European Partnerships under Horizon Europe

Partnership on Animal Health and Welfare (PAHW)

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Contents

Preamble

The present document is based on the version drafted in May 2020 (v2.6), which was assessed and commented on by the Directorate General Research and Innovation (DG RTD) services in June 2020. In the autumn of 2020 and the spring of 2021 Directorate General Agriculture and Rural Development (DG AGRI) as the lead DG, together with the chair of the SCAR Collaborative Working Group on Animal Health and Welfare Research (CWG AHW[1]) set up a core group and working groups with European experts and in which the European Food Safety Authority (EFSA[2]), the World Organisation for Animal Health (OIE[3]) and the animal health industry (Animal Health Europe[4] and Diagnostics for Animals[5]) and

[1] www.scar-cwg-ahw.org
[2] www.efsa.europa.eu/fr
[3] www.oie.int/en/home/
[4] www.animalhealtheurope.eu
[5] https://diagnosticsforanimals.com/

the SCAR CWG on fisheries and aquaculture research (SCAR FISH[6]) were represented. The outcome of the expert working groups was presented during a full day online webinar on 29 June 2021 with contact persons designated by countries for the partnership, additional potential actors, CWG AHW members and experts, Commission services and stakeholders. It was followed by an online consultation and online meetings with CWG AHW on 25 August, 28 September, 9 November 2021 and 16 December.

Update on progress was provided to SCAR Plenary on 30 June and on 7 December. A webinar was organised on 17 December to discuss the pre-final draft document with SCAR members, Cluster 6 Programme Committee members, contact persons designated by countries for the partnership, and associated Commission Services.

This document, finalised after the last meetings above, follows to a large extent the template provided by DG RTD.

The candidate Partnership Animal Health & Welfare (PAHW) is listed in the Horizon Europe Strategic Plan 2021-2024. It is planned to be a Co-Funded partnership 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.

The industrial partners that the authors contacted in preparation of this document support the approach to future R&D options for animal health and welfare as outlined in this version of the proposal.

1 General information

1.1 Draft title of the European Partnerships

Partnership on Animal Health and Welfare (PAHW)

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1.4 Summary (max 500 characters)

Through a coordinated public-public and public-private collaboration of most major actors in Europe, the Partnership Animal Health & Welfare (PAHW) will generate key knowledge and foster its uptake, generate innovative methodologies, tools and products helping to reduce the socio-economic and environmental impact of animal infectious diseases and to strengthen animal welfare in production animals (livestock and aquaculture)

[6] https://scar-europe.org/index.php/fish-mission-and-aims

PAHW will also reinforce preparedness against upcoming and re-emerging threats (including those originating from resistant microorganisms), and support evidenced based intervention and policy making in both the fields of animal health and welfare at the same time.

2 Context, objectives, expected impacts

2.1 Context and problem definition

Animal health and animal welfare constitute a Global Public Good[7], whose preservation and continuous improvement is the mission of the proposed PAHW. The creation of the partnership is timely, as never before has the need for such an initiative been so pressing and the opportunity of achieving significant and sustainable progress been so favourable in the context of the Farm to Fork strategy[8]. The challenges at hand and the mobilisation of resources to achieve them require a systemic, cross-cutting, interdisciplinary and coordinated approach at the transnational level.

The **livestock sector plays a major economic role** in agriculture, accounting for €168 billion annually, 45% of total EU agricultural activities, creating 4 million jobs[9], many of them in rural areas, while linked sectors (dairy products, eggs and meat processing, feed for livestock) have an annual turnover of approximately €400 billion[10]. The value of EU aquaculture production reached €5.6 billion in 2017[11].

While the ever-growing human population increases the need for proteins, the livestock and aquaculture sector provides high nutritional values proteins such as meat including fish, crustacean and mollusc, milk and eggs, contributing to food security (SDG2) and nutrition (SDG3). Furthermore, it enhances economic growth (food and non-food products) (SDG8), rural development and vitality of many EU marginal territories (SDG9, SDG15) and certain production systems preserve biodiversity on earth (SDG2, SDG15). A healthy and sustainable livestock sector is a prerequisite for providing sufficient and healthy food to citizens and to establish well-functioning circular sustainable agri/food systems, in the most efficient way possible.

Global change, which pace has quickened in recent decades, has far-reaching climatic, economic, sociological and environmental consequences. 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 and habitat loss, increasing efficiency of animal farming and husbandry practices or increased trade to meet the growing demands of developing societies. The impact of global change on the availability, quality and temperature of bodies of water can affect terrestrial and aquatic production by, for example, influencing the biology and transmission dynamics and paths of the pathogens of farmed animals. In particular, rising temperatures will have a progressively relevant impact on animal farming, linked to a multitude of issues associated with animal welfare. As an example, temperature affects the physiology of both animals and pathogens, and has the potential to lead to

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

[8] COM(2020)381final

[9] Animal Task Force, "Why is European animal production important today? Facts and figures", 2017.

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

[11] https://www.europarl.europa.eu/factsheets/en/sheet/120/aquaculture-production-in-the-european-union

significant increases in disease outbreaks and in antimicrobial resistance[12][13] within livestock and aquaculture systems, resulting in severe financial impacts[14].

Similarly, the increase in deforestation transforms the interactions between pathogens, vectors and hosts in multiple and complex ways[15]. In recent decades, there has been a surge in the emergence or re-emergence of endemic or epidemic animal diseases (e.g. Schmallenberg virus infection, porcine epidemic diarrhoea, avian influenza, African swine fever, West Nile Fever, infectious salmon anaemia, infectious heamatopoietic necrosis), with serious consequences not only for the sustainability of livestock and aquaculture/fish farming, but also for animal and public health[16], as a significant number of infectious agents affecting animals have zoonotic potential, with or without showing disease in the animal host. Regarding influenza, re-assortment between different strains harboured in e.g. pigs, can lead to new subtypes with the ability to spread between humans, as seen in 2009 during the worldwide H1N1 influenza pandemic. The COVID-19 pandemic, with a suspected source in wildlife and/or farmed animals (e.g. fur production animals[17]) has shown how far systems of surveillance, prevention and response are a challenge for such health systems and need to be improved, by applying a consistent "One-Health" approach[18].

The societal demand for improved animal welfare develops apace, as the 'End the Cage Age' European Citizens' Initiative demonstrated, with 1.4 million validated signatures[19]. There is growing public concern about rearing of livestock in cages, about slaughter practices and about animal transports. 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 and will contribute to responses to animal needs, and the societal and political demands in this field. The demand is legitimised not only from the ethical standpoint, but also by the role that animal well-being plays in resilience to infectious as well as non-infectious diseases and diminution in animal morbidity and mortality. Also, livestock and fish kept with low welfare standards are less efficient and therefore mean a greater environmental footprint per kg of produced food and a waste of

[12] https://www.sciencedirect.com/science/article/pii/S258900422030208X

[13] https://www.nature.com/articles/s41558-018-0161-6

[14] Mediterranean Aquaculture in a Changing Climate: Temperature Effects on Pathogens and Diseases of Three Farmed Fish Species. https://doi.org/10.3390/pathogens10091205

[15] Jessica H. Leibler et al, Industrial Food Animal Production and Global Health Risks: Exploring the Ecosystems and Economics of Avian Influenza. EcoHealth. DOI: 10.1007/s10393-009-0226-0
IPBES (2020) Workshop Report on Biodiversity and Pandemics of the Intergovernmental Platform on Biodiversity and Ecosystem Services. Daszak, P., das Neves, C., Amuasi, J., Hayman, D., Kuiken, T., Roche, B., Zambrana-Torrelio, C., Buss, P., Dundarova, H., Feferholtz, Y., Foldvari, G., Igbinosa, E., Junglen, S., Liu, Q., Suzan, G., Uhart, M., Wannous, C., Woolaston, K., Mosig Reidl, P., O'Brien, K., Pascual, U., Stoett, P., Li, H., Ngo, H. T., IPBES secretariat, Bonn, Germany, DOI:10.5281/zenodo.4147317

[16] Jones, K. E., Patel, N. G., Levy, M. A., Storeygard, A., Balk, D., Gittleman, J. L., & Daszak, P. (2008). Global trends in emerging infectious diseases. Nature, 451(7181),990-993. https://doi.org/10.1038/nature06536
Smith, K. F., Goldberg, M., Rosenthal, S., Carlson, L., Chen, J., Chen, C., & Ramachandran, S. (2014). Global rise in human infectious disease outbreaks. Journal of the Royal Society Interface, 11(101), 1–6. https://doi.org/10.1098/rsif.2014.0950; Animal diseases on the rise due to climate change, warns industry, EURACTIV, 2015; The growing threat of vector-borne dissease in humans and animals, IFAH-whitepaper, 2014

[17] Mallapaty S. (2021). Did the coronavirus jump from animals to people twice? Nature 597, 458-459 (2021): https://www.nature.com/articles/d41586-021-02519-1; Lytras, S., Xia, W., Hughes, J., Jiang, X., Robertson, D.L. (2021). The animal origin of SARS-CoV-2. Science 373 (6558), 968-970 (2021): https://www.science.org/doi/10.1126/science.abh0117

[18] Zinsstag, J., Utzinger, J., Probst-Hensch, N. et al. Towards integrated surveillance-response systems for the prevention of future pandemics. Infect Dis Poverty 9, 140 (2020). https://doi.org/10.1186/s40249-020-00757-5

[19] https://www.endthecageage.eu/

resources, counteracting the UN SDGs. Better animal welfare will give a better adequacy between the consumer expectations and the way the food products they buy are really produced.

Finally, the use of chemicals, particularly pharmaceuticals, including antibiotics, has contributed to the development of the livestock sector. At the same time, their unjustified or excessive use is contributing 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[20]. This dilemma appears also in other domains, e.g. resistance against anti-parasitic treatments such as anthelminthics[21] and acaricids[22], harmful effects on invertebrates, etc.

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 and improve animal welfare (see below). The challenges for both the science and management are so vast that they cannot be met by individual countries, nor by single or small groups of actors and stakeholders. An international constellation of disciplines, of private and public sectors, at the pan-European level and beyond is required. A partnership to sustain ambitious and integrated research efforts to support innovation in the control of animal infectious diseases (AID) and improved welfare is needed to address the intensifying global threats to our 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 Problems in animal health and welfare

Animal production. Around 20% of animal production loss is still related to animal diseases worldwide[23]. Reducing the burden of diseases would improve the use of natural resources, which is all the more important since by 2050 the world's population is expected to have reached nearly 10 billion people. Despite the increasing use and development of alternative proteins for food and changing eating habits, livestock and aquaculture are of great importance for food production. The likely increase in animal production will create new challenges, especially with regard to disease prevention and control, as well as animal welfare.

Emerging animal infectious diseases. Many AID are transboundary in nature and an increasing number of exotic (zoonotic) diseases is reaching Europe due to global trade, climate change, increased travel, land use, etc. (see the example of COVID-19). Indeed, climate change increases the risk of emergence and spread of exotic vector-borne diseases (e.g. bluetongue, West Nile Fever, Lumpy Skin Disease, etc.). International coordinated action is therefore of high importance. 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 (re)emergence of novel pathogens, whether viruses, bacteria, parasites, fungi, or prions, arise as a result of the exacerbation of drivers of emergence, such as globalisation and climate change, is increasing due to several

[20] Tackling drug-resistant infections globally: final report and recommendations. The review on antimicrobial resistance chaired by Jim O'Neill, May 2016

[21] Ten Events That Defined Anthelmintic Resistance Research. S.C. Sangster et al, Trends in Parasitology, July 2018, Vol. 34, No. 7 https://doi.org/10.1016/j.pt.2018.05.001

[22] Sparagano, O.A.E., George, D.R., Harrington, D.W.J., Giangaspero. A.(2014) Significance and Control of the Poultry Red Mite, Dermanyssus Galline Annu. Rev. Entomol. 2014. 59:447–66

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

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 also act as a shield in this area[24]. Likewise, the speed of spread is accelerating because of growth of global trade and travel as the rapid spread of ASF over several continents shows.[25] Other emergent risk hitherto unknown to European regions have been the sudden emergence of BTV-8, or of Schmallenberg virus or the migration of LSD up through the European Southeast, whose further spread was prevented by vigorous vaccination. The spread of ASF into hitherto unaffected European territories is a constant risk and the introduction of PEDV, another fatal porcine infectious disease, into Europe is an indicator for an increasingly looming risk at the horizon. On the aquatic side, emerging (bacterial and viral) diseases are having an important impact on animal health for both finfish and bivalve molluscs. On a global scale, economic losses in aquaculture due to diseases are estimated to amount to at least several billion US$ per year (World Bank, 2014)[26]. Photobacteriosis, caused by Photobacterium damselse subsp, which until recently was a minor issue in aquaculture, has now emerged as major problem in the Mediterranean aquaculture, with new virulence factors linked to increasing water temperatures.

Therefore, improved preparedness for and response to emerging infectious diseases will be more and more critical. Moreover, changes of husbandry practices in response to animals needs and societal demand (open-air breeding, natural food…) may also expose animals to new biological threats (pathogens, vectors, wild life, etc.), but mitigation measures exist or can be sought.

Costs. Major 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) entail costs of several hundred million (HPAI), sometime billions of Euros (FMD, BSE, ASF). Also, many infectious diseases are endemic and less 'visible', yet extremely costly, mainly to farmers but also to society and contributing to environmental impact. For instance, the annual costs inflicted by coccidiosis, a common AID in commercial poultry, have been estimated at €2 billion[27] worldwide. Similarly, the economic impact of necrotic enteritis in poultry is estimated at US$ 2 billion per year due to death, poor performance and cost of prevention and treatment[28]. Porcine Reproductive and Respiratory Syndrome (PRRS), a global problem affecting the swine industry worldwide, leads to reproductive failure and causes pneumonia and increased mortality in young animals. In 2013, it was estimated that the annual costs in Spain, Germany and Denmark were €324 million, €275 million and €63 million respectively, and in the US amounted to $664 million ($115 per sow and $5.6 per pig)[29] The cost of gastrointestinal nematode infections with

[24] Keesing, F., Belden, L., Daszak, P. *et al.* Impacts of biodiversity on the emergence and transmission of infectious diseases. *Nature* 468, 647–652 (2010). https://doi.org/10.1038/nature09575

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

[26] https://documents1.worldbank.org/curated/en/110681468054563438/pdf/882570REPLACEM00NAME0Reantaso0Melba.pdf

[27] 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

[28] 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

[29] PRRS cost for the European swine industry - Articles - pig333, pig to pork community; PRRS disease cost | PRRS.com;

resistance against macrocyclic lactones was estimated to be €38 million [€11–87 million] annually[30].

For the period 2007-2013, more than €1 billion was allocated by the EU to fund animal health measures in the MS, from emergency measures to programmes for the eradication, control and surveillance of animal diseases and zoonoses.[31]. The amount is comparable for the period 2014-2021[32]. Up to end of 2021, € 230 million were devoted to ASF related measures.

In addition, diseased animals are treated with antibiotics, leading to increased resistance, further therapy failure in the population and additional costs.

Trade and consumption. Beyond direct costs and losses, AID can lead to major crises disturbing animal-based food trade and supply, affecting public health and jeopardising consumer confidence. The salmonella in eggs scare of the late 80s in the UK is an illustration. At the time of the BSE and AI crises or other zoonotic and food-borne diseases, 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, importantly threatening the pig farming sector in those countries/regions.

One Health perspective. The 'One Health' principle well recognises that human, plant, animal health and the health of the environment are closely linked[33]. If one group is affected, this influences the health of the rest. In a One Health perspective, certain AID have an impact, directly or indirectly, 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 AID are zoonotic[34]. At global level, a study conducted by ILRI[35] showed 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 €3 billion a year. The COVID-19 pandemic has underlined the importance of a robust and resilient food system that functions in all circumstances, and is capable of ensuring access to a sufficient supply of affordable food for all citizens[36]. It has also made us acutely aware of the interrelations between our health, ecosystems, animal reservoirs, supply chains, consumption patterns and planetary boundaries. Spread and

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[30] Charlier J, Rinaldi L, Musella V, Ploeger HW, Chartier C, Rose Vineer H, Hinney B, von Samson-Himmelstjerna G, Băcescu B, Mickiewicz M, Mateus TL, Martinez-Valladares M, Quealy S, Azaizeh H, Sekovska B, Akkari H, Petkevicius S, Hektoen L, Höglund J, Morgan ER, Bartley DJ, Claerebout E. Corrigendum to "Initial assessment of the economic burden of major parasitic helminth infections to the ruminant livestock industry in Europe" [Prev. Vet. Med. 182 (2020) 105103]. Prev Vet Med. 2021 Mar;188:105213. doi: 10.1016/j.prevetmed.2020.105213. Epub 2020 Nov 29. Erratum for: Prev Vet Med. 2020 Sep;182:105103. PMID: 33261929

[31] https://ec.europa.eu/food/system/files/2016-12/cff_updated-report-2005-2013_en.pdf

[32] https://ec.europa.eu/food/horizontal-topics/funding-procurement-grants_en

[33] https://www.onehealthcommission.org/en/why_one_health/what_is_one_health/

[34] 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

[35] https://assets.publishing.service.gov.uk/media/57a08a63ed915d622c0006fd/ZooMapDFIDreport18June2012FINALsm.pdf

[36] OECD Policy Responses to Coronavirus – Food Supply Chains and COVID-19: Impacts and Policy Lessons (2020) https://www.oecd.org/coronavirus/policy-responses/food-supply-chains-and-covid-19-impacts-and-policy-lessons-71b57aea/; Niles, M.T., Bertmann, F., Belarmino, E. H., Wentworth, T., Biehl, E. and Neff, R. The Early Food Insecurity Impacts of COVID-19. Nutrients, 12(7), 2096 (2020). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7400862/

emergence of resistant bacteria also arise in the environment, due to pharmaceutical leaks, pollution, fertilizers of faecal origin, etc. and are passed onto the livestock[37]. It is clear that we need to do much more to keep ourselves and the planet healthy. The increasing recurrence of droughts, floods, forest fires and new pests are a constant reminder that our food system is under pressure and has to evolve towards more sustainability and resilience[38]. Intervention on livestock and other relevant animals will have an impact on public health. 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 livestock[39]. It focussed on poultry, requiring hygienic measures and where necessary, vaccination of animals.

Antimicrobial resistance (AMR) arising from antimicrobial usage (AMU) is another health threat for which veterinary medicine can contribute to find a solution. 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 EU[40]. It is also estimated that AMR costs the EU €1.5 billion per year in healthcare costs and human productivity losses[41]. Sales of antibiotics for use in animals in Europe decreased by 34% between 2011 and 2018 (although the situation remains contrasting among countries[42]). Many countries have implemented action plans based on recommendations of international organisations (Tripartite Food and Agriculture Organization (FAO), OIE, World Health Organization (WHO)). The significant fall in AMU in food-producing animals[43] suggests that the measures taken at country level to reduce use are proving to be effective. Further efforts are needed, however, to reduce, replace and rethink the use of antimicrobials in livestock production and aquaculture, not least following the target set in the Farm to Fork strategy to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030[44].
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 antimicrobials[45].

Nevertheless, the need and necessity for potent antimicrobial treatment will always remain and research in novel drug targets and identification and development of new potent antimicrobial substances is urgent and indispensable. Market and regulatory aspects (e.g. limited patient sample because of identification as reserve antibiotic) form substantial barriers

[37] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6651

[38] A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions COM(2020) 381 final

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

[40] Cassini, A., et al. The Lancet Infectious Diseases, November 5, 2018, 19(1), 56-66. https://doi.org/10.1016/S1473-3099(18)30605-4

[41] http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf

[42] https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac

[43] Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA, EFSA (2021): https://www.efsa.europa.eu/en/efsajournal/pub/6712

[44] A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions COM(2020) 381 final

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

and have to be addressed as well as incentives for research into novel antimicrobials and develop them towards marketability.

Animal health and welfare are connected. There is a link, not much addressed by research so far, between animal health and welfare, and between production conditions and animal health and welfare. While poor animal health is obviously detrimental to animal welfare, animals poorly managed (e.g. stress) are more likely to develop certain diseases and lesions. 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 diseases including zoonoses. The conditions under which animal production takes place and the level of animal welfare therefore should be improved, in first place for ethical reasons, but also to increase health standards. This will decrease needs for veterinary drugs, thus slowing down the possible triggering of antimicrobial-resistant micro-organisms and improving food safety and quality. More resilient animals can also be bred thanks to genetic selection, as well as through interventions to boost the "right" (protective) immune and metabolic response (immunostimulation, host-directed therapies, metabolic rewiring via food).

Societal concerns. Beyond practices that are already widely discussed or rejected (e.g. piglet castration and tail docking, beak-trimming), 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, harvesting and slaughtering of farmed fish) is being called into question. In response to the 'End the Cage Age' European Citizens' Initiative[46] (ECA) and to the demand for a transition to more ethical and sustainable farming systems, the Commission intends to put forward a legislative proposal by the end of 2023 to phase out and finally prohibit the use of cages for all the animal species and categories referred to in ECA[47]. This change may raise new welfare issues as alternative non-cage systems are developed. A Commission consultation on the EU legislation on animal welfare was launched on 15 October 2021[48] and the related inception impact assessment identifies various options for changes in the way animals are farmed, transported and killed as well as proposals for animal welfare labelling including more animal-based measures. In addition to the elements acknowledged above, there is the need to reduce animal testing in research, medicines and vaccine development, hence the requirement for "animal-free models" (in silico, organoids etc.).

One Welfare. Animal welfare cannot be considered in isolation. It becomes increasingly relevant to include and further explore the concept of One Welfare that emphasises the link between animal welfare, animal health, human wellbeing, biodiversity and the environment and complements the One Health concept. Although animal welfare is not explicitly mentioned in the SDGs, there are strong indications for a mutual beneficial relationship between improving animal welfare and achieving several of the SDGs[49]. This should have potential impact on the representations expressed by farmers and other animal workers (job satisfaction, work facilitation, recognition by society ...) and the development of management and housing conditions that improve animal welfare and human wellbeing. Possible challenges should also be addressed, e.g. alternative housing systems (e.g. outdoor, mixed

[46] https://www.endthecageage.eu/

[47] Communication from the Commission on the European Citizens' Initiative (ECI) "End the Cage Age". C(2021) 4747 final

[48] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12950-Revision-of-the-EU-legislation-on-animal-welfare/public-consultation_en

[49] Keeling, L., Tunón, H., Olmos Antillón., G., Berg, C., Jones, M., M., Stuardo, L., Swanson, J., Wallenbeck, A., Winckler, C., Blokhuis, H. (2019) Animal Welfare and the United Nations Sustainable Development Goals. Front. Vet. Sci 6.336 doi: 10.3389/fvets.2019.00336

farming) and increased risk of transmission of pathogens between wildlife and production animals, as well as a reduction in economic profitability when competing with conventional production systems, which currently forms a major barrier in introducing more welfare-friendly production systems.

The Treaty of Amsterdam (1999) recognises animals as sentient beings and calls on the Union itself and Member States, to "pay full regard" to the welfare of animals in agriculture, transport, fisheries etc. Indeed, scientific developments in animal welfare give more insight in sentience of both terrestrial and aquatic animals to support this position. The scientific concept of good welfare has evolved even further, and now includes positive emotions of animals, besides in addition to the well-known "five freedoms of animal welfare". This implies that farm animals cannot just feel pain or fear, but also value positive experiences. There is a growing body of evidence from so-called cognitive bias studies that choices made by animals are affected by their 'emotional state'.

Data on animal welfare. There is a considerable lack of data on the status of animal welfare in the European Union, and the prevalence of welfare problems. Currently, only a limited amount of welfare data is routinely collected, and most of those are related to animal health or food safety issues. The main obstacles for welfare data collection include the lack of standardisation of animal based measures (despite substantial progress being made through EU funded projects such as Welfare Quality®, or AWIN), and the time and expense it takes to collect the measures. Other problems relate to the relative weights and importance that should be given to the various indicators to judge if overall welfare is good or bad. These obstacles need to be addressed.

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

Societal and Economical. An important challenge for health and welfare of animals rests in the socio-economic conditions under which animal production takes place. The social vulnerability of the livestock and aquaculture sectors linked to the loss of public and consumers' confidence, the loss of productivity through endemic and emerging AID, or even the abandonment of the livestock/fish farming by future generations has an impact at individual, family or community level, which is difficult to quantify. 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: Common Agriculture Policy (CAP) indicators), and the income of livestock farmers is usually at the lower end within the agriculture sector[50]. 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, especially when third-country production is not asked to reach the same high standard. 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: in 2018, the global animal healthcare market (pharmaceuticals, vaccines, feed, diagnostic) was estimated to be about €35 billion (current prices), representing a small fraction (3.5-3.8%) of the human medicine market[51].

Technological / scientific. New technologies such as omics (e.g. metagenomics and genomics based on next-generation sequencing technologies) and new vaccine/diagnostic platforms are available and scientific progress in microbiology, microbiome knowledge, immunology, vector biology, new therapies and welfare supportive research find their way in

[50] 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).
[51] Global Benchmarking Survey 2020 – Report for Europe

the sector of animal health, but are still complex and expensive. Opportunities for innovation undoubtedly exist, but are difficult to implement in this vulnerable sector.

AID control needs constant vigilance and continuous research regards emergent risks and unceasing refinement of control instruments. Efficacious preparedness is cost- and labour extensive. Each MS cannot develop sustained research on all aspects of all AID in all relevant species; the epidemiological situation may not require it (see 'Political'). 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.

Environmental. Microorganisms are constantly evolving, spontaneously or under the influence of their environment, for instance other microorganisms, the host, treatments used to control those, chemical compounds, residues, or biocides, increasing water temperatures, etc. 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, SARS-CoV-2, Nipah virus, Hepatitis E), sometimes affecting humans through zoonotic spill-over[52], even leading to the emergence of new forms of diseases in new species or larger epidemics after establishing human-to-human transmission chains. Also vector migration driven by climate change creates further risk for emergence and introduction of new pathogens into hitherto unaffected regions. The environment may as well have a role in the emergence and spread of AMR in animals, potentially jeopardising their health, and certain practices may increase the risks of AMR emergence in the environment (e.g. disposal of manure)[53] as well as of contamination (pharmaceutical leaks, pollution[54], etc.).

Political. While the EU regulatory and policy framework on animal health and welfare aims to ensure a high level of health and welfare, it can be a hurdle for research and innovation:

- The animal health standards in the EU are generally high, and a number of epidemic diseases are absent from Europe, although some disease incursions require temporary eradication measures. Depending on the disease and the epidemiological situation, certain AID may be controlled, notably by vaccination. However, in certain cases, the default control strategy for regulated AID in Europe is a 'sanitary policy' (e.g. avian influenza, bovine tuberculosis, etc.), with testing and elimination of infected animals, which facilitates faster recovery of export access. Indeed, the use of vaccines against certain AID influences the health status of countries and may impinge on the easiness to trade products internationally. In this framework, the EU as well as the global market for veterinary products against regulated diseases, not least for vaccines, is limited and provides little incentive for the industry to develop such control tools. Public research funding may be needed to progress.
- The fight against AMR in a One Health approach requires a number of actions, not least to reduce the (need to) use AMs in both human and veterinary medicine. The market conditions are so that the innovation pipeline is already drying off in the medical domain, but this is even worse for the veterinary sector, where highly critical AMs for human health are subject to extreme restrictions for use in veterinary medicine. Unfortunately, the animal health industry is far from having the capacity to invest and bring new AMs on the market, mainly due to regulatory hurdles and risk

[52] 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

[53] https://www.efsa.europa.eu/en/efsajournal/pub/6651

[54] https://www.frontiersin.org/articles/10.3389/fmicb.2021.603967/full

that new, effective antibiotics will be reserved for human use. Therefore, prevention and alternative to AMs are essential to enable reduction in AMU.

- Each MS tends to try to 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 duplication of research among MS. However, the regulatory framework on animal health aims to align certain aspects of AID control, e.g. detection and surveillance, which stimulates MS to focus on common priority areas and encourages transboundary cooperation.
- Animal welfare remains very important for European citizens. In addition to Eurobarometer results of 2016, this was emphasized recently by the 'End the Cage Age' citizens' initiative, which aims to end "inhumane treatment of farm animals" kept in cages. However, although the EU legislation on animal welfare is recognised globally as advanced, it has not been kept up to date with new scientific knowledge nor the changes in societal perceptions. The last main legislative act on animal welfare was published in 2009. For several farmed species, there is no detailed welfare legislation. The Commission set out plans for a legislative proposal to prohibit cages for a number of farm animals. The proposal will come as part of the ongoing revision of the animal welfare legislation. The usually low benefit margins of farmers in the animal production sector in a global market, make it uneasy for farmers to invest in better animal welfare. The transition process to implement these new rules, the associated technical knowledge and practical solutions to adopt and accept new husbandry and management practices will take time and resources, which may not readily be available within the sector or individual MS.

2.1.3 Main research, development and innovation needs and gaps related to existing policy uptake, and opportunities

Efforts by the EC and MS to improve the surveillance of, preparedness against and recovery from AID concentrates on regulatory diseases and AMR, and undoubtedly created progress. However, past and recent outbreaks (e.g. HPAI, ASF) are showing that more action and coordination is needed in order to improve preparedness[55] and reduce economic losses due to (re)emerging and endemic infections. In addition, regarding animal welfare, a common European plan for the collection and assessment of data is even less developed. A renewed initiative including research and innovation is needed, as the existing approach to animal health and welfare research proved not fully capable of addressing all issues.

New opportunities are offered by upcoming disciplines (at the interface between scientific fields) and technologies that yet require coordination and cooperation of various research and innovation actors to deliver, share and exploit large experiments/data sets.

In addition, 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 avoid duplication and therefore, to encourage complementary developments.

In order to address the above-mentioned challenges and opportunities, the PAHW will bring together all major European players in the field of animal health and welfare. The partnership will facilitate high quality research by organising external open calls that will enable new developments and innovations in the field of animal health and welfare. In addition, PAHW will organise internal calls and other activities that will strengthen the cooperation and

[55] Responding to emergencies through preparedness and resilience - OIE - World Organisation for Animal Health

collaboration of animal health and welfare stakeholders, including competent authorities, in order to enhance their preparedness against future animal disease outbreaks (including zoonotic diseases and AMR that threaten public health) and to reinforce animal welfare of livestock and aquaculture throughout Europe.

Surveillance systems for animal health and welfare based on innovative diagnostics solutions

For many AID, official **surveillance and monitoring programmes** exist, often in the context of the European legislation and supported by OIE's guidelines[56]. The EU has set up a number of European reference laboratories for selected infectious diseases in animals, also in food and feed[57]. Other surveillance and monitoring programmes have been set up in some MS, often for endemic production diseases. Existing European and international networks of AID reference laboratories (e.g. OIE, FAO) and research centres offer a unique opportunity to build a partnership, providing a solid community that can be further built on. For animal welfare the monitoring programmes are less well developed. The EU has set up three EU reference centres for animal welfare (EURCAWs), but their mandate does not include the routine collection of data. Indeed, the European Food Safety Authority (EFSA) has more than once identified a lack of standardised and readily available data for risk assessment to support animal welfare policies. Strong research coordination, both on animal health, including wildlife, on animal welfare and on cross-sector collaborations, will help strengthen preparedness to prevent and respond to infectious AID, support national and EU policy development on animal welfare, standardise methods and harmonise their implementation where relevant, reduce wasteful duplication, ensure joint efforts, enable synergies and maintenance of a know-how at the European level.

By including new methodologies and advanced technologies, such as video imaging and machine learning, **diagnostics and welfare assessment** may be improved (more rapid, early, cost effective and reliable), thus improving the overall detection and characterization capacity. An animal health example is Next Generation Sequencing (NGS), which needs further efforts to be integrated and implemented as a routine method for monitoring and surveillance of animal health in the EU. For animal welfare assessment, novel -omics techniques could be developed for post mortem detection of chronic stressors during the animal's lifetime, or rapid sensor technologies to detect e.g. bruises and skin lesions on carcasses processed in high-speed slaughter lines. Data on AID other than regulated diseases, as well as data of animal welfare, are uncommon and scattered. Data science can be harnessed for extraction and interpretation of epidemiologically relevant data from multiple digital sources along the entire value chain from primary production to harvest and processors, retail and ultimately consumers (on lab, on farms, at the slaughter line, data collected at country/local level, population data, production data, quality assurance systems, meteorology, habitat and vector monitoring, and many others), shared and combined, thus potentially providing near real-time monitoring of health and welfare issues, and thus the earliest possible warning of potential areas of concern. In most, if not all, of the above listed opportunities, the application of machine learning techniques is poised to accelerate and transform exploitation of the cognate datasets.

Risk assessment and alert systems

Scientific information arising notably from surveillance/monitoring and tools for **risk assessment** are important to properly identify and control animal health and welfare problems, and to timely intervene if needed. Delivering on sufficiently detailed epidemiological data requires development of new platforms and tools including e.g. sensor

[56] OIE Terrestrial and Aquatic Code and Manuals https://www.oie.int/en/what-we-do/standards/codes-and-manuals/#ui-id-2

[57] European Union Reference Laboratories.

development, real-time data collection, mathematical modelling and methods to handle big data, standardisation, and ambitious coordination, sharing and cohesion among actors at a pan-European level, regarding both animal health and animal welfare. Such detailed data will contribute to the estimation of the health or welfare problem / burden of disease, which in case of zoonoses is also relevant for public health.

The rapidly developing **omics technology,** notably 2nd and 3rd generation sequencers, can be exploited, for example, for discovery of pathogens and prediction of their evolutionary trajectories and risk of emergence. The omics technology also allows for comprehension of microbial ecology (metagenomics), with the ambition of piloting microbial ecosystems of animals to promote animal health, resilience to stressors, and reduce the need to use antimicrobials. Datasets obtained by other high-throughput omics approaches, not least genomics, which can increasingly be extended to complex pathogens and arthropod vectors, but also transcriptomics, proteomics and metabolomics, can now be integrated in surveillance programmes and laboratory strategies to provide systems-level understanding of host-pathogen interactions, thus disclosing unsuspected vulnerabilities amenable to immunological or therapeutic intervention. Metabolomics will help to identify chronic stress situations on farm, and allow assessment of welfare improvement measures in a standardised and routine way. Omics based on high throughput 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. They can also help designing adjunctive therapies such as host-directed therapies, immunostimulation and metabolic reprogramming to help the host fighting pathogens. Trained immunity for example is a concept that should be developed for farm animals as it is now for humans. Personalized medicine is an intensive area of research and development in human medicine and ambitious programs should also be undertaken to go towards personalized veterinary medicine. This will need to develop data science and machine learning on farm animals' biological parameters.

Farming practices

The development of various, digitally assisted, **on-farm monitoring technologies** is increasingly enabling precision management of animal health and welfare. Some examples are the determination of the welfare status of animals from animal-based measures such as the sound they make, their movements, spatial organisation in the group or fish tank, feeding and drinking behaviour and their social interactions. In addition, there is substantial scope to further develop and operationalise bio-sensors that record body temperature, blood pressure, heart rate, brain activity and other indicators related to endocrine, neural and digestion processes. The search for these and novel animal-based indicators requires a multi-disciplinary approach, including physics, sensor development, mathematics, artificial intelligence, etc.

Research is also needed to improve the knowledge about how and to what extent animal welfare is affected by the levels of physiological stress and the immune response, by using state-of-the-art technologies like transcriptomics. New husbandry systems allowing greater behavioural freedom will require applied research. Such systems will require new knowledge on issues like space allowance, weaning age and accommodation, indoor versus outdoor housing conditions, global warning and increasing ambient temperatures, ventilation and novel feeding solutions, etc. There are also several management aspects that require more investigation: examples are the welfare of young animals, e.g. how to lower their mortality and how to raise them (hygiene / biosecurity, enriched housing, presence of mother or other adult, etc.). Another area where additional knowledge is needed and existing knowledge has to be applied is animal transport: how to deal with heat stress, lack of space allowance and fitness to travel. Similarly, stunning and killing practices need to be adopted to the latest scientific evidence on consciousness and pain perception, as do painful management

procedures such as castration, tail docking and beak trimming. For the latter, activities to develop and improve husbandry systems and practices have to be initiated to reduce or to make them redundant. Finally, breeding strategies and other approaches to promote resilience and welfare of animals need to be developed. We need to understand why and to what extent improved well-being makes animals more resilient to infectious and non-infectious diseases, in terrestrial as well as in aquatic animals. On the aquaculture side there is a clear need to develop codes of good practice on the management of aquatic diseases that are not regulated, particularly for the shellfish sector concerning live movements. Above all, to make sure these novel husbandry systems and management practices will be used, they need to be effective from an animal health and welfare point of view, as well as achievable for the farming industry.

Treatment, prevention and vaccines

As regards **therapeutics**, a continuous challenge is to avoid the further development of resistance to treatments. Inevitably, animals are becoming ill and will need treatment, also with antibiotics or anthelmintic drugs. Antimicrobials are essential for the wellbeing of the infected animals and to avoid production loss. At the same time, antimicrobials should be used prudently and according to evidence-based guidelines to maximally avoid resistance. With the reduction in the availability of antibiotics (some of which are critical for human use), the search for alternatives to antimicrobials needs to be strengthened, either as means of treatment or for prevention (e.g. feed additives) as well as the search for novel antimicrobials. Resistance to anti-parasitic treatments, notably against helminths and coccidia is growing and requires new approaches and products.

To move from a curative approach to a more intensive **prevention of diseases**, further efforts are needed on biosecurity and on ways to promote resilience of animals, areas where many knowledge gaps exist and can be addressed by research and innovation. A better knowledge of the animal immune and metabolic system is needed to propose new interventions to rewire it and improve resilience of farmed animals. Early and predictive signatures (immunological metabolic) of the clinical status of an animal (productive infection and shedding) would also greatly help farmers to remove contaminating individuals from flocks/herds and which could avoid massive culling of the animals. The development of preventive measures, including novel housing systems and management practices 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. In preventing the appearance or the extension of diseases, vaccination of animals 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, bluetongue). For other diseases (e.g. ASF), 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. For farmed fish production, the development of cost-effective vaccination protocols is especially difficult due to the generally shorter immunological memory of these animals. With modern technologies (cfr. mRNA vaccine technology or multimeric scaffold particles) 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, and last but not least new insights into the working of the immune system before products could be ready for commercialisation. The authorization process may need adaptation, also taking into account what is learned from the COVID-19 pandemic. In general, platform approaches

allowing a faster and more flexible reaction on pathogen threats have to be further supported and optimized.

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 vaccine is in the licensing process 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 and 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.

The epidemiological situation regarding ASF made it possible to attract funders and mobilise additional budget to launch the ERA-NET on the international coordination of research on infectious animal diseases in 2019: ICRAD[58].

However, ASF is already implying huge costs to the sector/EU measured in billions of Euros. 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 efficiently tackle emerging infectious diseases such as ASF in an early stage. The costs of such a partnership are negligible when comparing the costs of a pan-European ASF outbreak.

2.1.4 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' (Thematic Priority 8). FP7 funded a number of projects on animal health and welfare, welfare being often embedded in other aspects of animal production[59].

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 comparable[60].

Collaborative projects were organised in most sectors, in certain cases with the industry, but there were hardly any collaborative projects of pan-European nature and little strategic interaction with industry upstream (few projects seem to have led to uptake by the industry). The European Technology Platform on Global Animal Health[61] was put on hold during FP7. Still the DISCONTOOLS FP7 project[62] was a tangible result, providing a tool to prioritise

[58] www.icrad.eu

[59] '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)

[60] https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/factsheet-agri-animals-health_en.pdf; https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/factsheet-agri-animal-production-systems_en.pdf

[61] https://cordis.europa.eu/project/id/22515

[62] www.discontools.eu

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 is among the sources that will be used to elaborate the SRIA. In that way, PAHW will link with the industry to enable a strategic approach to support innovation and to develop pan-European activities.

There was much more coordination among public research actors during FP7 and H2020 work programmes. 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 research (CWG AHW)[63], on the basis of which ERA-NETs arose, as well as an international network of research funders, STAR-IDAZ.

STAR-IDAZ is an international network of public research funders aiming to maximise global coordination on animal health research, supported by FP7, and followed up by an International Research Consortium (STAR-IDAZ IRC)[64]. Throughout its global and regional activities, STAR-IDAZ has established a network of organisations managing research budgets or programmes, which counts around 70 countries among members and associated countries opening new avenues for global cooperation.

CWG AHW developed a Strategic Research Agenda, with the latest version in 2018[65]. The CWG collaborated with the SCAR Strategic Working Group SCAR FISH, to develop a SRA on disease prevention in farmed fish[66]. Comparable documents were developed on animal welfare[67].

There is a history of successful EU public-public research partnerships mainly ERA-NETs: The FP7 EMIDA[68] (animal infectious diseases), followed by ANIHWA[69] (animal health and welfare), succeeded in mobilising in total over 70 million euros in 5 joint calls funded from member countries.

ICRAD ERA-NET for international coordination of research on infectious animal diseases[70], with 28 funding partners from 14 MS, 3 ACs, plus Russia and Switzerland, started in October 2019; Its first call mobilised 20 million euros and a second call was launched in 2021. Those activities provided improved collaboration on research prioritisation and procurement for public institutions while companies were involved marginally into research projects until now. It is expected that a number of funding organisations in ICRAD will join the PAHW consortium.

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 Production[71], and CORE Organic Co-fund on Organic Food and Farming Systems[72].

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63 www.scar-cwg-ahw.org

64 www.star-idaz.net

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

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

67 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

68 https://www.era-learn.eu/network-information/networks/emida

69 https://www.era-learn.eu/network-information/networks/anihwa

70 www.icrad.eu

71 https://era-susan.eu/

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

The One Health EJP co-fund project[73] under Horizon2020 is a consortium of 44 partners from 22 European countries and is composed of partners from animal health, public health and food safety research performing organisations (RPO) with reference activities. A number of these centres, among which the level of 'trust' is high, are very relevant for PAHW as they have reference activities in animal health and/or welfare. Ample experience has been acquired on preparedness, on epidemiology and cross-sector collaboration undertaken through projects performed following internal calls with provision of in kind resources by consortium members. It therefore represents a solid basis for PAHW.

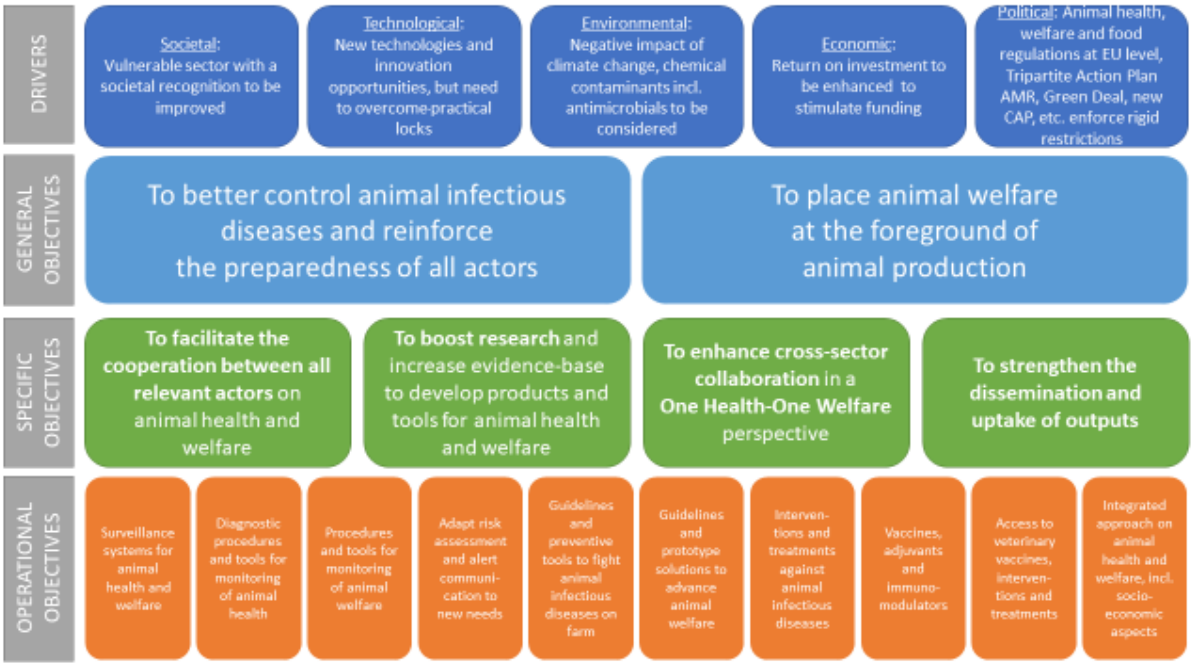
The EPIZONE network on epizootic disease diagnosis and control[74] was started under FP6 as a Network of Excellence and thereafter successfully followed up by the self-sustainable EPIZONE European Research Group[75], which is now the largest European Research Network on Epizootic animal diseases, including those that may have zoonotic potential. EPIZONE will be invited as a PAHW partner or stakeholder, in order to benefit from its expertise and activities.

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. Notably, PAHW will mobilise a critical mass of resources; stronger collaboration with industry will ensure that research and innovation activities performed at low to high Technology Readiness Levels (TRLs) will facilitate uptake of results by industry and other users.

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, specific and operational objectives of PAHW.

Figure: Intervention Logic of PAHW



[73] www.OneHealthEJP.eu
[74] https://cordis.europa.eu/project/id/16236
[75] https://www.epizone-eu.net/

2.2.1 Vision and ambition

The vision of the PAHW is to provide society with reassurance on the control of infectious animal diseases with appropriate means, where antimicrobials are prudently used, and on the respect and improvement of the welfare of animals, thus contributing to sustainable animal farming and the protection of public health and the environment. This vision and ambition will be achieved through strengthened cooperation between public research and innovation entities, and the association of relevant partners, including relevant authorities, the animal health industry, other stakeholders, including animal welfare NGOs.

The ambition of PAHW is to build a strong research and innovation framework strengthening Europe's capacity to raise healthy animals and to improve welfare standards.

2.2.2 General objectives

For the purpose of this partnership, **animals** mean living farmed/managed animals, whether **terrestrial or aquatic**[76], including bees, as well as companion animals and wildlife when there is a potential threat to public health or health of production animals. Causative agents responsible for animal infectious diseases (AID) include bacteria, viruses, parasites, fungi and prions. Activities related to sustainable farming and breeding are in scope of PAHW as long as they can be directly linked to animal health or animal welfare. All production systems are considered, including for instance organic farming.

PAHW focuses on following areas:

1. Regulated and emerging diseases (AID) for which prevention and control has an important policy dimension because of their impact on animal health, food production/safety, regional or global trade and public health.
2. Priority production and endemic AID that cause detrimental economic losses to farmers and the animal production sector, and may lead to weakened animal welfare, increased antimicrobials use and, consequently, risk to public health and health of ecosystems. Some of those diseases are often complex to control and may be notifiable in a number of countries.
3. Animal welfare, to strengthen the well-being of animals and accommodate animals' needs societal and political demands and a growing interest from the market. Improved welfare and research on animal welfare will also support prevention of disease, e.g. by improved resilience of animals against AID.

The PAHW will reinforce the One Health-One Welfare principles and will reach out to authorities responsible for and scientists active in the sectors of animal health, animal welfare, public health, food safety, economic sustainability and the environment. The area of activities will include farm management, animal based (welfare) measures, livestock resilience, zoonoses, vector-borne, food-borne pathogens and emerging diseases at primary production, and issues such as AMR.

It should be noted that research relating to AMR is being defined in cooperation with and complementary to the planned EU Partnership One Health – AMR. Similarly, as regards animal welfare cooperation is planned with the EU Partnership on Agroecology.

[76] Aquatic animals include marine and freshwater fish.

The general objectives of PAHW are as follows:

GO1 To better control animal infectious diseases and to reinforce the preparedness of all actors

Improved animal health surveillance, more accurate diagnostics, risk assessment tools adapted to new types of data, modern farming practices including efficient biosecurity management, and new or better vaccines/treatments, will lead to less production loss, decreased use of antimicrobials and reduced AIDs with possibly less spill-over of zoonotic infections and resistant germs to humans.

Potential indicators:

- Reduced occurrence of some selected AID.
- Reduced use (sales as an estimate) of antimicrobials in livestock production and aquaculture.
- Reduced burden (e.g. economic, societal) of some selected AID.

GO2. To place animal welfare at the foreground of animal production

Mitigating or removing animal welfare challenges addresses societal concerns, increases animal resilience to diseases that may impair productivity, and deepens the understanding of the links between animal health and welfare. Research on animal welfare will accompany the implementation and further development of the new European animal welfare legislation and contribute to increase the interest of food chain actors and consumers in improved animal welfare. Finally, a One Welfare approach will strengthen both human wellbeing and animal welfare and facilitate sustainable livestock production and aquaculture.

Potential indicators:

- An increase in available data on trends of animal welfare at farm, transport, at slaughter in the EU for policy, commercial and scientific purposes (EFSA, OIE, EU Reference Centres for Animal Welfare)
- A significant reduction or ban of inadequate husbandry systems and management practices
- A wider adoption of animal welfare labelling systems in Europe

2.2.3 Specific objectives

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

SO1. To facilitate the cooperation between all relevant actors on the monitoring, prevention and control of AID and on animal welfare issues

Offering all public and private players in the field of animal health and welfare the possibility to set up research and other kinds of integrative activities, training and education actions, and to share experience, will lead to a reinforced cooperation that will support the realisation of the general objectives of PAHW.

Potential indicators:

- Needs from stakeholders integrated in the PAHW call organisation and experimental designs (e.g. industry, regulation).

- Number of organizations taking part in joint integrative activities (common research projects, PhD, other activities, i.e. harmonization of methodologies, ring trials, simulation exercise, etc.).
- Number of new formal collaborations (MoU and alike) and shared resources/tools, including experts (e.g. AHW specialists, risk assessors, economists, social scientists, ethologists…), biobanks, sort term missions, etc. between organizations and stakeholders, common webinar or meetings to exchange information and results.

SO2. To boost research and to increase the evidence-base to develop products and tools for animal health and animal welfare monitoring and control

Joint transnational research and other research and innovation activities will create new knowledge, methodologies, techniques, procedures, data and databases, models, system designs, insights, networks and products, etc. that will be available for further uptake.

Potential indicators:

- Number of joint transnational calls organised, number of projects selected for funding.
- Number of scientific papers/communications produced by PAHW.
- Number of novel deliverables (i.e. methodologies, techniques, procedures, data and databases, models, preventive/curative/diagnostic tools, etc.) produced.

SO3. To enhance cross-sector cooperation and collaboration (One Health-One Welfare perspective)

The contribution of PAHW to a multidisciplinary approach (i.e. the design and implementation of surveillance and monitoring systems, the harmonization of tools and procedures, the design of husbandry systems and management practices, the alignment of the risk assessment, etc.) across sectors dealing with animal health and welfare, public health, food safety, farm economics and the environment regarding zoonoses, antimicrobial use and resistance and animal welfare will enable targeting actions contributing to sustain the health and welfare of animals, people and ecosystems.

Potential indicators:

- Number of initiatives that have been set up across sectors, i.e. regarding design and implementation of welfare monitoring and disease surveillance systems, laboratory methods, risk assessment, with PAHW involvement and that support public health.
- Number of cross-sector PAHW outputs, e.g. common publications on epidemiology and trends of zoonoses or AMR, on farming's effects on animal welfare and the interrelated impact on public and animal health.
- Number of contributions (e.g. reviews, studies, trials, etc.) from PAHW to wider One Health-One Welfare initiatives like Tripartite + or other.

SO4. To strengthen the dissemination and uptake of project outputs to societal, political and private stakeholders

Upstream and continuous interaction with stakeholders to identify their needs and demands, general and targeted communication on the outputs of PAHW, both dealing with animal health and animal welfare, dissemination of its deliverables to partners, national and international stakeholders, and to all other possible users, will stimulate their uptake and implementation all over Europe.

Potential indicators:

- Uptake of PAHW outputs by EU reference laboratories and EUCAW.
- Use of PAHW outputs in reports/opinions of EFSA & ECDC, in global reference bodies (e.g. OIE, FAO, WHO), in EU regulatory initiatives, EU and MS welfare labelling schemes, regarding treatments/vaccines by the European Medicines Agency (EMA).
- Uptake of PAHW outputs by livestock industry and other end users: Intellectual Property Rights/ patents/ marketing authorisations secured, filed or granted or in progress.
- Increase in the number of research projects from open calls in which an industrial partner is involved, compared to ERA-NETs (target 30%).
- Number of new procedures, endorsed in day-to-day practice in laboratories and welfare reference centres.
- Number of innovations at Low TRL (Technology Readiness Level) that have been brought to a high(er) TRL.
- Number of leaflets, newsletters, website visits, meetings and webinars with external participants.

2.2.4 Operational objectives

The following operational objectives are defined together with proposed activities and some envisaged indicators.

OO1. To design and harmonize surveillance and monitoring systems for animal health and welfare

Action 1. Optimize and extend to other countries current surveillance systems for animal health and zoonotic infections and to develop new ones where needed.

Action 2. Set up a European wildlife network (both terrestrial and aquatic animals), based on existing wildlife disease surveillance and reporting systems, to coordinate and expand their activities, to analyse wildlife populations in Europe, and to analyse what specific data with reference to potential threat to animals and humans are needed.

Action 3. Create networks that bring together bio-informatics and epidemiology, to harmonize metagenomic data and data collection methods, to integrate genomic, clinical and epidemiological data, applicable to both livestock/aquaculture and wildlife.

Action 4. Monitor pathogens of veterinary importance (that are not covered in One Health calls) and their antimicrobial resistance profiles.

Action 5. Build networks, develop FAIR data and implement FAIR principles for the monitoring of (re)emerging animal health and welfare issues, and to develop a hazard monitoring and early warning service.

Action 6. Create a platform on animal welfare in the EU with the objective to provide scientific and technical support to all stakeholders, in particular related to data necessary for the monitoring of animal welfare; develop animal welfare surveillance systems and their evaluation.

Potential indicators:

- Number of networks and reports related to surveillance of health and monitoring of welfare in livestock and aquaculture and wildlife.

- Number of guidelines concerning genomic surveillance of AIDs or AMR in animal pathogens (that are not covered by other calls).
- Number of pilot studies on novel or improved methods and tools for surveillance and/or participants in those studies.

OO2. To develop diagnostic procedures, methodologies and tools to support the monitoring of animal health

Action 1. Gain knowledge on priority pathogens (i.e. bacteria, parasites, viruses, fungi, prions including resistance patterns) responsible for important economic losses or high risk of transmission to humans and their detection methods, including metagenomics approaches, molecular markers of interest, etc.

Action 2. Development, optimisation and standardisation of reliable, faster, potentially automatable and/or scalable direct antigen/genome amplification/detection and indirect detection/immune response assessment tools/technologies; tools for the rapid detection of drug-resistant bacteria, viruses, fungi or parasites; on-farm, pen-site diagnostics for pathogens and antimicrobial resistance; focus on priority pathogens and those that do not have EURL.

Action 3. Development, optimisation and standardisation of tools to distinguish between (i) infected and vaccinated individuals (DIVA) as well as (ii) dead and infectious pathogens for the study of pathogens survival in the environment or in effluents and (iii) to study of inter-species (including wild animals) circulation of pathogens or resistant variants.

Action 4. Development of quantitative and multi-target diagnostics to identify infection levels and silent microorganisms that can interfere with animal production for informed treatment/prevention measures decisions in enzootic production diseases in animals.

Action 5. Development of non or less invasive and more convenient sample collection methods, including new matrices as well as transport, storage, treatment strategies and corresponding diagnostic tools, also suitable for the detection of diseases in free-ranging or wild animals.

Action 6. Application of new methodologies, i.e. research focusing on application of new detection and characterisation methodologies, on in vitro models; study host-pathogen-environment interactions, i.e. focusing on drivers and markers, on characterisation of microbial ecosystems, on drivers of resistance.

Potential indicators:

- Number of scientific publications (general, across pathogen-types, across animal species, considering AH & AW integration, considering One Health).
- Number of new markers for e.g. host response/vaccine efficacy, drug resistance/efficacy, variants, zoonotic potential, infectivity/virulence, etc.
- Number of new diagnostic procedures, validated and harmonized.
- Number of new reagents developed, optimised, automatized and/or harmonised.
- Number of new biobanks, stocks of reference materials, models etc. to be shared with other partners.

OO3. To develop procedures, methodologies and tools to support the monitoring of animal welfare

Action 1. Focus on positive welfare (positive emotions), identification of behavioural, endocrine and neurological indicators of positive welfare: research focusing on animal cognition, preferences and motivation to obtain rewards.

Action 2. Development of technologies on the slaughter line to assess animal welfare (on farm and/or during transport). Identification of suitable animal-based measures (ABM) with appropriate level of validity, sensitivity and specificity; development of in-line sensors, large scale data collection.

Action 3. Animal welfare at slaughter: i) consciousness and death: development of technologies, procedures and/or protocols to increase the reliability of methods to assess consciousness and death at the slaughter line; ii) improve stunning and killing methods; iii) work on design of slaughter facilities in order to avoid welfare issues like stress, fear and pain at pre-slaughter phase; related staff training.

Action 4. Development of physiological indicators to measure acute and chronic negative animal welfare consequences on farm. The indicators should identify stress, pain, fear, discomfort, etc. at individual and group levels: measure of physiological stress, impact on immune response and omics (e.g. transcriptomics and metabolomics). Integration of these to metadata welfare tools.

Action 5. Development of digitally assisted monitoring technologies on farms for increasingly enabling precision management of animal (health and) welfare. Technology includes recording visual and auditory signals related to animal-based measures for welfare, analysing records with deep learning technology, data processing techniques and decision support systems.

Action 6. Development of technologies to assess animal welfare during transport. Affordable and reliable solutions to prevent serious welfare problems through early detection of signals before and whilst in transit, e.g. lameness, lesions, heat stress, aggression, thirst or hunger, exhaustion, etc. Development of sensor technology, data analysis tools, data collection and integration platforms, decision support for the driver; related staff training.

Potential indicators:

- Number of scientific publications on the assessment of welfare on farm, during transport and at slaughtering.
- Number of new welfare indicators and markers endorsed by the animal welfare community.
- New guidelines and tools, e.g. for welfare diagnosis, for monitoring positive animal feelings, etc.

OO4. To adapt risk assessment and alert communication to the new needs in animal health and welfare

Action 1. Enhance rapid risk and consequence assessment methodologies, to assess the economic, social, environmental and cross sectoral consequences of animal health and welfare issues.

Action 2. Study and assess epidemiological associations between human interventions such as hunting, trade, transport, rewilding and translocations of wildlife and disease spread, in order to propose harmonized tools to support alert systems.

Action 3. Adapt existing, or develop new methodologies to integrate genomic surveillance data in risk assessment and to draft risk assessment guidelines for the integrated use of epidemiological and genomic data.

Action 4. Assess the risk of spread of resistant animal pathogen clones and genes encoding resistance.

Action 5. Build or further map and coordinate emergency networks for scientists and communities, to increase risk knowledge by systematically collecting data and undertaking

risk assessments (availability of risk maps and data, knowledge on hazards and vulnerabilities).

Action 6. Develop animal welfare surveillance and its evaluation, develop indicators and alarm levels, produce factsheets and any relevant digital infrastructure that enable risk assessment of any breach in animal welfare.

Potential indicators:

- Number of existing networks, methods, tools, data and protocols mapped, described and analysed.
- Number of new assessment guidelines and models.
- Number of dashboards with integrated data and functionalities for real time management implemented.

OO5. To develop guidelines and preventive tools to fight against animal infectious diseases on farm and during transport

Action 1. Establish a multidisciplinary network of experts with focus on biosecurity measures to prevent and control AID on farm and during transport, and draft foresight and priority studies on animal health, public health, pandemics and the role of biodiversity, the changing climate, emerging vectors and vector-borne diseases, bird and fish migrations, epidemiology/ modelling, bioinformatics, etc. for all animal species, including minority species and aquaculture.

Action 2. Reduce the entrance and spread of AID by reinforcing external and internal biosecurity in both terrestrial and aquatic animals, while limiting antimicrobial use, set up innovative systems and models with focus on biosecurity and integrated management.

Action 3. Perform research on prudent use of antimicrobials: research on treatment concepts for antimicrobial and antiparasitic usage, on alternatives to antimicrobials including feed additives/nutrition, studying improved vaccination strategies, etc.; development of best practices for administration/application of Veterinary Medicine Products (VMP) in livestock and aquaculture production systems.

Action 4. Reinforce animal resilience/resistance (the natural ability of animals to withstand pathogens), through feeding and breeding; establish a pan-European network of experts in genetics (breeding), feed additives including pre- and probiotics and leading experts in immunology to produce foresight and priority reports; both fundamental and applied research supporting animal resilience will be set up.

Action 5. Evaluate the need and possibility to set up a pan-European network of experimental farms.

Potential indicators:

- Foresight reports
- Number of guidelines on biosecurity measures
- Number of research projects on animal resilience
- Number of new concepts / knowledge produced by PAHW and endorsed by breeding companies.
- Number of experimental farms being active part of the network (to be discussed)

OO6. To develop guidelines and prototype solutions that advance animal welfare on farm, during transport and at the end of life

Action 1. Establish a multidisciplinary network of experts to draft foresight and priority studies with focus on sustainability aspects related to non-cage systems, indoor and outdoor systems for livestock, animal transportation and slaughter, killing on farm, in slaughterhouses or at sea, and focussing on ending mutilations, including aquaculture production systems.

Action 2. Perform research on how to improve animal welfare while maintaining or increasing farm economic and environmental sustainability. Involves animal cognitive capacities and emotions adapted to each species' needs, opportunities for pain relief, and environmental enrichments technologies. Aims to develop innovative housing systems and addresses the opportunities and consequences of reducing the use of cages in a sustainable way, in terms of economic and environmental impacts.

Action 3. Perform background science to identify indicators and to develop systems to assess the state of consciousness and death, develop appropriate Precision Livestock/fish Farming and killing technologies to limit pain and reduce stress, alert systems for poor welfare during transport, etc.; develop innovative systems in livestock/fish transport and slaughter.

Action 4. Improve animal welfare through feeding and breeding strategies.

Action 5. Evaluate the need and possibility to set up a pan-European network of experimental farms.

Potential indicators:

- Foresight reports
- Number of on management- and resources-based indicators for animal welfare.
- Number of new welfare technologies on farm, during transport and at slaughter.
- Number of welfare technologies brought to higher TRL levels.
- Number of experimental farms being active part of the network (to be discussed)

OO7. To develop new interventions and treatments, or improve existing ones, against specific priority animal infectious disease

Action 1. Perform basic research (TRL 1-2) to study interactions between pathogens and host microbiome, focussing on the immune system (e.g. pathobiome), and direct or indirect interactions between pathogens (e.g. co-infections), antimicrobial and antiparasitic drugs and host microbiome, mechanisms of anti-microbial (antibiotic and antiparasitic) resistance; trained immunity.

Action 2. Develop tools such as (i) experimental farm approaches; (ii) in vivo, in vitro and in silico infection models for testing efficacy and safety of new drugs with reduced need for animal testing, new drug-delivery devices, therapeutics including leads for new antimicrobials; and (iii) bioinformatic pipelines for analysis of microbiome and pathogen data; this will be done in collaboration with industry, where appropriate.

Action 3. Build on the results of Action 1&2 to develop or improve interventions and treatments and deliver first proof of concept, where appropriate, in collaboration with industry: demonstration of immunogenicity and efficacy (minimum immunizing dose) in target species; representative (small scale) animal (challenge) model (TRL 3-4)

Action 4. In collaboration with industry: bring outputs to higher TRL in early/pre-clinical development (GMP-material; TRL 5-6); (i) for non-food animals: demonstration of efficacy and field safety at large scale in representative animal models or approved alternative methods; (ii) for food animals: lab-scale assessment of animal safety and initiation of

environmental safety, user safety, and (if needed) microbiological safety assessments; absence of toxicity/side effects; carcinogenicity studies initiated if needed, and demonstration of efficacy and field safety at large scale in a representative animal model and toxicology studies. Work on TRL 7 to 9 (late/clinical development, marketing authorisation and lifecycle management) will be performed by industry itself.

Potential indicators:

- Number of evidence based treatment schedules.
- Number of novel drugs, immune-modulators, alternatives to antimicrobials.
- Number of devices for individual and group treatment of animals.
- New tools such as improved (and standardized) assays for assessing efficacy and safety of drugs.

OO8. To develop new vaccines or improve existing vaccines, including adjuvants and immune-modulators

Action 1. Study the role of the immune system of farm animals, including the innate immune capacity of new-born animals; the mechanisms that elicit protective immunity at the entry site, factors affecting immune response to vaccines, mode of action of adjuvants (basic research; TRL 1-2).

Action 2. Develop tools such as vaccine platforms and expression systems, immunological toolboxes (cell lines, reagents, etc.) and delivery systems, etc.; this will be done in collaboration with industry, where appropriate

Action 3. Build on the results of Action 1&2 to develop or improve vaccines and immune-modulators and deliver proof of concept: demonstration of immunogenicity and efficacy (minimum immunizing dose) in target species; representative (small scale) animal (challenge) model (TRL 3-4) or approved alternative methods; this will be done in collaboration with industry, where appropriate.

Action 4. In collaboration with industry: bring outputs to higher TRL in early/pre-clinical development (GMP-material; TRL 5-6); (i) demonstration of animal safety in target and non-target species; and (ii) demonstration of efficacy in a representative and validated target animal challenge model. Work on TRL 7 to 9 (late/clinical development, marketing authorisation and lifecycle management) will be performed by industry itself.

Potential indicators:

- Number of models, immunological and computational tools.
- Number of potency tests to evaluate efficacy of vaccines (3Rs).
- Number of new pilot vaccines and adjuvants developed.
- Number of vaccine platforms, platforms for antigen discovery, production and delivery.
- Number of new or improved delivery systems.
- Number of new immune-modulators developed

OO9. To increase access to veterinary vaccines, interventions and treatments and uptake of said vaccine interventions and treatments in the field

Action 1. Monitor the results of the PAHW projects and evaluate if they can be the basis of new patent applications.

Action 2. Manage intellectual property (IP) and further development of the deliverables towards European Innovation Council (EIC) or similar programmes and industrial partners.

Action 3. Prepare the regulatory process for novel and innovative vaccines and treatments developed by the PAHW, with implementation of regulatory experts (for each of the projects in the implementation phase), interaction with national regulators and with EMA, taking into account its recently published paper (Regulatory Science Research Needs[77]).

Action 4. Develop methods and procedures for comparative evaluation of clinical efficacy of veterinary antimicrobials to feed into antimicrobial guidelines and policies.

Potential indicators:

- Number of advices on regulatory aspects for each vaccine/treatment-lead.
- Number of business plans for new vaccine/treatment-leads that will be successful at the end of the implementation phase.
- Procedures for comparative evaluation of clinical efficacy of veterinary antimicrobials.
- Guidelines for registration of alternatives to antibiotics

OO10. To develop and integrated approach on animal health and welfare including socio-economic aspects of animal health and animal welfare

Action 1. Assess the burden of selected priority diseases (including resistant pathogens), including their control (e.g. cost-benefit of different surveillance components and risk mitigation options).

Action 2. Set up social science studies among farmers, consumers and other actors along the production chain on their behaviour (also in relation to AM use) to maintain and improve animal health, including consumers' willingness to pay for improvements; incentives and barriers to adopt innovations and practices.

Action 3. Set up social science studies among farmers, consumers and other actors along the production chain on their behaviour to maintain and improve animal welfare, including consumers' willingness to pay for improvements; incentives and barriers to adopt innovations and practices, including welfare labelling schemes.

Action 4. Study the integration of AID mitigation and improved animal welfare in the overall context of sustainable livestock production and aquaculture in the EU.

Action 5. Develop integrated strategies for the control of diseases, including emergency situations, taking into account relevant criteria, e.g. epidemiological situation, cost-benefit, etc. in order to support decision making by national and international risk managers and other relevant stakeholders.

Potential indicators:

- Number of scientific publications on socio-economic studies related to health and welfare
- Number of new animal welfare labelling schemes initiated by MS and / or industry
- Number of policy briefs on intervention strategies

[77] https://www.ema.europa.eu/en/documents/other/regulatory-science-research-needs_en.pdf

2.2.5 Amount of R&I investments needed to achieve impacts

A first estimation of R&I investments has been done in line with the objectives and proposed activities. Considering the breadth of the scope of PAHW, prioritisation will need to be made through continuing consultation of potential partners as well as stakeholders. Such a consultation has been done for drafting the dossier during dedicated webinars and is planned for the SRIA that will be developed in the course of 2022 as well as for its continuous update.

Activities will need to match the budget available to PAHW, both for animal health and for animal welfare, both for terrestrial and aquatic animals. Therefore, while this section provides indications on budget needed, it will be completed once the resources and budgets made available by partners to PAHW are known. Member States and interested Associated Countries will be invited to communicate their indicative commitments during the first months of 2022.

In order to achieve optimal integration of public research actors (RPO like research centres, reference laboratories and reference centres) supported by funding organisations (FO), and thus generate essential new knowledge that supports innovation in the fields of PAHW (support of livestock and aquaculture, public health and animal welfare), the budget should be a significant proportion of national expenditures (MSs spend circa €300-€400 million/year). Mobilisation of resources will depend on whether resources and programmes are redirected and aligned within activities of RPO members of the PAHW consortium (internal activities including research calls mostly with in kind contribution), and/or whether research activities are performed mainly through external calls requiring 'in cash' funds from FO.

The contribution from the private sector (industry) will depend on the number of FO that can fund industry and on industry's commitment to participate to the PAHW with their expertise and in kind contribution. For instance, the animal health pharmaceutical industry spends circa €500 million/year in R&D including for pet animals, i.e. 7.8% of their turnover [78] (livestock including birds represent around 50% of the turnover).

The animal health industry or other relevant sectors (e.g. feed industry) will not be member of PAHW consortium, but can contribute (i) as member of the stakeholder committee and/or the scientific advisory board to discuss the industry's needs and/or to evaluate the market potential of technologies in projects; and (ii) through in kind contributions in R&I projects selected through external calls, in particular for those projects at TRL 4 or above (early/pre-clinical to late/clinical development).

On surveillance, the various activities considered on animal health and welfare amount to around €80 million, with a balanced share between the 6 themes proposed: livestock health surveillance, wildlife health surveillance, genomic surveillance, AMR surveillance, horizon scanning using FAIR data, and welfare surveillance.

Estimation of work related to support to monitoring of animal health, including diagnostics and animal welfare, as well as on risk assessment, is not easy to estimate. It will be a domain where significant, possibly expensive, basic research will be needed, to support epidemiology, diagnostic, treatments and vaccine development and uptake. It will depend largely on the diversity of pathogens targeted. €100 million would enable to undertake substantial research.

On farming practices, the various activities considered amount to around €60 million, with a balanced share between the 5 themes proposed: preventive tools (other than treatments/ vaccines) to fight AID, reduction of AMR (e.g. biosecurity), increasing resilience (e.g.

[78] https://www.animalhealtheurope.eu/resources/124:facts-figures-2020.html

through breeding), prototype solutions to advance animal welfare, respectively 'on farm' and 'during transport and at the end of life'.

According to figures from business intelligence, development cost of veterinary vaccines is on average in the area of 10-20 million euros[79]. This is much less than in the medical domain, where cost was estimated to be around USD 100 million in a study on several infectious diseases for research up to phase 2a assuming no risk of failures[80]. Accounting for probability of success, costs can go up to USD 400 million. Development tracks for veterinary vaccines are shorter (no preclinical research in animal models but directly in target species), less costly and de-risked at an earlier stage of development when compared to human vaccines. It is unlikely that the partnership can bring products beyond TRL6-7, but according to experts involved in the preparation of PAHW, an investment of e.g. €100 million could potentially end up in around 25 implementation outputs (TRL 5-7) with 80% probability of success in next stage, out of 200 initial Proof of Concept studies.

The above considerations lead to a very rough estimation of €350 million, as a minimum, to perform the planned research activities, to which management costs and certain other activities (education and training, communication, etc.) need to be added, meaning at least an extra 50 million. The total amount of R&I investments necessary to reach the objectives would be €400 million as a minimum. The ratio between in cash and in kind will depend on the respective contributions of the countries.

2.2.6 Relevant transformational changes; impact

Use of antimicrobials and protection of animal welfare are among concerns raised by citizens as regards livestock production and aquaculture, next to the safety of food. More recently with COVID-19, the risk of diseases transmitted from animals has further increased in importance. PAHW will address these concerns, directly or indirectly. Indeed, the vision of PAHW is a society reassured on the control of infectious animal diseases with appropriate means, where antimicrobials are prudently used, where animal welfare is respected and improved, thus contributing to sustainable animal farming and the protection of public health, also through the safeguarding of antimicrobial efficacy.

Providing knowledge, guidelines and tools on appropriate welfare measures across the entire chain (i.e. on farms, during transport and in slaughterhouses) is expected to address societal concerns raised in e.g. the Citizens Initiative 'End the Cage Age'. It will facilitate an improvement of the wellbeing of terrestrial and aquatic species kept for farming purposes, and create a life worth living for millions of animals. A high standard of welfare will also help to securing good productivity and promoting increased resilience to avoid disease and infections. This will likely lead to an increased share of high welfare products in food stores and facilitate compliance of animal owners. In addition, innovative animal-free models will reduce the need for animal testing in the development process of new medicines, thus responding to another societal pressure relating to animal welfare.

An efficient R&I coordination between animal health, animal welfare, public health and the environment (One Health-One Welfare approach) will enhance timely exchange of information and common action. It will build trust among partners across policy domains or disciplines and shorten time of reaction and commitment to common investments in cross-sector methodologies (procedures, databases, management structures, new husbandry systems, etc.).

The authorities (ministries responsible for agriculture/fishery, environment, public health, economy) and the society will profit from the outcomes of PAHW. For instance, sensitive

[79] GlobalBenchmarkingSurvey2015_EuropeReport14Jan2016noappendices 1 (1).pdf
[80] http://dx.doi.org/10.1016/S2214-109X(18)30346-2

surveillance systems, and related laboratory techniques and databases, practices (including biosecurity), treatments and vaccines as alternatives to the use of antimicrobials, simulation exercises, reliable high welfare labelling of products, etc. all lead to improved health, reduced loss of production and increased consumer confidence.

Project outputs and outcomes will serve to build further research on, thus having an impact on research and technology. Furthermore, 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. In addition, project outcomes can be taken up by the industry for further development at later TRL (registration (TRL 8) and lifecycle management (TRL 9). Examples are development and innovation efforts in different domains such as diagnostic tools, vaccines, therapeutics, alternatives to antimicrobials and new welfare marketing concepts, which will represent an economic impact of the Partnership. Elaborate procedures regarding the creation and utilisation of foreground will guarantee a fair sharing of investments and economic benefits reaped by partners from the outcome.

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

The Partnership will create a strong public-public and public-private cooperation framework consisting of the main actors in the participating MS/AC (and potentially third countries) involved in animal health and welfare. Since not only RPO (public reference laboratories and reference centres, and research organizations), but also FO, authorities and industry will take part in PAHW, the uptake of the results into the normal tasks of these actors will be ensured. For instance, new and improved surveillance and monitoring systems will be introduced, more sensitive and specific laboratory procedures and animal-based measures will become available, new risk assessment models and methodologies would be utilised, etc. The expected impact of PAHW illustrates that some of the activities will be stopped, some may be extended and new ones proposed. In addition, PAHW activities will fill only certain priority gaps and new shortages and needs for applied or basic research in the domain will be identified.

During and at the end of PAHW, an assessment will be undertaken of which themes, activities, domains etc. need further EU support to bring added value, of what can be self-sustained (some models, tools etc.) or can be taken on by stakeholders, including the industry, agencies, or authorities.

Depending on the achievements, on the breadth of the identified further needs, on the success of the cooperation among the public research actors and with the private sector, on their interest and eventual commitment to move further ahead or not, various options can be considered as exit strategy:

- As a minimum, some lasting outputs of PAHW will be self-sustained or be taken up by stakeholders. Moreover, certain additional needs could be addressed by:
    - usual topics in the EU Framework Programme and/or,
    - country funding organisations deciding to organise joint calls for transnational research activities outside the EU Framework Programme;
- PAHW could be the foundation for a stronger public-public partnership;
- PAHW could be the foundation for a public-private partnership in animal health and welfare research.

Where appropriate, a scope broader than animal health and welfare could be considered in a follow up partnership.

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

PAHW will be backed by a Strategic Research and Innovation Agenda (SRIA) based on a clear intervention logic that links the objectives of the Partnership with the expected deliverables, expected outcomes and impact. It will include a prioritisation process and cross cutting aspects and provide a framework for the thematic priorities and the type of R&I actions needed. It will encompass enough flexibility to be adapted to evolving priorities or new needs.

The development of the SRIA has not started from a clean sheet. Indeed, networks and initiatives that will potentially be partners/actors or stakeholders of the PAHW have developed SRAs or similar documents (see section 2.4 "Partner composition"). In autumn 2021, arrangements have been made that the PAHW SRIA is being drafted in close collaboration with representatives of ERA-NET International Coordination of Research on Infectious Animal Diseases (ICRAD), with input from at least CWG AHW, SCAR FISH, STAR-IDAZ IRC, DISCONTOOLS, EPIZONE and One Health EJP. In addition, relevant international (e.g. ECDC, EFSA, OIE, EMA), national and regional stakeholders, relevant authorities and private sector organisations (e.g. AnimalHealthEurope, European Aquaculture Technology Platform; FABRE TP) will be consulted as well, to prioritize their needs and to obtain input from a broad range of experts in the field of animal health and welfare. This is also relevant for AMR topics and activities (see Tripartite FAO, OIE and WHO).

The process of assessing the existing and relevant SRIA takes place in parallel with the finalisation of the PAHW dossier. In autumn 2021, the working groups on surveillance, diagnostics, farm practices and treatment & vaccines, have been developing the intervention logic for the operational objectives, based on a first broad consultation of candidate stakeholders and authorities in June 2021 and a subsequent online survey. This output has been the basis of the present PAHW dossier and will further feed into the PAHW SRIA as well. A second consultation of country representatives and stakeholders, as well as the CWG AHW was done in December 2021.

It is planned that in early spring 2022 an advanced draft of the SRIA PAHW will be available. It will be further developed in co-creation with possible actors, stakeholders and the Commission.

During the lifespan of PAHW, the SRIA will be revised through open consultation of actors and stakeholders, including related Partnerships.

2.3 Necessity for a European Partnership

A pan-European **alignment and integration of national public research programmes regarding animal health and welfare** is foreseen, so the form proposed for PAHW is a co-funded partnership with significant in-kind contributions from RPO, i.e. research centres and reference laboratories for animal health and reference centres for animal welfare. The Partnership will encourage cooperation and synergies among its partners, thus avoiding duplication, and will leverage resources to support improvement of animal health and welfare.

It is the ambition of the Partnership to reach out to all appropriate national and international RPO to collaborate broadly with FO, national authorities and with the industry (animal sector, diagnostics, and pharmaceuticals). Research, innovation and other activities will be set up in cooperation with major international and national stakeholders (e.g. ECDC, EFSA, OIE and EMA) and other interested parties, so as to guarantee successful science to policy transfer with efficient leveraging effect.

2.3.1 Why do we need a Partnership on animal health and welfare?

Directionality

Based on the challenges, R&I gaps and opportunities as described before (2.1.2 'The main drivers' and 2.1.3 'Main research, development and innovation needs') PAHW will strive to better manage AID, to place animal welfare at the foreground of animal production, and to set up research projects to deliver on developments and innovations in animal health and welfare and to reinforce the preparedness of all actors. Whereas at the moment, there is no cooperation of RPO, FO or authorities to align their research programmes regarding animal health and welfare, the PAHW will commit itself to bring all relevant partners in Europe together to align forces.

No single European country has the capacity on its own to address all the R&I challenges to generate the required knowledge and innovations to ensure surveillance of known and unknown hazards, to set up detection and monitoring systems, to improve or develop new alert systems, and to standardise and validate necessary tools for automated welfare assessment, diagnostics and vaccines in the diverse livestock sectors. When billions can be mobilised quickly for a vaccine against COVID-19, only millions are mobilised for a vaccine against a deadly animal disease such as African swine fever. There is substantial duplication of work among countries, especially in the domains addressing needs by risk managers due to regulatory requirements or particular health situations e.g. emerging risks. The intended integrative activities in PAHW will reduce useless repetition of research, bring added value (e.g. harmonisation) and contribute to better preparedness of AHW actors. A significant part of these activities will be performed between RPO members of the PAHW consortium.

In most domains of PAHW, there is an increased need for data management, not least for disease surveillance, welfare monitoring and related risk assessment activities. PAHW is expected to play a key role in this domain at least for priority diseases (to be defined), ensuring a broad geographical coverage that could certainly not be achieved without PAHW. To this end, pan-European platforms will likely be established.

Additionality

PAHW aims to mobilise a critical mass of resources and leverage public research funding to counter animal health and welfare issues in an aligned and coordinated manner.

There is sometimes insufficient interest or investments by industry in certain domains, or lack of uptake of research outputs by private sector. In PAHW, the strategic and operational interaction with the industry as advising stakeholder, the continuum of research from low to high Technology Readiness Levels and the design of research topics targeted to industry will lead to an improved participation of the industry in projects and a better uptake of research outputs. It is expected that in kind resources will be brought by the private sector in the projects launched through open calls. The international cooperation could potentially bring in additional actors and resources.

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

The general objectives of PAHW are to better control animal infectious diseases and to reinforce the preparedness of all actors, and to place animal welfare at the foreground of animal production. PAHW will notably contribute to reducing production losses, decreased use of antimicrobials and reduced AIDs with possibly less spill-over of zoonotic infections and resistant germs to humans. It will also facilitate a European level playing field with respect to improved animal welfare, as well as commercially relevant opportunities for labelling of products based on validated and readily available data. This will strengthen both

human wellbeing and animal welfare and facilitate sustainable livestock production and aquaculture.

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, 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-One Welfare and Sustainable Development Goals/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 Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, was adopted in 2020[81]. As part of it, The Commission committed to take action to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030. The Commission also committed to revise the animal welfare legislation, including on animal transport and the slaughter of animals, to align it with the latest scientific evidence, broaden its scope, make it easier to enforce and ultimately ensure a higher level of animal welfare.
- As part of the Farm to Fork strategy, an Action Plan on the development of organic production was published early in 2021[82]. It will help to reach the objective of at least 25% of the EU's agricultural land under organic farming by 2030. Animal welfare will play an important role in livestock and fish organic production.
- The new CAP. The Communication on the Future of Food and Farming[83] 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." The Farm to Fork Strategy recognises the role of the CAP in supporting the transition to sustainable food systems. In the context of and subject to the ongoing legislative procedure regarding the CAP, a new system is envisaged from 2023 whereby Member States will be able to use 'eco-schemes' to support a transition to better animal welfare[84].

[81] COM(2020)381 final

[82] COM(2021)141 final

[83] COM(2017)713 final

[84] The list of potential agricultural practices that eco-schemes could support is available at https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/key_policies/documents/factsheet-agripractices-under-ecoscheme_en.pdf

- In its communication on the European Citizens' Initiative (ECI) 'End the Cage Age', the Commission set out plans for a legislative proposal to prohibit cages for a number of farm animals. The proposal will come as part of the ongoing revision of the animal welfare legislation. The Communication stated that Horizon Europe would help provide decision-makers and actors with additional scientific evidence, not least with the creation of a European Partnership on Animal Health and Welfare to be proposed for the 2023-2024 work programme.
- Replacement, reduction and refinement (3Rs) of animal testing is a long-standing objective of the European Directorate for the Quality of Medicines and Healthcare (EDQM)[85]. Needs for transition to reduced animal use in medicine development are increasing. On 16 September 2021, the European Parliament has adopted a resolution on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education[86]. In addition, there is the ongoing European Citizens Initiative on a Europe without animal testing, which will likely require new initiatives in this field[87].
- AMR is subject to an EU AMR action plan[88], with one pillar on research highlighting needs notably in the animal production sector. A number of the PAHW operational objectives mentioned above are addressing these needs.
- Regarding the contribution of animal health to the preparedness of countries against cross-border and cross-sector infectious threats to humans, PAHW will seek to cooperate as appropriate in the EU4Health programme and the European Health Emergency preparedness and Response Authority (HERA)[89].

More globally, because AID do not respect frontiers and threaten the lives of animals, compromising 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, improving animal health and welfare as planned by PAHW will have 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 ones:

Figure: Major Sustainable Development Goals in relation to PAHW

Since the challenges described above are not restricted to the European continent, networking with international projects and initiatives will be sought and international cooperation

[85] https://www.edqm.eu/en/alternatives-animal-testing
[86] https://www.europarl.europa.eu/news/en/press-room/20210910IPR11926/meps-demand-eu-action-plan-to-end-the-use-of-animals-in-research-and-testing
[87] https://eci.ec.europa.eu/019/public/#/screen/home
[88] https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf
[89] COM (2021) 576 Final

developed as much as possible. Interaction with international stakeholders such as OIE, FAO, WHO and UNEP, as well as international research alliances such as STAR-IDAZ International Research Consortium will enable such cooperation.

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

In the preparatory phase of PAHW, through SCAR and notably CWG AHW, all MS/AC were regularly updated and invited to discuss the PAHW proposal with national RPO, ministries, FO and food agencies where relevant, and to suggest activities for the partnership. The preparation of the PAHW SRIA is jointly done with the ERA-NET ICRAD and in alignment with EUP One Health-AMR (Cluster 1), as explained before (2.2.8).

The relevant ministries in the Member States and Associated Countries will be represented in the Governance structures of PAHW (see section 3.3).

Furthermore, the existing framework of SCAR and its CWG AHW and SWG SCAR FISH, composed of representatives of the main animal health and welfare research public bodies of over 20 countries (CWG AHW), will ensure a very good level of collaboration with Member States and Associated Countries.

Additionally, the success of past ERA-NETs, as well as the on-going ICRAD ERA-NET, where 31 public research funders/programme owners from 15 member States and 5 non EU countries are represented, focussing largely on issues relevant to EU policies, is reinforcing the science basis for regulatory framework. Many of the research centres and reference laboratories involved in ICRAD and CWG activities are also partners of the One Health EJP, where a close collaboration with representatives of EFSA, ECDC, FAO, OIE and WHO-Europe has been set up, thus facilitating the envisaged cooperation in the context of PAHW.

In addition, having regular contacts with these national and international stakeholders favours the uptake of PAHW outcomes by these interested parties. It will also help in the dissemination of outputs and outcomes within countries and at the international level.

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 networks/consortia CWG AHW (www.scar-cwg-ahw.org), STAR-IDAZ IRC (www.star-idaz.net), DISCONTOOLS (www.discontools.eu), EPIZONE (www.epizone-eu.net), ICRAD (www.ICRAD.eu), One Health EJP (www.OneHealthEJP.eu) and the MedVetNet Association (www.mvnassociation.org) support PAHW that will unite research funding organisations, research institutes, reference laboratories and centres for animal health and welfare, as well as, through R&I calls, academic institutions and universities in Europe and more widely at international level.

In order to open up to high-level technologies and new expertise, national funding organisations are invited to take part in PAHW. In that way, R&I calls can be organised to which not only partners, but also universities and private sector (e.g. industrial) partners can apply.

Negotiations are ongoing with the following industrial partners, to discuss on ways to ensure that their needs are considered in PAHW implementation and that they take part in relevant research projects:

- AnimalHealthEurope
- Diagnostics for animals

2.4.2 Type and composition of partners and stakeholder community

For the understanding of this dossier, the following definitions were adopted:

- Partners of PAHW are members of the partnership consortium; RPO (research centres with activities in the fields covered by PAHW, reference laboratories in animal health and reference centres for animal welfare) and FO (in some cases ministries or agencies are FO); also relevant ministries and food agencies are potential partners.
- Stakeholders have an interest in the outcome of the PAHW; they may have a role in the implementation/governance, but are not partners. Stakeholders may be research performing organizations, relevant ministries or companies (in particular industry) taking part in the initiatives and activities organised by the PAHW like communication and dissemination, trainings and education activities, open R&I calls for transnational research projects, or other activities like setting up databases or sharing infrastructure.

In the PAHW governance (see 3.3), a structure is proposed where partners can exchange with programme owners, with international stakeholders and with industry.

Research and other activities target both regulated 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 candidate partners of PAHW:

- Institutes housing national and EU Reference Laboratories (Animal Health/AMR/Food safety) and EU Reference Centres for Animal Welfare.
- National and regional funding organisations, cooperatives and charities/foundations.
- Research centres working on animal diseases and welfare and that provide specific complementary technologies, expertise and capacity (e.g. high containment facilities).

Universities and relevant industry partners (animal sector, diagnostics, pharmaceuticals) can join through open calls.

From the start, as many Member States as possible should join PAHW. The first candidates to reach out to are the interested Associated Countries.

The industry is considered essential for bringing the outputs of PAHW to a higher level and will be associated to PAHW, both as stakeholder and as research actors involved in relevant external open research projects.

International bodies, mainly EFSA, ECDC, OIE, FAO, WHO, UNEP and EMA, will be invited to join the Stakeholders Committee to give strategic input on research and other activities related to animal health and welfare, including zoonotic diseases and AMR.

2.4.3 List of candidate stakeholders

The stakeholders that will likely benefit most from the outputs of PAHW are policy makers, i.e. the national and regional Ministries that are responsible for animal health and welfare, which will be invited to take part, as well as national and regional food safety organisations, where relevant. These stakeholders will take part in the stakeholder board as is discussed in section 3.3. Relevant EC services will be involved in PAHW as important stakeholder as well.

CWG AHW; EPIZONE; STAR-IDAZ IRC; DISCONTOOLS; VetBioNet (Veterinary Biocontained facility Network; www.vetbionet.eu), EATiP (European Aquaculture Technology and Innovation Platform; http://eatip.eu/), COPA COGECA (European farmers, European agri-cooperatives; www.copa-cogeca.eu), FVE (Federation of Veterinarians of

Europe; https://fve.org) are considered core PAHW stakeholders, as well as the reference bodies OIE, FAO, WHO, UNEP, EFSA, ECDC, EMA.

Other potential stakeholders (will be contacted in course of the development of the proposal):

Animal Health

- EPRUMA (European Platform for the Responsible Using of Medicines in Animals; https://epruma.eu/)
- EAVLD (European Association of Veterinary Laboratory Diagnosticians; www.eavld.org/eavld/)
- IABS (International Alliance for Biological Standardization; www.iabs.org)
- FESASS (European Federation of Animal Health Services; www.fesass.eu/)

Animal welfare

- CIWF (Compassion in World Farming, www.ciwf.com/)
- DG SANTE's EU Platform on Animal Welfare (https://webgate.ec.europa.eu/awp/)
- Eurogroup for Animals (www.eurogroupforanimals.org/)
- Welfare Quality Network (www.welfarequality.net/en-us/home/)
- EuroFAWC (the European Forum for Animal Welfare Councils, www.eurofawc.com/home/1)

Animal production

- Animal Task Force (http://animaltaskforce.eu/)
- FABRE / EFFAB European Forum of Farm Animal Breeders (www.effab.info/)
- FEAP: Federation of Aquaculture producers (https://feap.info/)

Wildlife

- European Wildlife Disease Association (https://ewda.org/)
- Wildlife Health Specialist Group (WHSG) of Species Survival Commission (SSC) of the International Union for Conservation of Nature (IUCN) www.iucn-whsg.org)

Infrastructures: VetBioNet (www.vetbionet.eu/); TRANSVAC2 (www.transvac.org/transvac2); PIGWEB (www.pigweb.eu/); SMARTCOW (www.smartcow.eu/); INFRAVEC2 (https://infravec2.eu/); ELIXIR (https://elixir-europe.org/)

Other

- MedVetNet Association (www.mvnassociation.org)
- EASVO (European Association of State Veterinary Officers) (www.easvo.fve.org)

Due to the recognisable link with the EU Partnerships One Health-AMR, Innovative Health, 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. They could potentially become stakeholders involved in governance structures of PAHW.

3 Planned Implementation

3.1 Activities

3.1.1 Portfolio of activities

The planned activities can be summarised as follows. More details will be provided in the Strategic Research and Innovation Agenda, which is due by the end of 2022. Not only joint research calls, but also other activities will be set up.

- **Transnational research and innovation calls (R&I calls)** will be organised to advance basic and applied knowledge in most of the operational actions of PAHW, and to strengthen the preparedness of all actors in animal health and welfare. Research will focus on, among others, surveillance of animal health and monitoring of welfare, diagnostics, farming practices to improve animal health and welfare, economics, interventions such as vaccines and treatments, and supporting science including pathogen genomes, host-pathogen interactions, epidemiology, ethology, physiology, ecology, biosecurity, immunology, vectors, microbiomes, food safety and AMR (if not addressed by other partnerships). To this end, both open and internal calls will be organised:
    - **External open calls**: Funding organizations (FO) will mobilise in cash budgets to organise open calls and thus involve e.g. research organizations, academic laboratories and private partners. The aim of open calls is to develop new knowledge, both basic and applied research in the fields of animal health and welfare, which will bring in new expertise and new technologies for e.g. diagnostics, monitoring, treatments or vaccine development, new husbandry practices, biosecurity measures, breeding technologies, etc. Certain call topics may benefit from the participation of stakeholders, including the private sector. To facilitate their involvement in the external projects, clear and transparent guidelines describing what is expected from the stakeholders will be developed.
    - Partner RPO will organise **internal calls** aiming at reinforcing cooperation and alignment of programmes and activities among reference laboratories, reference centres and research centres, to strengthen preparedness (surveillance, laboratory, risk assessment and risk management) for animal health and One Health, by setting up mainly integrative projects also in animal welfare. Probably, the areas of the internal calls will focus on applied, policy driven research i.e. priority regulated health and/or welfare issues, e.g. for AID: zoonoses, vector-borne infections and AMR (in alignment with domains and topics as defined in the European partnership One Health-AMR), including reference tasks, infections/diseases where no EU-RL exist. No RPO outside PAHW, nor private partners will normally take part in internal calls. Internal calls are EC co-funded and participating RPO contribute through in-kind funding.

RPO member of PAHW may be willing not only to take part in research performed internally but also to apply to external open calls. In order to enable this but avoid conflict of interest (if RPO in PAHW would have privileged access to external open call topics), the proposed provisions on governance are described below (3.3. Governance).

Other activities

Besides the external open and internal R&I calls, other joint activities will be set up. The communication, dissemination and exploitation events are based on the outputs of the

partnership, as well as on experience and expertise of its partners. Obviously, these activities will expand as the PAHW moves on. Communication should be balanced on animal health, animal welfare (across all animal species) and One Health.

- Consultation **meetings with stakeholders and interested parties** will be organised to identify needs and gaps identified by scientists and policy makers, but also the broader community of farmers, veterinarians and the consumer, and will contribute to the regular update of the SRIA.
- **Education and training activities** (e.g. events like dissemination workshops and summer schools, early career workshops for young researchers, scientific meetings, short term missions, creation of a 'Young PAHW Community, 'stable schools' where farmers and veterinarians can exchange needs, challenges and solutions, demonstration opportunities, etc.) will be set up. Other formats are envisaged as well, e.g. training material (leaflets and brochures on the projects funded with focus on the main outputs, video's explain the project deliverables, their use and possible uptake by others, etc.), dedicated webpages, knowledge hubs, etc. Certification of education activities should be considered.
- **Capacity building** of diagnostic and research laboratories and regarding welfare assessment and monitoring by organizing harmonization and standardization efforts and proficiency tests, inventories of databases and of existing technology networks of common interest, a patent service to protect project outcomes and to support regulatory aspects, etc.
- **Dissemination and communication** on activities: both scientific conferences and communication of the outcome to a larger public, disseminate outcomes in policy briefs, etc. An encompassing communication strategy will be set up to identify the main outputs to disseminate, the most susceptible audience, along a suitable time line.
- **Exploitation** regarding uptake of PAHW outputs by partners, but also RPO that are not part of the PAHW, by risk assessors, risk managers, and by the industry.

Another series of activities will be focussing on the integration of RPO actors within PAHW, and deal with laboratory, risk assessment and risk management work and the means to support preparedness (prevent-detect-response) of all partners involved. These activities may be organized through calls.

- **Shared infrastructure** (e.g. animal facilities or laboratories of BSL2 or higher).
- **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.
- Open access, cross-border and cross-sector **animal health databases and (if possible) animal welfare** will be set up that can be linked to existing databases, including those related to public health (e.g. ECDC, EFSA, FAO and OIE).

3.1.2 Complementarity mechanisms, avoid unnecessary duplications

The key to avoiding overlap and duplication of work is coordination among partners. Therefore, it is important to have most of the PAHW partners on board when organizing joint activities. By timely consulting with the authorities, there will be a broad basis for the endorsement of planned activities; this approach will avoid that comparable activities will be launched in those countries. Such discussions should be held in a transparent way, to further avoid unintended duplication of work.

In the European animal health and welfare community, there is a positive experience of coordination of public research programmes, in particular through CWG AHW, ERA-NETs, or One Health EJP. This coordination will be brought to a superior level, with intended integration of relevant actors, and mobilisation of critical mass and resources. RPO and FO that already collaborate in existing animal health and welfare consortia (i.e. CWG AHW, STAR-IDAZ IRC, DISCONTOOLS, EPIZONE, ICRAD and One Health EJP) are expected to be stakeholders of PAHW and will thus add their research and network achievements in order to further implement coordination of new research activities and avoid duplication of research.

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 order to facilitate interaction and complementarity with other European partnerships (i.e. Biodiversity, Safe and Sustainable Food Systems, Agroecology, One Health-AMR and Pandemic Preparedness), their representation in relevant PAHW governance structures is foreseen.

The following European Partnerships have been identified for possible alignment.

- Candidate EUP One Health-AMR: while the One Health approach is relevant for epidemiology, surveillance, detection, possibly stewardship of AMR, measures to fight against AMR in the animal domain, aimed at reducing the (need to) use of AMs, and replacing AMs, will be tackled in PAHW. Also working on AMR epidemiology for animal pathogens is planned. At this stage, One Health-AMR partnership is planned for call 2024; alignment of the planned activities in both Partnerships are being discussed with JPIAMR representatives to avoid overlaps and foster synergies instead. Interaction also with the Coordination and Support Action to be selected to prepare the EUP One Health-AMR (topic in Cluster 1 Work-Programme 2021) will be organised from 2022 onwards, in respect of SRIA development. Reciprocal participation in Advisory structures of both partnerships can be proposed. Reporting on programme, activities and outputs can be ensured. The possibility of coordinated calls could be considered.

- Candidate EUP Pandemic Preparedness: Contacts with representatives of INSERM in France and ISCIII in Spain are ongoing to identify possible common interests and to understand where possible activities regarding animal health and One Health may overlap between both partnerships. At this stage, this Cluster 1 partnership is planned for call 2024; interaction with the Coordination and Support Action to be selected to prepare the EUP Pandemic Preparedness partnership (topic in Cluster 1 Work-Programme 2021) will be organised from 2022 onwards.

- Biodiversa-Plus: it is understood that this partnership is planning a flagship on biodiversity and health, but not within the first 2 years of operation. Interaction with Biodiversa-Plus will be organised in the process of SRIA development in 2022.

- Candidate EUP Agroecology: this partnership, like PAHW is planned for call 2023; coordination will take place in the process of development of respective SRIAs. This partnership will also include organic farming and animal welfare actions, in line with one of its guiding principles for implementation.

- Candidate EUP Safe and Sustainable Food Systems (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 boundaries of this partnership.

- Candidate EUP Blue Economy: it is expected that no substantial work on animal health and welfare in aquatic animals will be addressed in that partnership, as PAHW intends to address both terrestrials and aquatic animals. Coordination will notably take place through discussion among SCAR CWG AHW and SCAR Fish.
- Candidate EUP Innovative Health (planned follow-up to IMI-2): 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, AQUAAXCEL2020, TRANSVAC: TRANSVAC2 and TRANSVAC-DS), 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 JPIAMR is on-going; interaction with JPI HDHL, JPI Ocean, JPI FACCE is to be explored

Synergies with other Programmes is at this stage not yet discussed, nor the possibility to obtain funding through other sources such as charities, but this may arise once the PAHW partners are confirmed and the consortium is built.

3.2 Resources

3.2.1 Contributions from partners

The proposed format enables resources both in kind (through RPO members of the PAHW consortium) and in cash (through FO members of the PAHW consortium).

The available budget will be known once the commitments by countries is provided early in 2022.

As mentioned above (2.2.5), the total amount of R&I investments necessary to reach the objectives and expected impact of PAHW would be roughly €400 million. Obviously, more could be done if more budget becomes available. If a lower budget would be available, reducing the scope of PAHW would be required.

Coordination tasks for such large initiative must not be underestimated, especially considering the combined mode of operation with RPO and FO in the consortium and related organisation of internal calls and activities that will be performed via external open calls.

3.2.2 Other investments or conditions

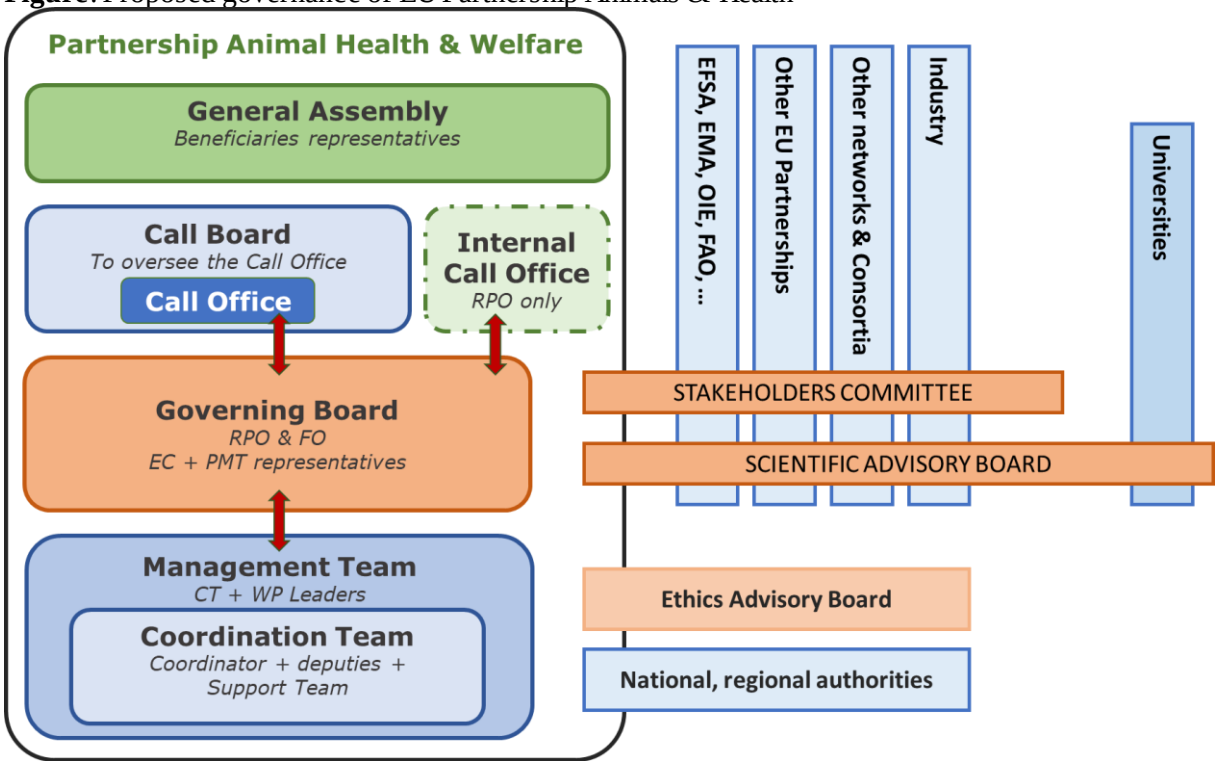
Beyond scientific progress, the impact of the partnership will depend on the level of uptake of outputs by stakeholders, users, related initiatives; from laboratories to industry, to decision makers, to veterinarians and farmers and related services. The strategic objectives described, together with the 'other activities', including dissemination and communication, explain the efforts that PAHW plan to facilitate uptake and reach the expected impact.

3.3 Governance

3.3.1 Governance and advisory structures

At this stage, where exploratory discussions have taken place with some potential RPO, FO and ministry partners, including with the private sector, a co-funded partnership model centred on public research actors is proposed. The following governing and advisory structures are suggested, which will be further discussed at the PAHW proposal phase.

Figure: Proposed governance of EU Partnership Animals & Health



The **General Assembly (GenA)** is composed of all partners/beneficiaries of PAHW, one representative per partner. It will be yearly informed about the progress of PAHW and is the ultimate decision making body dealing with the Grant Agreement (GA). For other decisions the GovB will decide. The GenA will strive to reach consensus and if consensus cannot be reached, the GenA will vote on different options. GenA Quorum and voting arrangements will be elaborated on in the Consortium Agreement.

The **Governing Board** (**GovB)** is the highest strategic and decision making body to oversee the partnership resources, to approve modifications of the organization and of the SRIA, defining the work programme including the open and internal call domains, the structure and information flow and to monitor the possible outcome and the expected impact of the PAHW. It is composed of representatives from the participating RPO and the FO (and the food agencies and foundations, to be decided). The GovB consists of a maximum of two representatives per PAHW participating country, and probably with additional representatives from EURL, EURCAW, and from other advisory and stakeholders organizations. The GovB will regularly consult the Stakeholders Committee and /or the Scientific Advisory Board. The participation of PMT in GovB meetings, the role of GovB Chairs, GovB quorum and voting arrangements will be elaborated in the Consortium Agreement.

The GovB has a strategic role to ensure consistency and completeness in the implementation of the PAHW SRIA through internal calls and external open calls, as well as other activities performed without calls. The GovB will define the high-level domains of the R&I calls, whereas the precise call topics will be defined by the Call Board.

The **Partnership Management Team (PMT)**, composed of the Coordination Team and all WP leaders, will be the forum to discuss details of the PAHW progress, annual work plans, use of related resources and to prepare the GovB meetings. PMT will meet regularly (e.g. once per month).

The **Coordination Team (CT)** will consist of the coordinator and Coordinator deputies, the project managers, one or more project managers, communication officer, financial and legal officer and assistants. The CT is the central body and will carry out the day-to-day operational management by supporting PAHW partners and is also responsible for the active monitoring of the PAHW progress (KPI). CT will meet frequently, e.g. every week.

The **Call Board (CB) and Call Office**. The Call Board is composed of FO and RPO (and Ministries, to be decided) in a variable configuration, depending on the call (in order to avoid conflict of interest - CoI). The CB is responsible for defining the call text that includes the call topics, and oversees the organization of the R&I calls by the Call Office. The call topics are defined on the basis of the domains decided by the GovB. For the external open calls, mainly FO propose topics, whereas for the internal calls, the call topics are proposed by RPO. The CB may consult the Stakeholders Committee and the Scientific Advisory Board. The CB will use a defined methodology (e.g. Multi Criteria Decision Analysis or similar) to decide on the final call topics. It will supervise the Call Office that will collect pre- and full proposals, organize the external independent evaluation and list the project proposals for funding, according to harmonized procedures for open and internal calls. The CB will select the project proposals and may ask the GovB for arbitrage.

To avoid CoI, in case a RPO is involved in the CB or Call Office that manages a particular call, that RPO cannot take part in the projects of that call, be it open or internal call.

Another option would be that RPO manage the internal call independently from external open calls, without intervention of FO (and Ministries, to be decided).

Boards outside PAHW

European Commission and its Steering Group follow up PAHW according to the Horizon Europe criteria. Interested Commission services will be invited as observers in the GovB.

Ethics Advisory Board (EAB): With the aim to comply with the European ethical and legal frameworks, independent, external experts will be appointed in charge of advising on and monitoring ethical/ legal (including CoI)/ regulatory issues of the Partnership, of the Data Management Plan, as well as of the projects funded within Partnership.

Scientific Advisory Board (SAB): The SAB is invited by the GovB or/and Call Board for giving input to the research strategy, for joint transnational calls or other activities. The SAB consists of international experts from universities, RPO outside PAHW partners or similar, with expertise in the fields addressed in PAHW animal health and welfare. Composition and modus operandi will be established in due course.

The **Stakeholders Committee** is composed of representatives of all stakeholder organizations. They will regularly share their expertise, advice and recommendations for inclusion in the PAHW activities. Composition and modus operandi will be established in due course. Subgroups may be established depending on the type of stakeholders and the interactions expected (e.g. the animal health industry may have a special role for providing advice on framework conditions for performing experiments in order to facilitate uptake of results to bring them to a further stage of product development; welfare organizations may be consulted on societal interest in particular priorities).

3.3.2 Involvement of Commission

European Commission services (EC) are taking a proactive and co-leading role in the preparation of the partnership, including the drafting of the SRIA.

The relevant European Commission services will be invited to take part in the Governing Board meetings as observers (details to be discussed). The EC role will be to oversee the implementation and regular updating of the SRIA/Roadmap and to assess which areas may be addressed by topics in the Horizon Europe work-programmes rather than in the partnership, as complementary approach. 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 involvement of all relevant actors (as partner or as stakeholder) is at the core of the partnership. The discussions so far involved SCAR CWG AHW, SCAR Fish, SCAR Steering Group, together with representatives from different projects, initiatives and bodies like e.g. One Health EJP, EPIZONE, STAR-IDAZ IRC, ICRAD ERA-NET, OIE, EFSA, plus the experts in the working group that proposed detailed objectives and activities. On the industry side, exploratory discussions were held with AnimalHealthEurope and Diagnostics for Animals, as perceived main actors. The member States and Associated Countries will be consulted by the EC (DG RTD).

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

The participation of research actors in transnational projects selected through external calls will ensure a high level of inclusiveness as regards sectors and geographical areas, next to the RPO that will be part of the PAHW consortium. In addition, new partners will be able to join the PAHW consortium: additional FO will be able to join at any time, while RPO may be able to join if their expertise/mandate fits the criteria of PAHW. Particular efforts will be devoted to involve actors in lower performing countries in PAHW. Consideration will be given to reserve part of the budget during the first years, for potential additional partners.

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

Once PAHW will be established, a dedicated website will be set up where the SRIA and the outputs of the R&I activities will be published. Furthermore, webinars, regular workshop, conference and meeting will be organised for the research community. Their results together with main results of R&I activities will be disseminated throughout appropriate communications channels for a wider audience of stakeholders. The current document (PAHW proposal, version December 2021) will be published on the CWG AHW website.

A Communication and Dissemination Plan will be developed and implemented together with experts in scientific communication. The plan will specify the different tools for effective communication with different stakeholders such as: social media for researchers, programme owners, citizens (LinkedIn, research gate, Facebook, Twitter…), newsletters, brief policy advice, posts, press news, etc. Specific efforts should be put in the communication and

dissemination of outputs and outcomes to professional non-research parties (regional, national and international authorities, sectors, industries, etc.) and to the public, who has a specific interest in improving the welfare of livestock and fish.

A PAHW publication policy will be drafted with guidelines for optimal dissemination of scientific manuscripts. All publications and deliverables will be made publicly available following the Open Science and FAIR principles.

3.4.3 How will the partnership establish a proactive recruitment policy

This will be determined during further discussions on the final PAHW proposal.

At this stage, the main candidate partners should be aware of the construction of PAHW, since, besides the many EC efforts to communicate on Horizon Europe and its Partnerships, the CWG AHW was regularly updated on the progress of the PAHW dossier. In addition, DG AGRI has organised a stakeholder webinar in June 2021 and a TC in mid-December 2021. Therefore, many stakeholders are already identified and contacted 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 AHW, as well as the contact persons identified by the Member States / associated countries for this partnership and who were associated to the discussions, have been ensuring coordination within their own country.

On the industry side, contacts were made with two 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.

Furthermore, throughout the lifespan of the partnership, possibilities to join the partnership by additional funders could be make available with the establishment of transnational calls on shared priorities.

3.4.3 Process for establishing annual work programmes

This should be determined during the development of the SRIA.

The first AWP will be based on the SRIA and both documents will be updated through input of the Scientific Advisory Board and the Stakeholder Committee.

Annexe 1 Contributions

CWG Animal Health & Welfare

The CWG AHW was closely involved in the preparation of this document, and is composed of Funding Organizations, Research Performing Organizations and experts from the following countries: Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Lithuania, Luxembourg, The Netherlands, Norway, Poland, Portugal, Russia, Slovakia, Spain, Sweden, Turkey and the United Kingdom.

Among its observers are: AnimalHealthEurope, COPA-COGECA, COST, EFSA, the European Commission and OIE.

Collaborating entities

In the preparation of the drafting of this document, contact has been taken with the following entities: DISCONTOOLS, EATiP, EPIZONE, FVE, ICRAD, MedVetNet Association, One Health EJP, STAR-IDAZ IRC and VetBioNet.

Working groups

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