Tripartite OIE, FAO, WHO). Further efforts are needed, however, to reduce, replace and rethink the use of antimicrobials in livestock production. Intervention on livestock and other relevant animals will have an impact on human illnesses. As an example, a decrease of some 50% in the number of reported human cases of salmonellosis occurred within 10 years of the implementation of the EU Regulation on the control of *Salmonella* in livestock¹⁸. It focussed on poultry, requiring hygienic measures and where necessary, vaccination of animals. Of note, through two workshops organised by OIE, a list has been established of AID for which the development or improvement of vaccines is predicted to contribute to a reduction of the use of antimicrobials¹⁹.

The conditions under which animal production takes place and the level of animal welfare as consequence should be improved, in first place for ethical reasons. This is also a concerns for the society as is AMR also. Beyond practices that are already widely discussed or rejected (e.g. piglet castration and tale docking, debeaking), or systems decried for producing animals of very low economic value (e.g. male dairy calves, male day old chicks of laying lines), the acceptability of other aspects of animal management (for instance intensive farming, housing, high mortalities of young animals, handling of animals during transport and in the slaughterhouse) is being called into question. There is a link, not much addressed by research so far, between animal health and animal welfare, and between production conditions and animal health and welfare. While poor animal health is obviously

¹³ http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Key_Documents/ANIMAL-HEALTH-EN-FINAL.pdf Jones et al, Nature Vol 451|21 February 2008 ; doi:10.1038/nature06536

¹⁴ https://assets.publishing.service.gov.uk/media/57a08a63ed915d622c0006fd/ ZooMapDFIDreport18June2012FINALsm.pdf

¹⁵ Cassini, A., et al. The Lancet Infectious Diseases, 19(1), 56-66. https://doi.org/10.1016/S1473-3099(18)30605-4

¹⁶

http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf ¹⁷ https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac

¹⁸ EFSA Journal 2019;17(2):5596, 155 pp. https://doi.org/10.2903/j.efsa.2019.5596 19

https://www.oie.int/fileadmin/SST/adhocreports/Diseases%20for%20which%20Vaccines%20could%20reduce%20Antimicrobial%20Use/AN/AHG_AMUR_Vaccines_Apr2015.pdf

detrimental to animal welfare, animals poorly managed (e.g. stress) are more likely to develop certain diseases. Increasing livestock numbers, faster animal turnover, areas with high livestock population density and habitat fragmentation without concurrent improvement of biosecurity measures and control tools can increase both the likelihood as well as the impact of outbreaks of emerging zoonoses. The conditions under which animals are bred and reared, can lead to poor welfare and increased use of antimicrobials.

Scientific developments in animal welfare give more insight in sentience of animals e.g. fish. The scientific concept of good welfare evolves and includes nowadays positive emotions of animals, besides the well-known "five freedoms of animal welfare". This concept is named "**positive welfare**". In addition, it is now relevant to explore the concept of **One Welfare** which emphasises the link between animal welfare, human wellbeing, biodiversity and the environment and complements the One Health concept. This should have potential impacts on the representations expressed by farmers (job satisfaction, work facilitation, recognition by society ...) and the development of management and housing conditions that improve animal welfare and human wellbeing.

2.1.2 The main causes/drivers of the problems are the following

- Microorganisms are constantly evolving, spontaneously or under the influence of their environment, for instance of other microorganisms, the host, treatments used to control those or other microorganisms, chemical compounds, residues, or biocides. Those conditions influence the generation of populations with new ecological features and pathogenic microorganisms may become less or more virulent, or develop resistance to treatments (e.g. AMR, anthelmintic resistance). Microorganisms may cross species barriers (see HPAI, MERS, Nipah virus, Hepatitis E), sometimes affecting humans through zoonotic spillover²⁰, even leading to the emergence of new forms of diseases in new species.
- Another important challenge for health and welfare of animals rests in the economic conditions under which livestock production takes place: there is fierce competition and economic margins at primary production are usually low. The average income of farmers represents 45% of the average wage in the EU in 2018 (source: CAP indicators), and the income of livestock farmers is usually at the lower end within the agriculture sector²¹. This puts pressure onto increasing productivity and decreasing costs, which can have an impact on capacity or willingness to invest in health and welfare related matters by the farmers. Similarly, it is a limiting factor for the animal health industry to develop products and it requires innovative solutions to make these veterinary products at an affordable price. This situation is very different from the medical sector.
- While the EU regulatory/policy framework of animal health and welfare aims to ensure a high level of health status, also facilitating export access, it can have detrimental side effects on research and innovation:
 - Each MS tends to try and maintain its research capacity for policy support. This results in both dilution of scarce resources on many diseases and related issues in many animal species at the level of each country, and a risk of

²⁰ Plowright, R., Parrish, C., McCallum, H. et al. Pathways to zoonotic spillover. Nat Rev Microbiol 15, 502–510 (2017). https://doi.org/10.1038/nrmicro.2017.45

²¹ In 2015, income per farm stood at the average of the EU farm income for dairy farms, above the average for granivore and was lowest for grazing livestock farms and also mixed-farms (DG AGRI, FADN data).

duplication of research among MS. The regulatory framework in animal health makes it important that certain aspects of AID control, e.g. detection and surveillance, are standardised, harmonised or assessed as equivalent.

- Depending on the disease and epidemiological situation, certain AID may be controlled, notably by vaccination. However, in a number of cases, the default control strategy for notifiable AID in Europe is a 'sanitary policy', with testing and elimination of infected animals, which facilitates faster recovery of export access. The animal health status in the EU is generally high, and a number of epizootic diseases are absent from its territory, although incursions require temporary measures to eradicate diseases. In this framework, the EU market for animal health products against notifiable diseases, not least vaccines, is limited and provides little incentive for the industry to develop such control tools. Except when the disease situation changes the market/policy features and/or public support to research is increased. See the example of African swine fever below.
- In many EU Member States (MS) public research budgets for animal health have a decreasing trend. Each MS cannot develop sustained research on all aspects of all AID in all relevant species; the epidemiological situation may not require it. Although no exact figures exist, the same trend is probably true for animal welfare. However, attenuating the impact of the emergence and spread of a highly pathogenic AID requires efficient preparedness and capacity for early detection in order to respond quickly and efficiently to the threat.

2.1.3 Main underlying research gaps/needs and bottlenecks

- Efforts up to now created progress, but the recent emergencies (e.g. ASF) are showing that more action is needed in order to **improve preparedness** and reduce economic losses due to emerging issues and current problematics. A renewed approach is needed, as the old-fashion approach to animal health research proved not fully capable of addressing all issues. Current preparedness and response mechanisms to emerging and re-emerging diseases are not optimal and research and innovation will play a key role in improving the situation.
- To move from a curative approach to a more intensive prevention of diseases needs further efforts, for instance on biosecurity and on ways to promote resilience of animals, areas where many knowledge gaps exist and can be addressed by research and innovation. The development of **preventive measures**, including also novel housing systems and management practices, and new/improved diagnostics (including DIVA methodologies) and testing schemes, are very important to avoid animals getting ill and to control AID. Vaccines play a role as preventive tools, even if they are often developed when the damage is already done, and the AID has reached the country, area, farm or stable. In preventing the appearance or the extension of diseases, vaccination of livestock is often the most cost-efficient applicable measure and can be an important tool to reduce the burden of diseases and reduce the use of antimicrobials. Vaccines have already been developed for a number of important pathogens (sometimes through EU Framework Programme projects, i.e. for CSF, blue tongue). For other diseases, it is challenging to design efficacious and safe vaccines due to complex and evolving pathogens with mechanisms to avoid immune response by the host, sometimes acting in combination with other microorganisms. With modern technologies the efficacy of certain existing vaccines might be further improved. Production of new vaccines and improvement of existing ones will require significant additional knowledge, such as new approaches to antigen selection and

production, antigen delivery, improved adjuvants, vaccine administration, before products could be ready for commercialisation.

- As regards therapeutics, a continuous challenge is the development of resistance to treatments. Resistance to anti-parasitic treatments, notably against helminths and coccidia is growing and requires new approaches and products. With the reduction in the availability of antibiotics (some of which are critical for human use), the search for alternative to antimicrobials needs to be strengthened, either as means of treatment or for prevention.
- Scientific information and tools for risk assessment are important to prevent or control animal diseases. Delivering on these requires development of new platforms and tools including e.g. mathematical modelling and methods to handle big data, standardisation, and ambitious coordination, sharing and cohesion among actors at a pan-European level.
- Further research is needed to improve the knowledge about **animal welfare.** For instance how animal welfare affects the level of physiological stress and the immune response of animals. There is also a need to invest in the identification of management practices and farm conditions (ex: animal density, weaning, housing conditions, temperature, ventilation, feed etc.) that enhance both welfare and health. Important topics to consider are the welfare of young animals, how to lower their mortality, improvement of animal welfare during transport (heat stress, space allowance, fitness to travel) and at slaughter (for instance stunning methods), best practices for keeping animals in systems that do not require mutilations (e.g. castration, tail docking, beak trimming), effect of breeding strategies on the resilience and welfare of animals, understanding why improved well-being make animals more resilient to pathogenic challenges.

2.1.4 Opportunities

New opportunities are offered by **upcoming disciplines and technologies** which yet require coordination and cooperation of various research and innovation actors to deliver, share and exploit large experiments/data sets.

- These include data science, which can be harnessed for extraction and interpretation
 of epidemiologically relevant data from multiple digital sources, potentially providing
 near real-time monitoring of disease and thus the earliest possible warning of disease
 outbreaks.
- They also include the rapidly developing **omic technology** of metagenomics, which can be exploited, to cite one example, for discovery of pathogens and prediction of their evolutionary trajectories and risk of emergence, and to cite another, for comprehension of microbial ecology, with the ambition of piloting microbial ecosystems of animals to promote animal health and diminish antimicrobial resistance. Datasets obtained by other high-throughput omic approaches, not least of which genomics, which can increasingly be extended to complex pathogens and arthropod vectors, but also transcriptomics, proteomics and metabolomics, can now be integrated to provide systems-level understanding of host-pathogen interactions, thus disclosing unsuspected vulnerabilities amenable to immunological or therapeutic intervention. Such datasets can notably be put to use for the discovery of immune correlates of vaccine efficacy, and along with structural vaccinology, for guiding the rational design of vaccines.
- Moreover, development of various digitally assisted monitoring technologies on farms is increasingly enabling precision management of animal health and welfare.

One example is determining the welfare status of animals from the sound they make, which is work ongoing. The search for such animal-based welfare indicators implies a multi-disciplinary approach, including physics, mathematics, artificial intelligence, etc.

- Finally, in most, if not all, of these examples, the application of **machine learning** techniques is poised to accelerate and transform exploitation of the cognate datasets.

Existing established European and international networks of AID scientists and research funders offer a unique and timely opportunity to build a partnership. They provide a solid starting platform that can be further built on. Strong coordination, both on animal health and welfare issues, will help reducing wasteful duplication, ensure joint efforts where appropriate, and enable synergies.

There is an increasingly perceived need to build a **strategic collaboration between public research and the relevant private sector**, notably the animal health industry, to facilitate shared priority setting, undertake fit for purpose research along the continuum from basic research up to innovation.

To illustrate the limitations of the current system and the need for stronger cooperation among animal health actors in Europe, African Swine Fever (ASF) can be used as an example. This viral disease is endemic in a large part of sub-Saharan Africa.. There had been incursions of ASF in the south-west of Europe (Spain and Portugal) in the mid-1950s and, with no vaccine being available, it took until 1990 to eradicate ASF from Europe (with the exception of Sardinia, where it remained endemic in some areas).

Until then, the scientific expertise in the EU was concentrated mainly in a few Member States, with limited research performed. At the EU level, some public research was done, notably through EU funded research, but the virus is complex and no efficacious and safe pilot vaccine has been developed until now. It is only when ASF emerged in the north-eastern EU in 2014 and subsequently spread in the EU, to other European countries outside the EU (including to Asia), that the EU veterinary officers called for urgent strengthened and coordinated research efforts on ASF.

Public and private research sectors are investing to better control the disease, not least to develop a vaccine. The future will tell us if/when those efforts will be successful, but new technologies to decipher microbial genome and its expression and related manipulation provide new venues for such developments.

While an ERA-NET proposal that originally mainly focussed on vaccinology did not receive enough commitment, the epidemiological situation regarding ASF made it possible to attract more funders and mobilise additional budget to launch the ERA-NET on the international coordination of research on infectious animal diseases in 2019: ICRAD.

However, ASF is already implying huge costs to the sector/EU. Establishing a partnership with a higher level of resources, alignment of research activities and strategic collaboration between actors will contribute to increase preparedness and response capability to better /sooner reduce the impact of emerging infectious diseases such as ASF.

2.2 Common vision, objectives and expected impacts

The diagram below summarises the problems and drivers identified above (2.1 Context and problem), as well as the general (strategic) and specific (operational) objectives of PAHW

Figure: Relation between drivers, problems and objectives



2.2.1 General objectives

For the purpose of this partnership, **animals** mean farmed/managed animals, whether **terrestrial** or **aquatic**, including bees, as well as companion animals and wildlife when there is a potential threat to public or animal health²².

PAHW focuses on <u>notifiable and emerging AID</u> for which the control has an important policy dimension because of their impact on animal health, food production/safety, regional or global trade and public health. Notifiable AID are often managed by official public research bodies and risk authorities. The Partnership will also address <u>priority production</u> <u>diseases</u> that cause detrimental economic losses to farmers and the animal sector, and may lead to increased usage of antimicrobials; those diseases may be endemic and complex to control, and some of those diseases may be notifiable in a number of countries. In addition, PAHW will reinforce the animal health part of the <u>One Health approach</u> and will reach out to authorities responsible for and scientists active in the sectors of public health, food safety²³ and the environment. The area of activities will include zoonoses, vector-borne, food-borne pathogens and emerging diseases at primary production, and issues such as AMR. It should be noted that work on AMR will be defined in cooperation with the planned EU Partnership One Health – AMR. Finally, the Partnership will take action to study and improve prevention of disease, <u>welfare of animals</u> all along the production chain, and support transition to more animal welfare and animal health friendly production.

The general objectives of PAHW can be summarised as follows:

 To support the European livestock industry by safeguarding animal health and through timely interventions in case of AID outbreaks and reduction of burden. Thus, PAHW will contribute to securing the provision of safe and healthy food for European citizens with respect to animal welfare, the environment and public health.

²² AnimalHealth Europe is in favour of a scope covering health of both livestock and companion animals and both infectious diseases and non infectious diseases

²³ A final decision on food safety related activities will be made when discussing cooperation with the EU Partnership Safe and Sustainable Food Systems

- To ensure the preparedness of laboratories against endemic, upcoming and emerging AID through reinforced and aligned collaboration among national and European reference laboratories for AID and relevant research institutes in Europe. The Partnership will acquire and implement the necessary new tools for animal health laboratories to detect and characterise diseases. High quality, aligned laboratories and animal facilities contribute to the timely detection of new and upcoming pathogens and to the efficient response of responsible authorities.
- To develop strong preventive and control measures in case of emerging infectious diseases. To this end, innovative research is needed to gain new knowledge and to come up with efficient new tools. Furthermore, risk evaluators and risk managers need all instruments and information to take appropriate prevention and intervention actions in the field.
- To support **public health** due to timely detect, prevent and control actual and potential zoonotic AID and resistant microorganisms from animals and the environment.
- To invest in research on the well-being and welfare of animals as an ethical imperative for the animals themselves, to make them more resilient to illness, improve their survival, reduce the impact of climate change (i.e. to support the prevention of disease), as well as to improve sustainability of productions systems and contribute to meet the needs and demands of the society.

2.2.2 Specific and operational objectives/Activities

Based on the general objectives outlined above, the following specific objectives and activities are proposed.

- To coordinate between reference laboratories and research institutes, and where necessary with other actors to develop and implement new technologies and innovative solutions for diagnostic and characterisation purposes, thus increasing the laboratory capacity and quality, particularly in regulated domains. It will notably help to harmonise detection techniques, define standards and develop new techniques where appropriate.
- To implement new and innovative technologies and tools to obtain confident epidemiological data for epidemiological purposes (i.e. incidence and prevalence, early warning of new and emerging AID). In order to get a better image of pathogens and diseases present and possibly entering the various animal populations and the (wildlife) vectors across Europe, research is needed to further understand hostpathogen interactions, to develop molecular techniques and increased usage and development of mathematical models, to propose appropriate surveillance systems, to set up and share appropriate data sharing platforms, etc. Surveillance is of particular interest for timely detection of regulated diseases and for new and emerging infections, but also to detect spread of resistant pathogens and to support cross-sector outbreak management of zoonoses. In addition, a Europe-wide animal welfare surveillance system, including precision farming techniques and appropriate mitigation techniques will support health improvement and thus good practices in animal production.
- To develop innovative intervention measures including prevention and treatment procedures, not only for known endemic, but also for upcoming and emerging AID. These measures will be based on innovative, novel and high quality technologies and research among research institutes and reference laboratories, among national and EU risk managers, and ideally in cooperation with private partners. The PAHW will

perform research to develop new management and intervention measures according to defined parameters (animal species, production status, age, infectious agent, wildlife reservoirs, epidemiological situation, etc.). Also new concepts including alternatives to the use of antimicrobial products will be developed. Important instruments to evaluate such measures are animal experiments, modelling and cross-border simulation exercises.

- To trigger the improvement or progress of vaccine development for priority diseases in close collaboration with industrial partners. Although the available timespan will not allow for fully developing and evaluating vaccine candidates, the PAHW will define the target product profile for new vaccines for priority diseases and help take part in the basic and applied research to deliver those products. Also new treatment concepts including use of antimicrobial products should be developed.
- To cooperate and collaborate between actors of animal health, public health and the environment (One health approach). Due to the direct link between animal and public health (zoonoses, vector-borne diseases, AMR) scientists with specific expertise on pathology, epidemiology, microbiology, molecular biology, immunology, bioinformatics, data management, etc. as well as risk assessors and risk managers will be gathered to facilitate cross-sector collaboration (from setting up surveillance systems to on-farm interventions). Organisations such as ECDC, EFSA, FAO and OIE will be contacted as stakeholders to build on their experience and to avoid duplication of work. The SRIA/roadmap for PAHW will define its role and activities when it comes to zoonoses that are not harmful for production and companion animals, but may have a detrimental effect on public health (SARS, MERS).
- To cooperate and collaborate between livestock sectors (e.g. poultry, pigs, cattle, small ruminants), as these sectors are structurally or geographically separated and tend to operate in 'silos'. Nevertheless, they often struggle with similar issues (e.g. identification of good indicators for animal welfare, detection and characterisation methods and reporting procedures for AID, assurance standards for food safety) for which common solutions and lessons to be learned from each other will be sought.
- To develop and implement innovative technologies to improve the welfare of production animals. The Partnership will consider the development and use of an animal equivalent to the Quality Adjusted Life Year system for humans (used in costing of medicines). Through cooperation with relevant stakeholders, it will exchange best practices regarding modern farming and housing systems in order to speed up improvements in animal welfare and thus support the prevention of animal diseases.

In order to support the achievement of these objectives, **underpinning research** will be performed in priority areas such as: ecology, host-pathogen interaction, immunology, vectors and transmission pathways, microbiome, epidemiology and modelling, and animal welfare. Research will encompass both regulated and production diseases in all animal species, including cross-sector interactions and animal welfare and will be based on the Strategic Research and Innovation Agenda that will be commonly developed with all partners and stakeholders. Both internal and open calls will be organised (see '3.1 Portfolio of activities').

AnimalHealth Europe indicated its priorities in precompetitive research :

- 1. Early detection
- 2. Alternatives to animal testing
- 3. Biomarkers and clinical outcome

- 4. Standardization of data and methods
- 5. Immunology tools
- 6. Antiparasitic resistance mechanisms
- 7. Alternatives to traditional antimicrobials
- 8. Microbiome research
- 9. Surveillance of emerging zoonotic Vector-Borne Diseases in Europe

It is important to mention that AnimalHealth Europe would refrain from supporting collective approach in e.g. diseases for which an openly competitive market and good solutions already exist.

2.2.3 Vision and ambition

A coordinated public-private Partnership on Animal Health and Welfare in Europe is needed to reinforce and safeguard animal production and to emphasise and control the impact of animal health and welfare on public health and on the environment (One Health approach).

It is the ambition of the Partnership to reach out to all appropriate research centres and reference laboratories for animal infectious diseases in Europe to collaborate broadly with funding organisations and to cooperate with the industry (animal sector, diagnostics, and pharmaceuticals). Research, innovation and other activities will be set up with consultation of major international and national stakeholders (EFSA, FAO, OIE, etc. and national competent authorities) and other interested parties, so as to guarantee successful science to policy transfer with efficient leverage effect.

2.2.4 Pillars

Activities of PAHW will be concentrated around **five pillars**, for each of which an <u>intervention logic</u> will be developed: needs, objectives, input, activities, output, results and impact. Since the proposed pillars are not independent from each other, an overall <u>technical</u> <u>task group</u> will be set up for common approaches and techniques, for instance for organising the open and internal calls to launch studies on notifiable and production diseases, where possible with industry, taking care and supervising antimicrobial use and AMR in animals, dealing with the activities concerning vaccine development and other transversal approaches, but also for setting up open access, cross-sector databases that link with existing ones, methodologies for validation of harmonised procedures for the diagnosis of notifiable and production diseases, where possible with the industry, etc.

The main 'Portfolio of activities' is presented under 3.1.

Activities Pillars	Open & internal calls for research	Other activities (KT, E&T, etc)	Reposi- tories, databases, sharing etc.	Cross- sector collaborati on	Social/ societal approach	AMU & AMR	Farm- specific manageme nt	Simulation exercises	Vaccine develop- ment
Detection & Preparedness	x	x	x			х			
Epidemiology & Risk assessment	x	x	x	x		х	х		
Intervention strategies	x	x			х	х	x	х	х
Public Health aspects	x	x	x	x	x	x	x	x	x
Animal welfare	x	x	x		x	x	x	x	x

Figure: Major transversal activities across the five pillars

The activities indicated in blue are transversal actions, whereas those in green are transversal themes

KT: Knowledge transfer, E&T: Education & Training

The following pillars are proposed:

- Pillar Detection of disease and infection, and preparedness of laboratories. Laboratories across Europe need aligned and harmonised diagnostic tools (tests and procedures, including DIVA technologies) to timely detect and characterise microbial agents, immunological reactions, antimicrobial resistance patterns (for animal pathogens) or alike, not least in the framework of official controls. Special attention will be given to notifiable diseases, to new and emerging infections and priority production diseases. There is a continuous need to validate existing and new test methods (animal and human infectious diseases), especially in those cases where no reference network of AID exists. Appropriate open access databases for collections of strains, reference materials, genetic information (WGS data, metagenomics, including bioinformatics) and infrastructures and equipment in Europe and neighbouring countries are needed.
- Pillar Epidemiology and Risk assessment. For all notifiable as well as for priority production diseases reliable data on incidence and prevalence will be made available for all Member States. Adequate surveillance and monitoring systems/models will be set up in relevant animal species (livestock including bees, fish and shellfish, companion animals, wildlife with possible links to livestock), their vectors and the environment (e.g. residues of antimicrobials and biocides, resistance genes). New technologies such as surveillance based on e.g. increased usage of big data, artificial intelligence, mathematical models and genetic information, will be broadly implemented. Laboratory results and epidemiological data will be safely stored, and efforts will be done to share databases among all animal health and public health partners (open access). Functional links with existing databases (e.g. ECDC, EFSA, FAO, OIE) will be set up and duplication should be avoided. Modelling techniques and scenarios will help to predict possible spread of infection and evaluate intervention techniques.
- Pillar Intervention strategies. Both for animal health and animal welfare, existing and new intervention measures to prevent and fight against emerging, notifiable and production diseases will be developed and implemented. These will include improved diagnostics and surveillance tools, on-farm protective actions (biosecurity and hygiene procedures in collaboration with the farmer) and use and development of vaccines and therapeutics as appropriate. Precision farming techniques, biosensors and biomarkers will help to identify critical points on farm and to monitor interventions. Overall, multidisciplinary on-farm approaches (among owners, veterinarians, authorities, consultants, etc.) and the socio-economic impact will be estimated. Modelling techniques and simulation exercises will help to evaluate effectiveness of measures.
- Pillar Cross-sector collaboration (One Health approach). Adequate detection and identification of (new and emerging) infections in livestock, companion animals and wildlife are beneficial for public health surveillance since certain animal infections can pass on to humans through food, direct contact, arthropod vectors or the environment. Vector-borne infections with zoonotic potential need specific attention, also due to climate change and intensive global trade. Animal health laboratories will be encouraged to report to animal health and public health risk managers (cross-sector, one health approach) in order to collaborate efficiently, to exchange data and to set up common surveillance systems and intervention measures. As for AMR, risk managers responsible for animal health will take appropriate actions to encourage prudent use of antimicrobials (antibacterials, antivirals, anthelmintics) and to introduce measures that are alternatives for antibiotic use or reduce the need for

antibiotic treatment. Also, research in this area, including the development of vaccines and new treatment protocols for animal diseases, will be encouraged. The precise activities dealing with AMR will be decided in cooperation with the planned EU Partnership One Health-AMR.

Pillar Animal Welfare. In order to define new animal welfare legislation in Europe (Council recommendation December 2019; Green Deal), more knowledge is needed to understand and monitor animal welfare, as well as on the interplay between animal welfare and health (prevention of disease): underlying mechanisms, role of well-being on the resilience of animals to pathogens and recovery from disease, role of immune competence, endocrine regulation of stress, microbiomes, etc. Cost-benefit studies will clarify economic consequences of improved animal welfare at all stages of the production chain and production parameters. The identification of management and housing conditions that improve animal welfare can lead to a better health status of the farm, reducing antimicrobials use. The participation of partners with different animal production models enhance information and data integration that can contribute to a better definition of animal welfare standards, taking into account the specific constraints of different geoclimatic areas and farming systems. There should be intensive attention for the dissemination of the new knowledge among livestock farmers and in the whole chain.

2.2.5 Building on past research and existing initiatives

The EU has supported research on animal health and welfare along the successive Framework Programmes. While FP6 Thematic Priority (TP) 5 had a focus on food quality and safety, significant research was performed on animal health and welfare, in particular under 'scientific support to policy' (TP8) and FP7 funded a number of projects on animal health and welfare, welfare being often embedded in other aspects of animal production²⁴.

The cumulative EU contribution to animal health and welfare research in FP7 under Theme 2 (Food, Agriculture and Fisheries, and Biotechnology) is estimated at around 230 million euros. The investment under H2020 Societal Challenge 2 (Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy) over the same length of time (7 years) is expected to be comparable²⁵.

Collaborative projects were organised in most sectors, in certain cases with the industry, but there were hardly any collaborative projects of pan-European nature (unlike FP6 with the Networks of Excellence) and little strategic interaction with industry upstream (actually few projects seem to have led to uptake by the industry). The European Technology Platform on Global Animal Health became dormant during FP7. Still the DISCONTOOLS FP7 project²⁶ was a tangible result, providing a tool to prioritise specific diseases (over 50) and to inventory not only available tools, but also gaps and needs. DISCONTOOLS is now sustained by national funders of research from a range of countries with industry providing secretariat support. It will be among the sources that will be used to elaborate the SRIA and roadmap. In that way, PAHW links with the industry to enable a strategic approach to support innovation and to develop pan-European activities.

²⁴ 'Food Quality and Safety in Europe' FP6 project catalogue (ISBN 92-79-02693-3); A decade of EU-funded animal health research (2012; ISBN 978-92-79-21035-8; doi:10.2777/73975); a decade of EU-funded animal production research (2013; ISBN 92-79-02693-3; doi:10.2777/19235)

²⁵ https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/factsheet-agrianimals-health_en.pdf; https://ec.europa.eu/info/sites/info/files/food-farming-

fisheries/farming/documents/factsheet-agri-animal-production-systems_en.pdf

²⁶ <u>www.discontools.eu</u>

There was much more coordination among public research actors during FP7 and H2020. This was linked to the setting up in 2005 of a Collaborative Working Group of SCAR (Standing Committee on Agriculture Research), dealing with animal health and welfare (CWG AH&W Research)²⁷, on the basis of which ERA-NETs arose, as well as an international network of research funders projects, STAR-IDAZ. CWG AH&W Research developed a Strategic Research Agenda, with the latest version in 2017²⁸. CWG AH&W Research on disease prevention in farmed fish²⁹. Comparable documents were developed on animal welfare³⁰.

There is a history of successful EU public-public research partnerships mainly ERA-NETs: The FP7 EMIDA (animal infectious diseases), followed by ANIHWA (animal health and welfare), succeeded in mobilising in total over 70 million euros in 5 joint calls funded from member countries. A new ERA-NET for international coordination of research on infectious animal diseases (ICRAD)³¹ started in October 2019). Those activities provided improved collaboration on research prioritisation and procurement for public institutions while companies were involved marginally into research projects until now. Other H2020 ERA-NETs address animal welfare to a certain extent, and animal health to a limited range, as part of more general or transversal approaches:, i.e. SusAn on sustainable animal production³², and CORE Organic Co-fund on Organic Food and Farming Systems³³.

The One Health EJP co-fund project³⁴ under Horizon2020 is a consortium of 38 partners from 19 member states and is composed of partners from food safety, public health, animal health reference professionals. Ample experience has been acquired on preparedness, epidemiology and cross-sector collaboration and thus represents a solid basis for PAHW.

The EPIZONE network was started under FP6 as a Network of Excellence and thereafter successfully followed up by the self-sustainable EPIZONE European Research Group, which is now the largest European Research Network on Epizootic animal diseases, including those which may have zoonotic potential. PAHW can benefit significantly from the current EPIZONE activities.

An international network of public research funders, STAR-IDAZ was supported by FP7 and was followed up by an 'International Research Consortium (STAR-IDAZ IRC)³⁵, opening new avenues for global cooperation. PAHW will link to STAR-IDAZ IRC.

PAHW intends to build on these initiatives. The momentum exists to strengthen the level of collaboration between public entities, as well as with the private sector, but shifting gear is necessary.

2.2.6 Collaboration opportunities

Candidate <u>EUP One Health-AMR</u>: while the One Health approach is relevant for epidemiology, surveillance, detection, possibly stewardship of AMR, measures to fight

²⁷ <u>www.scar-cwg-ahw.org</u>

²⁸ https://www.scar-cwg-ahw.org/wp-content/uploads/2018/04/Final-Report-CWG-AHW-CASA_updated-EU-AH-SRA.pdf

²⁹ https://scar-europe.org/index.php/fish-documents

³⁰ https://www.scar-cwg-ahw.org/wp-content/uploads/2017/07/Gap-analysis-on-Animal-Welfare-research.pdf; https://scar-europe.org/index.php/fish-documents

³¹ www.icrad.eu

³² https://era-susan.eu/

³³ https://projects.au.dk/coreorganiccofund/

³⁴www.OneHealthEJP.eu

³⁵ <u>www.star-idaz.net</u>

against AMR in the animal domain, aimed at reducing the (need to) use of AMs, and replacing AMs, will be tackled in PAHW. Coordination will take place to avoid overlaps and foster synergies instead.

Candidate <u>EUP Safe and Sustainable Food Systems</u> (SSFS): PAHW intends to address food safety hazards at primary production, addressing both AID that are food-borne zoonoses, and by extension also food-borne pathogens that may not cause diseases in animals but of which animals are reservoirs. Coordination with EU Partnership SSFS will depend on the extent to which this partnership will address microbiological food safety.

Candidate <u>EUP Blue Economy</u>: coordination will take place if animal health and welfare of aquatic animals is included in the SRIA/roadmap of PAHW.

Candidate <u>EUP Innovative Health (planned follow-up to IMI-2)</u>: coordination may be useful to look for synergies between the medical and the veterinary sectors in specific domains, e.g; infectious diseases, including zoonoses; innovative technologies; animal models.

Coordination with other pillars of Horizon 2020:

- Pillar I Research infrastructures: PAHW will collaborate with relevant existing Research Infrastructures or their possible successors (e.g. ELIXIR, VETBIONET, INFRAVEC2), and see how they can contribute. Pillar III
 - Innovation ecosystems: collaboration will be explored. PAHW intends to contribute to the development of innovative (animal health) products and services.
- EIT: To be explored (e.g. KIC Health, KIC Food).

Coordination with other structuring projects and initiatives in related domains will take place

- JPI AMR, JPI HDHL, JPI Ocean, JPI FACCE, as appropriate
- EURCAW -pigs
- EURCAW poultry and small farmed animals.

Synergies with other Programmes:

- Synergy with European Structural and Investment Funds will be sought, provided connections exist to finance activities
- Synergy with the European Investment bank will be sought, provided connections exist to finance certain activities
- Synergy with Digital Europe Programme will be explored wherever large-scale deployment of products and services piloted in PAHW would be envisioned

Other sources of funding will be sought, such as charities and foundations.

2.2.7 Amount of R&I investments needed to achieve impacts

The amount of R&I investments will be discussed in line with the specific objectives and proposed activities; therefore this will be determined when developing the SRIA.

In order to achieve optimal integration of public sector research actors (research performing organisations supported by funding organisations), and thus generate essential new knowledge that supports innovation in the fields of the Partnership (support of livestock, public health and animal welfare), the budget should be a significant proportion of national expenditures (MSs spend circa \notin 300- \notin 400 million/year). Mobilisation of resources will depend on whether resources are redirected from within activities for which programme managers as member of the consortium are responsible (internal calls mostly with in kind

contribution), and whether research activities are performed mainly through external calls requiring 'in cash' funds.

The contribution from the private sector (industry) will depend on their commitment to PAHW and the format of their contribution. For reference, the animal health pharmaceutical industry spends circa \notin 450 million/year in R&D- including for pet animals³⁶.

Considering the breadth of the scope of the actual candidate partnership, prioritisation will need to be made through continuing consultation of potential partners as well as stakeholders.

2.2.8 Relevant transformational changes; impact

A further pan-European integration of public research programmes is anticipated, so that the form proposed for PAHW is a co-funded partnership with significant in-kind contributions from research centres and reference laboratories. The Partnership will avoid duplication, will enable synergies and will leverage towards sustainable animal production. For this, the line ministries (agriculture, public health, economy, research) are best placed to profit from the outcomes of PAHW, which is a science-to-policy system with efficient leverage effect. For instance, improved surveillance systems and related databases, practices (including biosecurity), treatments and vaccines as alternatives to the use antimicrobials, simulation exercises are all beneficiary to the competent authorities.

In addition, strategic collaboration with the private sector is envisaged and will be a new and key feature to better complement public research efforts, in ensuring that joint projects are performed and mutual goals are attained. Examples are development and innovation efforts in different domains such as vaccines, therapeutics and alternatives to antimicrobials.

How these forms of cooperation can be organised within a partnership will require further discussion and will depend notably on the type and level of involvement of the private sector, the interaction expected with the public sector and the legal/contractual requirements.

The diagram below is provisional and describes a possible format centred on a Co-funded partnership, with optional involvement of the private sector in a co-Programmed partnership component. This will require further discussion.

³⁶ https://annual-report.animalhealtheurope.eu/2019/key-figures/

Figure: Co- funded / Co-Programmed partnership model



The light blue dotted areas indicate that participation is only possible under precise conditions. The co-programmed part will be discussed with industry and the Commission.

Short term impact:

- Through intensive cooperation and coordination between research institutes, reference laboratories, universities and industrial partners, newest technologies will be introduced in the diagnosis and characterisation of animal diseases. In addition, through the enhanced collaboration between public and private sectors, new ideas will be developed and new initiatives will be taken. The efficient coordination of research on both animal health and welfare will certainly lead to less duplication of work.
- The further introduction and development of genetic techniques (array, metagenomics and others) in official surveillance programmes in the animal (and food) sector will lead to more sensitive, specific and standardised detection methods that can be automated, and will improve comparability and speedier delivery of results, probably EU legislation and reporting to ECDC & EFSA. Open access databases with such data and appropriate data handling methodologies will stimulate research and risk analysis EU-wide.
- Broadly supported, effective and validated intervention measures, including prevention, will lead to efficient, cost-benefit methods and fast reversion to the healthy state and thus optimal and long-term livestock production.
- An efficient coordination between animal health, public health and the environment (One Health approach) will enhance timely exchange of information and common action. It will build trust among partners and therefore improve time of reaction and commitment to common investments in cross-sector methodologies (procedures, databases, management structures, etc.).
- Appropriate welfare measures across the entire chain: on farms, during transport and in slaughterhouses will lead to an improvement of the wellbeing of animals securing their productivity and maintaining them with increased robustness to avoid

disease and infections. This will require a multidisciplinary approach and will lead to and increased acceptance by citizens and an improved compliance of animal owners.

PAHW will result in benefits to society through more efficient animal production (fewer losses) and related reduction of greenhouse gases as a co-benefit of better animal health; from better food security; from improved animal welfare, and its embedding in sustainable production. Also a reduction of risk to human health (reduction of risk of zoonoses, of AMR threat, of food-borne pathogens) is envisaged.

The benefits to the economy will be linked to the benefits mentioned above, and also to fewer food scares and smoother animal and food trade. The partnership will also advance the animal health industry by a strategic association with public research in order to increase its ability to deliver products and services, thus increasing the competitive position of the European animal health industry.

The partnership will provide socio-economic benefits in rural areas, providing additional tools to farmers and veterinarians to improve welfare and sustainability of production.

2.2.9 Exit- strategy and measures for phasing- out from the Framework Programme funding

This is a new initiative hence the focus at this very early stage would be on developing it rather than on phasing- out.

The development and 'validation' of products, such as treatments or new/improved vaccines may require a continuum in the R&I chain, starting from basic research on the understanding of the pathogen and its interaction with the host, to industrial production of innovative products.

The intended unprecedented integration of pan-European public research actors and expected strategic cooperation of the private sector are new features that will require time to deliver. It is therefore expected that this partnership will build the foundations of a public-private sector cooperation in animal health and welfare research, while it will likely require a second phase to demonstrate its full potential.

2.2.10 Description of the planned process for developing a Strategic Research and Innovation Agenda/roadmap

The partnership needs to be backed by a robust Strategic Research and Innovation Agenda (SRIA) based on a clear intervention logic and that provides a framework for the thematic priorities and the kind of R&I actions needed, with enough flexibility to define new priorities stage-by-stage. The SRIA needs to be ready for the adoption of the Horizon Europe work programme 2023-2024, which means tentatively between spring and autumn 2022.

Once the major interested partners have been identified, the governance model and modus operandi agreed, and the available funding defined, the consortium and stakeholders will develop the SRIA in close consultation with the European Commission.

This will not start from a clean sheet, as the networks and initiatives that will be members or stakeholders of the partnership have developed SRAs or similar documents (see section 2.2.7 above). One of the animal health industry sector with which exploratory discussions are being held, AnimalHealth Europe, identified priority areas of precompetitive research.

2.3 Necessity for a European Partnership

2.3.1 How the partnership will address the objectives of Horizon Europe, political priorities of the EU and its Member States, and global challenges

The strategic objectives are to improve the preparedness of animal infectious disease laboratories, to reduce disease burden in animals and where relevant people, to address animal welfare and the societal and economic dimensions of livestock production, and to fight against antimicrobial resistance.

The objectives of PAHW are well aligned with the provisions of Horizon Europe, Cluster 6, Intervention Area 3, whose broad lines advise that issues be addressed as follows:

- Control of contagious and zoonotic animal diseases and animal welfare.
- Prevention strategies, control measures and diagnostic and alternatives to the use of antibiotics and other substances/techniques also to tackle AMR.
- AMR and threats from biological hazards.
- Tackling the links between plant, animal, ecosystems and public health from One-Health and Global-Health perspectives.
- Fostering international partnerships for sustainable agriculture for food and nutrition security.

The objectives highlighted above fit well with important initiatives and policies of the European Commission/Union:

- The Green Deal of the European Commission, notably the forthcoming Farm to Fork Strategy. A more sustainable production, increased interest in animal welfare and, the need to reduce the use of antimicrobials are identified in these political priorities.
- The Commission proposals on the new Common Agriculture Policy. The Communication on the Future of Food and Farming³⁷ referred to" responding to societal expectations regarding food, in particular concerning food safety…"; "CAP should become more apt at addressing critical health issues such as those related to antimicrobial resistance (AMR) ... in line with an ambitious and encompassing approach with regard to human and animal health - as embodied by the "One Health" concept". "Identically the CAP can help farmers to improve the application of EU rules on animal welfare and to further increase standards through voluntary initiatives aimed at promoting the market value of animal welfare both within and outside the EU."
- AMR is subject to a EU AMR action plan³⁸, with one pillar on research highlighting needs notably in the animal production sector. A number of the operational objectives mentioned above are addressing these needs.

More globally, and considering that AID do not respect frontiers and threaten the lives of animals, compromise their welfare, engender significant food loss, endanger the integrity and diversity of ecosystems, jeopardise the livelihood of farmers and the socio-economy of regions and nations, cost billions of Euros for control and mitigation and place human lives at risk, whether directly by zoonotic transmission or indirectly by compromising food security, animal health has both direct and indirect impacts on the main cornerstones of Sustainable Development, as well as on most, if not all, of its 17 goals but notably on the following:

³⁷ COM(2017) 713 final

³⁸ https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

Figure: Major Sustainable Development Goals in relation to the EU Partnership Animal & Health



2.3.2 How the partnership will establish collaboration with Member States /Associated Countries and national/regional authorities

As mentioned above, the animal health, animal welfare and food safety domains in Europe are subject to a comprehensive regulatory framework, with decisions based on science. In this domain, the European Food Safety Authority is assigned to perform risk assessment and related scientific activities, providing advice to the European Commission and other Institutions. PAHW will cooperate strongly with EFSA, as well as with other relevant national and international bodies. The partnership will support the EU (and global) regulatory framework for animal disease control and related EU policies (e.g. zoonoses, food safety, animal welfare). When defining the activities within PAHW regarding food safety, cooperation with the EU Partnership on Safe and Sustainable Food Safety is needed.

These actions will translate into improved knowledge means of disease control for PAHW member countries and beyond and help reduce the cost to EU in its funding of disease control measures in Member States, and cost to Member States themselves.

The existing framework of SCAR and its CWG AH&W Research and SWG SCAR FISH, the success of ERA-NETs EMIDA and ANIWAH including the on-going ICRAD, the focus on issues relevant to EU policies and regulatory framework should ensure a very good level of collaboration with Member States and Associated Countries.

The involvement of the industry (see 2.4) will facilitate the development of innovative products and services based on research performed by or jointly with the public research sector.

PAHW will develop a large portfolio of activities around transnational R&I projects, but the ambition is beyond this, to develop a pan-European integration of public research programmes in coordination with the private sector, both on regulated and non-regulated domains, with the aim to facilitate disease prioritisation, establish common platforms, share infrastructures, facilitate uptake of research results, and increase capacity to detect and respond to threats. These are more likely to be achieved by PAHW than by classical topics in HE work-programmes.

2.4 Partner composition and target group

2.4.1 How the partnership will build on and strengthen or expand existing collaboration networks and initiatives

The existing consortia CWG AH&W Research (<u>www.scar-cwg-ahw.org</u>), STAR-IDAZ IRC (<u>www.star-idaz.net</u>), DISCONTOOLS (<u>www.discontools</u>.eu), EPIZONE (<u>www.epizone-eu.net</u>), ICRAD (<u>www.ICRAD.eu</u>), One Health EJP (<u>www.OneHealthEJP.eu</u>) and the MedVetNet Association (<u>www.mvnassociation.org</u>) support this Partnership Animal Health

& Welfare and unite research institutes, academic institutions and universities as well as reference laboratories for animal health and welfare in Europe and more widely at international level.

In order to open up to high-level technologies and new expertise, national funding organisations will be invited to take part in the Partnership. In that way, open calls can be organised where not only beneficiaries, but also universities and industrial partners can sign up.

In addition, negotiations are ongoing with the following industrial partners:

- AnimalHealth Europe
- Diagnostics for animals

2.4.2 Type and composition of partners and stakeholder community

Research and other activities target both notifiable animal infectious diseases and priority production diseases, the reinforcement of the animal health part of the One Health approach and the improvement of welfare of animals. Therefore, the following entities are invited to take part in the Partnership, as partners or in another form of collaboration:

- All European research centres working on animal diseases and welfare.
- All national and EU Reference Laboratories (Animal Health/AMR/Food safety) and Centres (Animal Welfare).
- All national and regional funding organisations, cooperatives and charities.
- Universities and relevant industry partners (animal sector, diagnostics, pharmaceutical) can join through open calls.

From the start, as many European Member States as possible should join PAHW. The first candidates to reach out to are the Associated countries and countries to the East of Europe. Also North African countries bordering to the Mediterranean Sea are invited to participate.

The industry is considered essential for bringing the impact of PAHW to a higher level and could be involved in or associated to PAHW according to different options, presented below in descending order of strategic collaboration.

- 1. A co-programmed component with industry is developed, complementary to the cofunded component for public research managers/funders, i.e. a mixed model. Both parts agree on a shared vision, common/shared objectives, shared/consistent SRIA/roadmap. This would be a tripartite collaboration, with the EC complementing the partnership with topics in the Horizon Europe work-programmes. Industry would be consulted on intended Horizon Europe work-programme and on priorities/topics of areas of the co-funded component, while EC and the co-funded component would be consulted on industry planning.
- 2. The industry would not be formally a member of the (co-funded) partnership, but would be consulted to facilitate strategic cooperation (on priorities, requirements etc.). Industry would take part in relevant projects performed by the partnership. The main model would be when the partnership would organize open (external) calls to select projects with partners that are not members of the partnership per se, but may receive funding if a funder (usually, the agency of the country where the research entity would perform the research) is a member of the partnership. Depending on the provisions of these funders, industry may, or not, be eligible for some funding. The industry would also develop own projects contributing to the objectives of the partnership. There would be no MoU between industry and the EU, but for the

partnership to make sense and demonstrate its ambition and impact, there could/should be a kind of MoU between industry and the consortium of members of the partnership. The EC would not enter into any formal commitment with the industry.

Another option would be to organise a co-programmed partnership involving both the industry and the Member States, instead of a co-funded model. This is possible, but is a new feature in Horizon Europe never tried before. Common vision/ objectives/ SRIA/ roadmap/ outputs/ impacts should be established. Industry and public research entities do the research on their side, hopefully jointly, according to the common SRIA etc. The contribution of EC is through topics in the Horizon Europe work-programme, to complement MS/industry actions.

While AnimalHealth Europe awaits further details on planned activities before deciding on any precise commitment., it provided an indicative list of assets it could potentially bring to such partnership, in particular: sharing existing disease surveillance platforms; enabling access to strain and reagent libraries; expertise in diseases, analytic tools, diagnostics, vaccinology, clinical models, studies and biostatistics; robust and validated analytical methods; formulation expertise; quality processes; market knowledge and economic modelling.

2.4.3 List of candidate stakeholders

As core stakeholders, national and regional Ministries that are responsible for animal health and animal welfare will be invited to take part, as well as national and regional food safety organisations, where relevant. Industry (animal sector, diagnostics, pharmaceuticals), if not partner in the Partnership, will be invited as essential stakeholders, as well as essential international entities (ECDC, EFSA, European Medicines Agency, EMA) and World Organisation for Animal Health (OIE). These core stakeholders probably take part in governing instances of PAHW (see section 3.3).

Other candidate stakeholders:

- Animal Task Force
- COPA COGECA (European farmers, European agri-cooperatives)
- DISCONTOOLS
- EPIZONE
- EASVO (European Association of State Veterinary Officers)
- EAVLD (European Association of Veterinary Laboratory Diagnosticians)
- European Wildlife Disease Association (https://ewda.org/)
- IABS (International Alliance for Biological Standardization; https://www.iabs.org)
- FESASS (European Federation of Animal Health Services)
- FVE (Federation of Veterinarians of Europe)
- Livestock industries: FABRE, EATIP, ECIP, EUPIG
- OneHealth EJP
- SCAR CWG Animal Health & Welfare
- STAR-IDAZ
- VetBioNet (Veterinary Biocontained facility Network)
- Welfare Quality Network

- Wildlife Health Specialist Group (WHSG) of Species Survival Commission (SSC) of the International Union for Conservation of Nature (IUCN) (<u>http://www.iucn-</u><u>whsg.org</u>)
- Stakeholders for Welfare:
 - CIWF
 - EU Platform on Animal Welfare
 - Eurogroup for Animals

Due to the recognisable link with the EU Partnerships One Health-AMR, Innovative Health, etc. Safe and Sustainable Food Systems for People, Planet and Climate, and Blue Economy, contact will be sought with the respective coordinators to look for collaboration and avoid overlapping activities. (See 'Collaboration opportunities' under 2.2.6).

3 Planned Implementation

3.1 Activities

3.1.1 Portfolio of activities

The activities that will be developed in this Partnership depend on the pillar, and can be summarised as follows. More details will be provided in the Strategic Research and Innovation Agenda.

- Transnational research and innovation activities will be organised to advance in most of the pillars, not least diagnostic tests, vaccines, basic and applied research on pathogens, their genomes, host-pathogen interactions, epidemiology, ecology, biosecurity, immunology, vectors, microbiomes, (pre-harvest) food safety and AMR (if not addressed by other partnership), animal welfare etc.. To this end, both open and internal calls will be organised:
 - **Open calls**: Funding partners will mobilise internal and external budgets, e.g. from pharmaceutical, biotechnical or diagnostic industries and livestock industries and cooperatives to organise open calls and thus reach out to e.g. other academic labs and private partners. The aim of the resulting research will be to perform research on relevant animal infections and diseases including emerging animal infections and zoonoses, as well as measures to reduce antimicrobial usage and antimicrobial resistance of animal pathogens, to bring in the best expertise and to capitalise on the involvement of the best available science through open competitions.
 - Research institutes & reference laboratories for infectious animal diseases will organise internal calls (among these partners) aiming to harmonise and align methodologies and increase preparedness and dissemination of results to stakeholders with reference to notifiable AID, including new and emerging infectious diseases and related issues (including AMR, to be defined in cooperation with the planned EU Partnership One Health-AMR).
- Shared repositories (e.g. collections of biological and genetic material, in line with Nagoya protocol) are needed when developing and validating new tests and for organising ring trials / proficiency testing to align and harmonise procedures.
- **Shared infrastructure** (e.g. animal facilities)

- Open access, cross-border and cross-sector animal health databases will be set up that can be linked to existing databases, including those related to public health (e.g. ECDC, EFSA, FAO and OIE).
- For major animal infectious diseases, new surveillance systems based in particular on genetics (arrays, metagenomics etc.) will be developed for the appropriate animal species or the environment, thus improving data analysis and risk assessment and enabling economic cost-benefit studies.
- Similarly, new advanced cross-border surveillance systems (biosensors, precision farming) will be developed to examine and monitor the overall well-being of animals. Such surveillance systems will include animal-based indicators on farm and in the slaughterhouse, e.g. the harmonised collection of mortality data, death on arrival and post mortem data across countries, etc.
- Develop activities complementary to those of EUP OH-AMR, including awarenessraising campaigns that aim at encouraging the prudent use of antimicrobials in animals.
- Organise multidisciplinary on-farm supportive activities to prevent diseases and suffering in collaboration with the owner/breeder, the veterinarian, authority representatives, consultants etc. to decide on overall farm-specific approaches.
- Organise on-site (farm, transport, slaughterhouse) field studies and measures: testing, assess biosecurity measures, perform simulation exercises and economic costbenefit studies.
- For priority infectious diseases, organise collaborative research or build on available achievements to develop/improve vaccines and therapeutics/alternatives to antimicrobials.

3.1.2 Complementarity mechanisms, avoid unnecessary duplications

The key to avoiding overlap and duplication of work is coordination among partners.

There is a positive experience of coordination of public research programmes; in particular through CWG AH&W Research and ERA-NETs. This coordination will be brought to a superior level, with intended integration of relevant actors, and mobilisation of critical mass of resources. Research performing organisations and funding agencies that already collaborate in existing animal health and animal welfare consortia (i.e. CWG AH&W Research, STAR-IDAZ IRC, DISCONTOOLS, EPIZONE, ICRAD and One Health EJP) are expected to be members of the Partnership and will thus build on their achievements and avoid performing duplication of work.

Certain activities planned in PAHW (see 3.1.1) precisely aim to reduce duplication and rather facilitate synergies, such as harmonisation of standards and methods and installing pan – European databases, repositories and systems.

In close collaboration with research centres, relevant ministries (responsible for agriculture, research, animal health and welfare or public health) and funding organisations, major areas of research will be prioritized and research topic areas will be chosen in consultation with relevant stakeholders. Depending on its status in the partnership, the industry will be represented as member or stakeholder, but consultation will be ensured.

When drafting and implementing the SRIA, relevant international (e.g. ECDC, EFSA, OIE, EMA), national and regional stakeholders will be consulted. In order to facilitate interaction and complementarity with other European partnerships, their representation in relevant PAHW structures is envisaged.

3.1.3 Coherence and synergies

See above

3.2 Resources

3.2.1 Contributions from partners

The available budget will depend on the governance model and modus operandi most appropriate for PAHW. It will be further discussed with the potential partners and stakeholders during the preparation process.

In a co-funded model:

- As regards public research actors, a mix of in cash (from funding organisations for the organisation of external calls) and in kind (from research performing organisations, not least the reference research centres, for projects initiated through internal calls) contributions is expected.
- As regards the private sector, contributions to the partnership are expected to be mostly in kind, through participation in projects launched by the partnership. This would likely be through participation in projects launched through external calls, but may extend to projects launched within the consortium if an appropriate process can be organised, such as third party participation

If a co-programmed component is part of the partnership, with upfront resources committed, a back-office will be established.

3.2.2 Other investments or conditions

To be determined at a later phase

3.2.3 International Dimension

The international dimension of animal health, notably animal infectious diseases and AMR, is obvious. Animal welfare is also increasingly recognised as an important component of prevention of disease and of animal production. The EU is considered as a front runner on animal welfare standards.

While the EU framework is essential for a number of areas targeted by PAHW, there are also international standards established by OIE, which is the reference body under the World Trade Organisation as regards Sanitary and PhytoSanitary measures.

As mentioned above, PAHW will address not only the objectives of Horizon Europe and political priorities of the EU and its Member States, but also global challenges, contributing to certain SDGs.

The animal health industry is concentrated and very much internationalised. A few large companies dominate the market and have their headquarters in various countries, they often oversee the global market or at least do not focus on a single region. Their production sites are established throughout the world.

International cooperation is animal health research is taking place already, not least for reasons similar to those mentioned under section 2.1 above. International alliances exist, such as the Global Foot-and-mouth diseases Research Alliance, the Global African swine fever Research Alliance, connected to the STAR-IDAZ International Research Consortium.

What will be important for the partnership is to ensure that knowledge and innovation generated will be primarily aimed to benefit the members in the partnership, the European animal production sector and society at large. The possible level of association and linkage

with entities and initiatives beyond Europe will be discussed during the continuing preparation process.

3.3 Governance

3.3.1 Governance and advisory structures

At this stage, where only exploratory discussions took place with some potential partners from the private sector, a co-funded partnership model centred on public research actors is proposed. Governance and management of the partnership will be defined in later stages.

In the spirit of the co-fund One Health EJP, it is envisaged that the Coordinator plus representatives of the consortium partners (research institutes, the reference laboratories, the funding organisations and the Communication/Dissemination Team) constitute the Coordination team, which leads the EU Partnership. The frequent follow up of all activities will be done in the Management Board, where Pillar/Work Package leaders are gathered. The highest level of governance is constituted by the Governing board, where representatives of the European Commission and the National Ministries take place, as well as representatives of the other relevant EU Partnerships, European and International key stakeholders (e.g. ECDC, EFSA, FAO, OIE) and the industry seat.

Other Stakeholders will form the advisory bodies (e.g. stakeholder board).

Figure: Proposed governance of EU Partnership Animals & Health



The suggested governance model is based on Co-Funded Partnership, where the role of the industry is rather restricted, as compared to a Co-Programmed Partnership

3.3.2 Involvement of Commission

The European Commission is taking a proactive and co-leading role in the preparation of the partnership, including the drafting of the SRIA/roadmap.

It is envisaged that the European Commission will take part in the Governing Board meetings as a full member, similar to the national Ministries/Stakeholders. Its role will be to oversee the implementation and regular updating of the SRIA/Roadmap, to monitor progress of PAHW according to the Grant Agreement and to assess which areas may be addressed by topics in the Horizon Europe work-programmes rather than in the partnership, as complementary approach (whether there would be a Co-Programmed component in PAHW or not). The EC will also ensure that appropriate interaction takes place with other relevant European partnerships and that policy developments are brought to the attention of the partnership.

3.4 Openness and transparency

3.4.1 How will the partnership establish a broad, open and transparent approach towards different sectors and geographical areas

Ensuring participation of all relevant actors (partners, stakeholders) is at the core of the partnership. The discussions so far involved existing structures (SCAR CWG AH&W Research, SCAR Steering Group) together with experts from different projects/initiatives,(e.g. One Health EJP, EPIZONE, STAR-IDAZ IRC, ICRAD ERA-NET). On the industry side, exploratory discussions were held with AnimalHealth Europe and Diagnostics for Animals, as perceived main actors.

It is intended to further organise discussions with(in) the above mentioned consortia and other experts and to organise more inclusive discussions on the basis of the present dossier, in order to refine the preparation of the partnership in coordination with Commission Services.

The stakeholders listed in section 2.4.2 will be invited to take part.

3.4.2 How will the partnership ensure easy and non-discriminatory access to information about the initiative and dissemination of and access to results

A dedicated website will be set up where results of the R&I activities are published. Moreover, regular workshops, conferences, meetings, etc. will be organised during the lifespan of the partnership for wider dissemination of activities and results with relevant stakeholders.

3.4.3 How will the partnership establish a proactive recruitment policy

This will be determined during further discussions

At this stage, the main stakeholders are already identified and will be associated in the further preparation of the partnership.

As regards potential partners from the public sector, it is expected that the representatives in SCAR CWG AH&W Research, as well as the contact persons identified by the Member States for this partnership and who will be associated to the discussions, will ensure coordination within their own country.

Foundations active in animal health and welfare research and innovation will be informed and where possible associated to the preparation and implementation of PAHW

On the industry side, contacts were made with 2 important European/International Associations that represent a vast majority of the actors in their domain. Depending on the possible development of objectives in areas where other private actors would be useful, these will be contacted as well.

3.4.3 Process for establishing annual work programmes

This should be determined during the development of the SRIA.