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Abstract:

This report describes the process that led to the decision of preparing the new animal health law, describing the norm itself as it appears at the current stage, and identifying the research gaps emerged during its drafting process, in order to provide help in research prioritisation.

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Identification of research drivers emerging from the drafting of the new Animal Health Law and other EU actions

WP2

Mapping and analysis of existing national research infrastructures and programmes

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ANIHWA Report: Identification of research drivers emerging from the drafting of the new Animal Health Law and other EU actions

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List of abbreviations

ADNS	Animal Disease Notification System
AH	Animal Health
AHS	Animal Health Strategy
AHL	Animal Health Law
ANIHWA	Animal Health and Welfare ERAnet project
AW	Animal Welfare
BIP	Border Inspection Posts
BSE	Bovine Spongiform Encephalopathy
CA	Competent Authority
CAHP	Community Animal Health Policy
CBPP	Contagious bovine pleuro-pneumonia
Copa-Cogeca	Committee of Professional Agricultural Organisations – General Confederation of Agricultural Co-operatives in the European Union
CVO	Chief Veterinary Officer
CWG	Collaborative Working Group on European Animal Health & Welfare Research
DG-SANCO	Directorate-General for Health and Consumers
EB	Executive Board
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMIDA	Coordination of European Research on Emerging and Major Infectious Diseases of Livestock
EMEA	European Medicines Agency
ERAnet	European Research Area network
EU	European Union
ETPGAH	European Technology Platform for Global Animal Health
FCEC	Food Chain Evaluation Consortium
FMD	Foot and Mouth Disease
FP7	7 th Framework Programme
MS	Member State
OIE	World Organisation for Animal Health
OsHV	Oyster Herpesvirus
SCAR	Standing Committee on Agricultural Research
SCFAH	Standing Committee on the Food Chain and Animal Health
SME	Small and Medium Enterprises
SRA	Strategic Research Agenda
STRAW	Strategic Research Agenda Workshop
WAHID	World Animal Health Information Database
WAHIS	World Animal Health Information System
WP	Work Package

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Analysis and comparison of research drivers emerging from the drafting of the new Animal Health Law and other EU actions.

Summary

The ANIHWA¹ (Animal Health And Welfare) project is an ERAnet (European Research Area network) funded by the European (EU) 7th Framework Programme (FP7). It aims to improve the cooperation and the coordination of national research programmes on animal health and welfare of farm animals, including fish and bees.

This report will present a desk study, performed by Work Package 2, about the new European Animal Health Law (AHL). Since science is the foundation of the new Animal Health and Welfare policy, future animal health and welfare rules are being developed on the basis of solid scientific information. Therefore, the analysis of that process will allow to identify future research drivers on animal health and welfare.

All the legislative framework regarding animals is now changing in the European Union (EU), driven by a simplification and harmonisation request by the social society.

This report will constitute a valuable help in achieving the ANIHWA objectives in several ways. The anticipation of its delivery at an early stage of project activities will provide a valid support to all other work-packages. Firstly, the information about the future research drivers gathered there will allow the selection of priority areas for the selection of the research topics for the launch of the ANIHWA second call, foreseen by the month of October 2013. Moreover, since several data sources are considered already in the analysis contained in this document, it represents a starting point for an in-depth analysis to detect research gaps, as foreseen in WP3. Lastly, it might be considered as a source of inspiration for the future ANIHWA Strategic research Agenda, to be delivered by WP5.

Given the relevance that this report is meant to have, the limitation of the study only to the new AHL itself appeared to be too restrictive. In the last ten years several gaps emerged in the European animal health and welfare policy, and several actions were taken in order to better define and solve these problems. The creation of a new animal health legislative framework was one of these actions. Since knowledge gaps are sometimes situated at the basis of these problems, some of the actions that the EU carried out were targeted to the identification of these gaps, and to subsequently fill them. It was then decided to broaden the scope of this report to the analysis of the more relevant among these “gap analysis” studies. The opinion of relevant stakeholders was also taken into account, in order to enlarge the collection of perceived existing needs and priorities in the field of animal health and welfare also to the general public. Lastly, an overview of the disease outbreak notifications in the ANIHWA partner countries was performed, in order allow the targeting of future research on emerging diseases in the European area.

The report consists of three main chapters:

¹ The ANIHWA project has a dedicated website, available at <http://www.anihwa.eu/>.

Chapter I:

Why the need for a single regulatory framework for animal health and welfare?

Chapter I:

The new Animal Health Law: drafting process and state of the art.

Chapter III:

Analysis of future research drivers emerging from the new Animal Health Law and other relevant EU actions.

In Chapter I the reasons are highlighted that brought the Commission to decide to start working on a new animal health regulatory framework. It starts from the evaluation of the last Community Animal Health Policy (CAHP) 1995- 2004, that highlighted the improvements that were needed to enhance the animal health legislative framework. Then, all further steps that led to the decision to start drafting the new norm has been detailed in the report, considering in particular the key role played by the Animal Health Strategy (AHS) 2007-2013.

In Chapter II, the drafting process of the AHL itself is analysed. Since its start in 2008 until today, the process is not concluded, but it is in an advanced stage of completion, and it is likely to undergo only slight changes from now on. Its analysis allowed to identify several research drivers in the field of animal health and welfare that are likely to be priorities over the next few years.

In Chapter III all the information gathered from the first and second chapters is analysed, in order to identify and detail the research drivers that could be derived from the whole process. The animal health and welfare policy that led to the new AHL stimulated several other important actions over the last few years, and some of them are directly linked to the identification of research gaps. An analysis of some of the more relevant efforts in this direction are presented in this chapter as well, together with the foresight studies of some relevant stakeholders. An overview on the infectious disease outbreaks that occurred across Europe in the last 4 years is also presented, in order to better target new research actions.

The research drivers that will be listed in the conclusive section of Chapter 3 will serve to better prioritise research in the second ANIHWA joint research call. Moreover, this preliminary analysis will support the actions of the other ANIHWA work-packages, easing the process to provide a valid playground to stimulate innovation and scientific research on animal health and welfare.

Chapter I:

Why the need for a single regulatory framework for animal health and welfare?

Introduction

More than ten years after the establishment of the single market, the Directorate-General for Health and Consumers (DG SANCO) of the European Commission assessed that it was appropriate and timely to undertake an external evaluation of the Community Animal Health Policy (CAHP). The evaluation commenced in July 2005 and was undertaken by the Food Chain Evaluation Consortium (FCEC). The final report was issued one year later, on the 25th of July 2006.

The report showed how successful the CAHP had been, both in terms of improving the general health status of animals in the Community, allowing appropriate reactions to animal disease epidemics and increasing the trust of consumers and Third Countries in the EC as a policy maker.

Nevertheless, several weak points were identified. Harmonisation on the implementation of norms among MS needed to be improved, as well as the adherence of EU rules to international and broadly accepted standards (e.g. OIE recommendations and standards). The establishment of risk-based procedures were needed to improve the efficacy of controls in a cost-effective way (e.g. to fight illegal trade) as well as the improvement of the existing animal traceability by the use of integrated electronic systems.

The main deficiency of the CAHP was the absence of a clear, transparent and unique strategy, together with a scarce involvement of the stakeholders in the decision making process. To tackle this issue, a new Animal Health Strategy (AHS) was issued in 2007, covering a 6-year period (2007-2013).

The aim of this on-going strategy is to replace the existing series of linked and interrelated policy actions with a single policy framework. The Animal Health Strategy will promote a single clear regulatory framework converging as far as possible with the OIE/Codex recommendations/standards and guidelines.

One of the main outcomes of this new AHS, which is pivotal for all other actions foreseen in the policy action period, is the modernisation of the animal health legislations through the issue of a single “horizontal” regulatory framework. This new Animal Health Law will provide a global basis laying down the general rules for all animal health concerns, including animal welfare and animal nutrition, putting a greater focus on incentives rather than penalties, and being consistent with other EU policies and converging with international standards.

Community Animal Health Policy evaluation process

The first mention of a need for a more harmonised regulatory framework regarding animal health emerged from the first external evaluation of the Community Animal Health Policy (CAHP), which took place between July 2005 and July 2006. During that year, the Food Chain Evaluation Consortium (FCEC) was asked by the Commission to carry out a complete review of the Animal Health policies between 1995 and 2004, working under the direction of a DG SANCO Steering Committee consisting of representatives from various Commission services, some Community agencies, and Member States (MS). The final report² was issued on the 25th of July 2006.

Since the number of European Union (EU) countries changed during the investigated time period, the report addresses the EU15 for the aspects pertaining to the past and the EU25 for those pertaining to the future.

Aim of this evaluation was firstly to assess the relevance, coherence, consistency and effectiveness of the CAHP, taking into account both efficiency and cost-effectiveness. Furthermore, when the evaluation of the results proved to be negative, it was investigated whether this was due to the inappropriateness of the legal provisions themselves or to the lack of implementation of the existing norms. Secondly, on the basis of this evaluation, new considerations for future policy options arose. Hence, this report had gone further than a simple work of evaluation, resulting in a pre-feasibility study for new European strategies on Animal Health (and Welfare). Those advices and evaluations served later on as a basis for the latter EC Strategy on Animal Health (2007-2013).

The Community animal health policy was not a single policy framework but rather a series of linked and interrelated policy actions. At that time, in the EU, the set of Animal Health legislations encompassed more than 400 Regulations, Directives and Decisions in force. This wide number of different pieces of legislation was due to the fact that, at the beginning, the Community animal health policy wasn't designed to be a single policy. Later on, many changes occurred that broadened the area of pertinence of the animal health policy in Europe. Firstly, with the setting up of the European single market the need arose of having an harmonised intra-Europe sanitary status. Later on, due to the highly publicised food crises (e.g. BSE), the general public concern about animal and food-borne public health issues increased. In the meantime, some large disease outbreaks (e.g. FMD in 2001) raised the awareness about the financial impact of animal health policy and engendered increasing worries about animal welfare and environmental protection during epidemic control. Also, the CAHP comprehended a wide range of policy actions, measures and tools that needed to be evaluated individually before drawing up the general conclusions. Finally, the evaluation task needed a very broad and well-concerted approach to get a valid result.

A wide range of evaluation tools were used to produce the report, with the main focus being on stakeholder consultation through surveys and interviews.

The survey included 12 Evaluation Questions (EQ) with a number of criteria each, amounting to a total of 86 questions, covering a range of animal species and the whole production chain, from "farm to fork" (see Table 1).

² The "Evaluation of the CAHP: Final Report" is available at http://ec.europa.eu/food/animal/diseases/strategy/archives/final_report_en.htm.

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Table 1: List of the evaluation questions.

EQ1	To what extent have Community rules for intra-Community trade in animals and their products, including the principle of “regionalisation” due to the presence of animal diseases, contributed to the functioning of the Single Market?
EQ2	To what extent has CAHP ensured consistent actions to control and eradicate major animal diseases? To what extent have these actions led to an improvement in animal health status across the EU?
EQ3	To what extent has the Community import regime prevented the introduction of animal diseases? To what extent was this efficient in terms of the financial and human resources deployed?
EQ4	To what extent have Community requirements for disease monitoring and surveillance ensured a rapid detection and reaction to exotic diseases and new emerging risks to animal and human health in the EU?
EQ5	To what extent are Community rules on the traceability of animals, their products, their feed, relevant? To what extent have they contributed to give effective animal health risk management tools?
EQ6	To what extent has CAHP contributed to a high level of protection of human health?
EQ7	To what extent have the Commission services succeeded in setting up an effective cooperation network with Member States and other organisations operating in the animal health field within its mission, in accordance with its mandate?
EQ7_2	Is this cooperation in line with a sound distribution of roles and responsibilities with reference to Community added value and subsidiarity aspects?
EQ7_3	What has been the contribution of this network towards the attainment of the CAHP objectives?
EQ7_4	Is this network the best way to achieve a common approach and coherence?
EQ8	To what extent do the management systems and processes of the Commission services contribute to the effectiveness and efficiency of the Community interventions in the animal health field?
EQ9	To what extent has Community funding for research, scientific advice and laboratory networks on animal health contributed to achieving the CAHP objectives?
EQ10	To what extent are the financial instrument and the amount of available funds at EU level adapted to the needs addressed by the CAHP?
EQ10_2	Insurance schemes: Based on the experience gained in some Member States, can “insurance schemes” or other similar financial schemes covering direct and/or indirect costs be considered as viable options to prevent major financial risks for the Member States or for the Community budget? Where they exist, have they led farmers to take more responsibilities in the prevention and resolution of animal health crises?
EQ11	To what extent does the current CAHP address the needs of stakeholders and the EU citizens? Are there areas where changes are necessary concerning objectives, scope, management systems or processes?
EQ12	To what extent does the intervention logic, objectives and activities linked to CAHP support or possibly conflict with those of other current EU policies?
EQ12_2	To what extent are the elements of CAHP’s intervention logic internally complementary, mutually supportive and consistent?
EQ12_3	How successful has CAHP been in promoting the necessary coherence and complementarity between the different EU policies in collaboration with the Commission and Member States?

Source “Evaluation of the CAHP: Final Report”

The consultation was designed to be as transparent and comprehensive of all potentially interested stakeholders as possible, both at European and MS and at third countries level. Due to the large number of interested parties, interviews were addressed to some of the key partners and stakeholders, while, for all other stakeholders and potentially relevant authorities, a large-scale survey was performed (over 600 recipients were consulted during this process). During the data analysis process, maximum flexibility was assured, adjusting the sample of relevant stakeholders, and updating the detailed list of questions used during the interviews with new findings and comments.

Stakeholders from all Member States of EU25 were interviewed during this survey. Given the wide scope of the survey, further in-depth analysis was performed in a more limited number of MS. These countries were selected according to the following criteria: population size, geographical position and characteristics, variety of animal health problems, intensity of production, and importance of different species. The selected MS were Germany, Italy, Greece, United Kingdom, Finland and Poland; a group interview was also organised with some key French stakeholders, in which the Ministry of Agriculture also participated. About 6-8 interviews were carried out in each MS, to target the Chief Veterinary Officers (CVOs), Ministries, national veterinary institutes, industry as well as consumer representatives.

Research in the CAHP: contribution of research to the achievement of policy objectives

The report highlighted that several different strategies were in place in the CAHP to safeguard human and animal health: one of them acted through the improvement of research on animal health issues. To achieve this objective, three main actions were put to use.

Firstly the cooperation among the Commission and the Commission's services on risk assessment and rapid networking on risk management and communication was improved. In the period of reference covered by the CAHP evaluation report, two independent Commission agencies were established, the European Medicines Agency (EMA³, 1995), dealing with both human and veterinary drug evaluation and supervision, and the European Food Safety Authority (EFSA⁴, 2002), dealing with food security issues. Both these agencies were involved in the providing of scientific risk assessment resorting under the mandate of animal health (the first one on veterinary medical products and the second one on feed safety). Both of them seemed to fulfil their mandate, enhancing the efficiency of risk assessment in Europe, although since no real crises occurred in that period in those areas the efficacy of their action can only be conjectured. A third agency was funded in 2005, the European Centre for Disease Prevention and Control (ECDC⁵), whose mission was to identify, assess and communicate current and emerging threats to human health posed by infectious

³ See Regulation EEC 2309/93 of 22 July 1993.

⁴ See Regulation EC 178/2002 of 28 January 2002.

⁵ See Regulation EC 851/2004 of 21 April 2004.

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agents, but its actions could not be evaluated due to the short period of activity before the start of the evaluation process.

A second action regarded the improvement of the Network of Reference Laboratories in the EU, to ensure timely and consistent diagnosis of animal diseases. These laboratories, funded by (the ?) DG SANCO, have the role of coordinating the diagnostic methods employed by the MS and to provide adequate training to the experts. The network capacity in the ten years of the CAHP appeared to be adequate.

The third strategy concerned the funding of research to develop new tools for the prevention, monitoring and control of animal diseases. The majority of the stakeholders agreed that EC funded research had a role in developing better tools to control animal diseases. In the 1994-2006 period the DG Research funded projects on animal health and food safety, through the Framework Programmes 4, 5 and 6, for a total amount of about 230 million euros (Table 2). This large amount of money, however, accounts only for 6% of the total budget publicly provided for that area, demonstrating how the majority of funding still comes from the MS.

Table 2: DG Research funding on animal health projects, 1994 to 2006.

Framework programme/activity	EU funding
FP 4 (1994-1998): FAIR programmes: 61 projects	
Area 4 Animal Health and Welfare: 34 projects	€30 million
Area 5 Fisheries and Aquaculture: 27 projects	€14 million
FP 5 (1998-2002): Quality of Life: 66 projects	
Key action 2: control of infectious diseases: 46 projects	€50 million
Key action 5: sustainable agriculture, fisheries: 20 projects	€23 million
FP 6 (2002-2006): 35 projects	
Food quality and safety: 15 projects ⁶	€91 million
Research for policy support: 20 projects ⁷	€22.3 million

Source "Evaluation of the CAHP: Final Report"

It was then concluded that funding risk assessment Agencies, Reference Laboratories and research had an important role in allowing the achievement of the aims of the CAHP to improve the general animal health status in the EU. Nevertheless, some areas for further improvement were identified, in particular regarding the choice of priorities for funding, which was considered not always being adequate.

In order to improve research prioritisation, the European Technology Platform for Global Animal Health (ETPGAH) was launched in 2004.

⁶ In FP6, thematic priority 5 (Food quality and safety) included a thematic area "safer and environmentally friendly production methods and technologies and healthier foodstuffs" which dealt with AH issues.

⁷ Including the call dedicated to Avian Influenza in 2006.

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The aim of the ETPGAH was "to facilitate and accelerate the development and distribution of the most effective tools for controlling animal diseases of major importance to Europe and the rest of the world, thereby improving human and animal health, food safety and quality, animal welfare, and market access, contributing to achieving the Millennium Development Goals". This Platform had the role of putting together all animal health stakeholders in Europe, both from the public and private sectors, to define strategic agendas on a number of strategically important issues. This would have facilitated the commitment of funds to implement research and helped to improve European growth, sustainability and competitiveness in the medium to long term.

The ETPGAH Strategic Research Agenda⁸ (SRA) was launched in May 2006 and contained indications about the priorities on which to focus research funding in the animal health area for the following 10 years. These recommendations had a direct impact on European research, being considered as one of the bases for the setup of the aims and themes of the 7th Framework programme (2007-2013).

The SRA, in order to perform an adequate prioritisation of the research, covered a number of relevant issues, one of them being a research gap analysis. Some results issuing from this analysis will be presented in Chapter III.

Results of the CAHP evaluation

Over the time span analysed for the drafting of the CAHP evaluation report, between 1995 and 2004, the Community Animal Health Policy became more and more successful in terms of achieving the objectives foreseen.

The report highlighted the lack of a general strategy for the animal health policy, which was more similar to a series of interrelated policies acting under a large umbrella of legislation than a structured policy. The lack of assessment tools for performance evaluation was shown to be a weak point too.

Anyhow, the overall evaluation was positive. Several policy improvements were obtained during that time, mainly led by the need to address some major crises that occurred in Europe during that period (e.g. classical swine fever in 2000 and FMD in 2001). In fact, all relevant "vertical" legislations concerning the control of the disease responsible for the crisis were revised and updated after the emergency, taking into account the lessons learnt, and allowing a better structured response to future crises. That led, over time, to a more effective response to crises and subsequently to a considerable reduction in the prevalence of a number of animal diseases.

Another positive aspect highlighted by the evaluation was that the role of the Commission as policy maker had a broader acceptance, both on an EU and on an international level. Nevertheless, a lack in consistency of actions to improve animal health and welfare among the EU countries became apparent, showing that the local policy still had a strong influence on the CAHP implementation. To better target relevant issues (e.g. disease), it was found that defining priorities at Community level

⁸ The ETPGAH Strategic Research Agenda is available at <http://www.etpgah.eu/component/downloads/downloads/58.html>.

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was more effective than at Member State level. The role of the Commission then was to guarantee a common approach and a standard to be followed in the EU, while the MS were carrying out the enforcement, keeping a certain degree of flexibility.

Animal welfare was included in the CAHP as well. Even if at the beginning of this policy, the population’s knowledge and awareness of animal welfare were very limited, the relevance of this aspect has grown fast year after year, engendering the need of developing specific animal welfare policies in the CAHP framework. The relevance of animal welfare issues in the EU can be deduced by the fact that the Eurobarometer, a Commission tool used to know the European citizen’s perspective towards relevant themes, was used in 2005 to know the attitudes of the consumers towards the welfare of farm animals (Special EUROBAROMETER 229 “Attitudes of consumers towards the welfare of farmed animals”, 2005). This survey highlighted that although a vast majority of European citizens thought that animal welfare protection was better, or at least not worse, in the EU as compared to other countries, 55% of the respondents declared that animal protection did not receive enough attention in the food and agricultural policy at that time. Therefore, the report concluded that there was a need to make EU policies concerning animal welfare more consistent.

Future options emerged from CAHP analysis

The evaluator provided, with their final report, a range of concrete options to improve the effectiveness of future European policies on animal health and welfare. All these proposals were previously discussed with the interviewed stakeholders and authorities, to ascertain their usefulness and public acceptability. Eight main options were proposed (see Table 3).

Table 3: Future options for the European policies on animal health and welfare

Future European policies on animal health and welfare options	
Option A	Further alignment of EU legislation to OIE recommendations/standards/guidelines
Option B	Adopting integrated electronic systems for EU procedures applied in animal movement
Option C	Improving intra-Community trade in live animals
Option D	Rationalising Committee procedures
Option E	Targeting illegal imports/fraud
Option F	Negotiating export conditions at Community level
Option G	Supporting on-farm bio-security measures
Option H	Providing assistance to third countries

Source “Evaluation of the CAHP: Final Report”

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The first proposed option (option A) was to align the EU legislation with the OIE recommendations, standards and guidelines, to improve the global transparency and global acceptance of European norms. Nevertheless, not for all themes covered by CAHP OIE guidelines were available and in some cases updates were needed, so the enforcement of norms on this aspect would have been premature.

Two other options regarded the improvement of the live animal trade, that was found to be one of the areas where major interventions were needed. To tackle this issue several actions were proposed. Firstly, (option B) the amelioration of animal traceability through the use of an integrated electronic system, that would have eased the communication among MS and decreased the administrative burden for the general management of the system. However, in order to avoid technical difficulties, it was advised to perform a feasibility study, to evaluate requirements and to estimate the impact of such an option. Electronic certification for animal transport was proposed as another option (option C) to avoid the problem of having multiple certificates to travel among different MS, thus obtaining an improvement of the quality of transport. Since animal transport could pose risks, both in terms of animal/public health and animal welfare, several stakeholders also proposed to reduce the intra-Community live transport as much as possible, replacing it with trade of safer products (e.g. semen and meat).

Trade was found to be another pivotal point for the future strategy. In order to reinforce the efforts against illegal imports in the EU, a risk-based approach, together with a more concerted action among different control authorities (e.g. among different veterinary Border Inspection Posts, BIP), was proposed (Option E). Moreover, assistance to Third Countries was proposed to upgrade their animal health status and in their compliance with the EU regulatory framework for import approval (option H). On the export side, to obtain an EU Animal Health Policy which is consistent with other EU objectives, the negotiation of common export conditions at Community level was proposed (option F). Nevertheless, even though this proposal would have eased the negotiation, it was disagreed with by several stakeholders, mainly because of competing interests.

To promote the competitiveness of EU operators, and to get a faster reaction in case of an emergency, a rationalisation of the Committee procedures was proposed (option D). In fact, allowing the endorsement of some procedures, such as the approval of contingency plans, to follow a simplified procedure instead of passing, as foreseen by the law (EC Regulation 178/2002), through the evaluation of the Standing Committee on the Food Chain and Animal Health (SCFCAH), would fasten the overall process significantly.

In order to improve disease prevention, the implementation of supporting actions for on-farm biosecurity was proposed (option G). Some other advice for future strategy was given about this theme but is not listed in table 3. In particular, the introduction of a disease classification system was proposed, in order to allow a better prioritisation of eradication and surveillance actions as well as research and development activities. To support all these actions, it was proposed to develop schemes for sharing responsibilities and costs of epidemic livestock diseases.

Lastly, the evaluation demonstrated the need to define a clear and transparent single strategy, accompanied by a communication strategy, also improving stakeholder engagement and

involvement in decision-making. This proposal opened the door to the preparation of the new Animal Health Strategy, which was launched in 2007.

The new Animal Health Strategy (2007-2013): “Prevention is better than cure”

The evaluation of the CAHP 1995-2004 made it clear that some changes were needed in the political approach to Animal Health in the European Union in order to keep the excellence earned during the years and the competitiveness on a global scale. Several major changes occurred in the EU in the last 20 years, that expanded from a Community of 12 MS to an Union of 25 (now 27) and where trade of live animals and animal products, with the open market, increased greatly. Big changes took place in the field of science and technology, and new challenges came from animal diseases (e.g. FMD outbreak in 2001). Clearly, the policy approach toward Animal Health needed to be changed to make it appropriate for the new framework.

DG SANCO has launched the Animal Health Strategy⁹ in 2007, which will cover a six-year period (2007-2013). Pivotal point of this new strategy was the focus on preventive actions instead of “curative” ones (“Prevention is better than cure”), both to improve efficacy and to reduce action costs using a risk assessment-based approach. Another important feature was the recognition that, due the relevance of the set objectives, it was not possible for the Commission to be successful on its own; moreover there was a strong need of making a number of relevant stakeholders more involved, keeping effective partnerships at all levels. This concerted action allows the strategy to be better targeted toward animal health at all levels and increases the customer’s confidence in the proposed actions.

The strategy sets out an Action Plan¹⁰, with a number of challenging goals (Table 4), which aimed to achieve a partnership approach, including everyone involved in animal health, not just the EU institutions and Governments but also stakeholders and interested citizens, working together to obtain a real improvement of animal health and welfare on a Community level.

Table 4: New Animal Health Strategy’s Goals.

Goal 1
To ensure a high level of public health and food safety by minimising the incidence of biological ¹¹ and chemical risks to humans.
Goal 2
To promote animal health by preventing/reducing the incidence of animal diseases, and in this

⁹ The Animal Health Strategy 2007-2013 is available at:

http://ec.europa.eu/food/animal/diseases/strategy/index_en.htm.

¹⁰ The Action Plan for the implementation of the AHS is available at

http://ec.europa.eu/food/animal/diseases/strategy/docs/COMM_PDF_COM_2008_0545_F_EN_AUTRE_PROC_LEG_NOUVELLE.pdf.

¹¹ Referring to animal diseases, food-borne diseases and biotoxins.

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way to support farming and the rural economy.
Goal 3
To improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements ¹² .
Goal 4
To promote farming practices and animal welfare ¹³ which prevent animal health related threats and minimise environmental impacts in support of the EU Sustainable Development Strategy ¹⁴ .

Source “A new Animal Health Strategy for the European Union (2007-2013) where “Prevention is better than cure”

As it can be noticed, the animal health strategy had a broad range of activities, since it was not just targeting the absence of animal disease but the relationship between animal health and welfare as well as food safety and public health.

To achieve these goals, 4 main activity areas (“pillars”) were set (Table 5), each one having its specific objectives and deadlines.

Table 5: Pillars of the Animal Health Strategy.

Pillar 1	Prioritisation of EU intervention.
Pillar 2	The EU animal health framework.
Pillar 3	Prevention, surveillance and preparedness.
Pillar 4	Science, Innovation and Research.

Source “A new Animal Health Strategy for the European Union (2007-2013) where “Prevention is better than cure”

In order to measure the progress and the level of achievement of the set goals, some simple and reliable indicators were developed as well, in consultation with relevant stakeholders, and kept updated whenever need arose.

Animal health is becoming a serious concern for European citizens, not only because of public health concerns (e.g. food borne diseases), but also for economic (e.g. costs of disease control) and ethic (e.g. animal welfare) reasons. The European Commission reckoned it therefore necessary to improve transparency about the EU policy on this issue, to allow the general public to be constantly aware of the progress made and to improve their trust in the whole system. A Programming

¹² The movement of animals has to reach a balance where the free movement of animals is proportionate to the risk of introducing and spreading of diseases and to the welfare of the animals during transport.

¹³ In coherence with the Communication from the Commission to the European Parliament and the Council on a Community Action Plan on the Protection and Welfare of Animals 2006-2010 (COM(2006)0013).

¹⁴ The European Council adopted in June 2006 an ambitious and comprehensive renewed EU Sustainable Development Strategy - DOC 10917/06.

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document, containing all the 31 necessary activities for the achievement of each pillar aim, was therefore developed and made available on the DG SANCO website¹⁵.

The modernisation of the EU animal health framework.

As highlighted by the CAHP evaluation in 2006, the European Animal Health framework was complex and composed by a large number of different norms not having a real strategy at the basis. Hence, the need for change in this situation was a priority, with the aim to allow the EU to be more efficient in responding to crises and to be more competitive on an international level.

The aim of Pillar 2 of the new Animal Health Strategy was to modernise the global EU framework on Animal Health. Four main areas of activity were foreseen to obtain the result set for this Pillar (Table 6).

Table 6: Pillar 2 area of activities and expected outcomes.

Area of activities	Expected outcomes
A single and clearer regulatory framework	<ul style="list-style-type: none"> • A single horizontal legal framework to define and integrate common principles and requirements of existing legislation (intra-community trade, imports, animal disease control, animal nutrition and animal welfare).
	<ul style="list-style-type: none"> • Simplification of the existing legislation and replacement by this new framework as appropriate, seeking convergence to international standards (OIE/Codex standards) while ensuring a firm commitment to high standards of animal health.
Developing efficient cost and responsibility sharing schemes	<ul style="list-style-type: none"> • Development of an harmonised EU framework of the criteria for responsibility and cost-sharing
Community influence on international standards	<ul style="list-style-type: none"> • Support of EU positions on the basis of sound scientific evidence, whenever necessary.
	<ul style="list-style-type: none"> • Community membership of the OIE in order to strengthen the active role of the Community.
Towards an expert strategy at community level	<ul style="list-style-type: none"> • A more efficient and transparent service for businesses, including SMEs, results-oriented and focussing on concrete sanitary problems that EU businesses face in third country markets.
	<ul style="list-style-type: none"> • Better prioritisation of actions against sanitary barriers in order to target human resources and to achieve the greatest economic impact.

¹⁵ http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_en.htm.

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	<ul style="list-style-type: none">• A strengthened role in negotiating EU export conditions and tackling export problems through the development of locally based EU Market Access Teams drawn from Commission Delegations, Member State Embassies and business organisations, where appropriate.
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Source "A new Animal Health Strategy for the European Union (2007-2013) where "Prevention is better than cure"

The Action Plan for the implementation of the AHS confirmed that "the main objective of the Strategy is the development of an EU Animal Health Law". The simplification of the existing legislation by issuing a single and clearer regulatory framework was then proposed as a first action. In fact, to react to epidemic diseases in livestock, which entail high costs and might have great economic and social impact, it is fundamental to have a constantly updated and flexible legislation.

Aim of this action will be the replacement of the already existing series of linked and interrelated policy actions by a single policy framework. The creation of this "horizontal" norm will be the more important tool for the real application of the new Strategy. It will be the main collector of all activities in the Programming Document in which most of the outcomes of the other strategy actions will flow into. This new regulatory framework should have as a basis the international standard (e.g. the OIE) and will cover not just animal health but also animal nutrition and welfare. The revision of the current co-financing tools will be taken into account as well. Since one of the main mechanisms for EU intervention in animal health is to keep a legislation in constant evolution, a certain degree of flexibility will be given to this new framework as well (e.g. to allow to provide efficient responses to changing situations). In the meanwhile, the Commission is committing itself also to ensure that unjustified local rules (both national and regional) will not represent an obstacle to the internal market and in making the Committee procedures more effective (reducing the number of practices needing SCFCAH intervention).

The role of research in the AHS

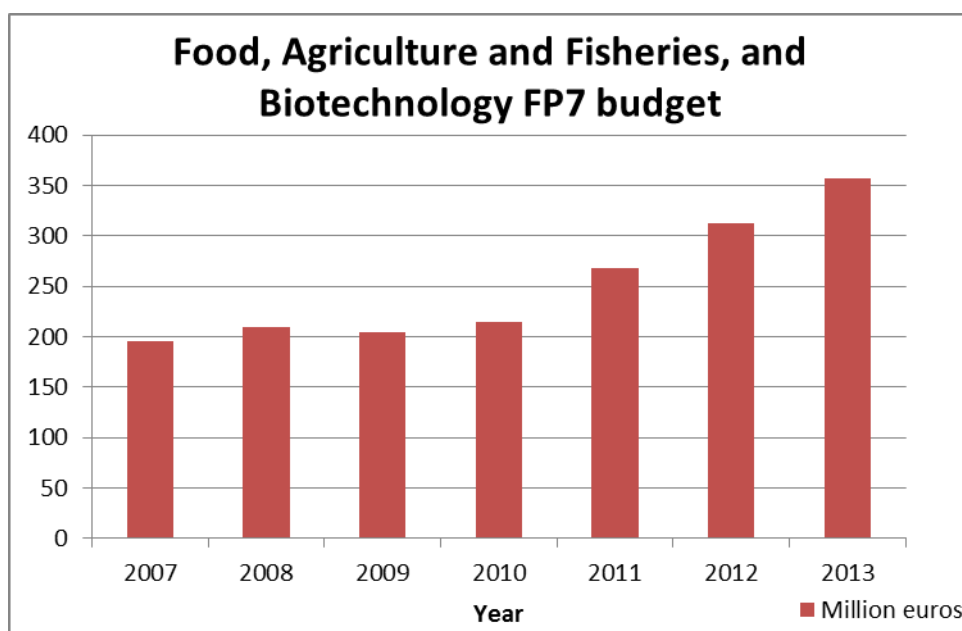
Research played an important role in allowing the Community Animal Health Policy to achieve good results between 1995 and 2006. In the new AHS its role became even more relevant, being one of the four pillars of the Strategy (Pillar 4).

The final aim of this pillar is to stimulate and coordinate risk analysis, science, innovation and research, to improve the animal and public health status in Europe and to increase the competitiveness of EU animal health businesses.

The activities carried out in the CAHP regarding National Reference Laboratories and European Agencies on scientific advice and risk assessment will be kept on-going and strengthened in the 6 years that the AHS will be applied. In order to improve the uniformity of diagnostic testing and disease control systems, the NRL network will be evaluated and its activities will be extended, if needed. The collaboration among European agencies and national bodies will be enhanced as well, to better provide a scientific basis to risk managers.

On the side of innovation and research the main outcomes expected from the AHS are the definition of a research action plan, prioritising actions and defining research gaps, and ensuring the appropriate funding for the chosen activities. The main tool for the achievement of these objectives has been the 7th Framework Programme, which provides funding for priority research. Proof for the relevance given to research in the period of the new AHS's application may be that the total amount of funding in FP7 was increased by 60% as compared to FP6, reaching a total amount of 50.521 billion euros. Of this global amount, 1.935 billion euros were appointed to Food, Agriculture and Fisheries and to Biotechnology¹⁶. The yearly breakdown of the FP7 budget in this area is shown in Figure 1. As may be noticed, the funding increases every year, exceeding 350 million in 2013.

Figure 1: Food, Agriculture and Fisheries, and Biotechnology FP7 yearly budget.



Source: http://ec.europa.eu/research/fp7/index_en.cfm?pg=budget.

The basis for the 7th FP was put in place before the beginning of the Strategy. The preparation of a FP, in fact, is a long process, taking about 3-4 years before the launch of the first call, hence its need to be planned with a relevant advance. For the first time in the history of the FPs, several European Technology Platforms contributed to setting the work programme. In the animal health area, the Strategic Research Agenda of the ETPGAH played a pivotal role on the definition of the main themes to be covered by the Programme.

The deep involvement of the stakeholders, including industry representatives, in the definition of the research areas was not interrupted after the drafting of the strategic research agenda of the ETPGAH. On the contrary, it was kept as a key aspect of FP7. In 2008, for example, a joint initiative of industry and a wide range of stakeholders (including the research community, regulators, users) was funded (the DISCONTTOOLS project) with the aim to prioritise research in order to hasten the delivery of new or better tools for diagnosis, vaccines and pharmaceuticals to control animal diseases.

¹⁶ Council press release 16887/06 of 18/12/2006.

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In order to obtain a real development of research the involvement of different stakeholders was not enough, a better coordination among them at all levels was also needed, among research institutions as well as among national and European funding bodies. A big effort was to be made in FP7 to step up the cooperation and coordination of research activities, through the funding of ERAnets (European Research Area network) in the field of animal health.

A first ERAnet on this subject, EMIDA (Coordination of European Research on Emerging and Major Infectious Diseases of Livestock), was funded in 2008 with the scope of improving coordination of EU research on emerging and major infectious diseases in livestock. The ANIHWA (Animal Health and Welfare) ERAnet, of which this report is one of the deliverables, could be considered as a successor of EMIDA, with its range of actions broadened to animal welfare and production diseases.

Conclusions

The Community Animal Health Policy was successful in the period 1995-2004 but was demonstrated to have some weaknesses. The main problem was the lack of homogeneity and planning of this policy, being composed by several actions taken mostly as a reaction rather than being performed to follow steps scheduled in advance.

During the last decades animal health and animal welfare have achieved an increased relevance for the EU citizens. The citizens have also become more aware of the importance of animal health policies for public health, and their economic and social relevance. Due to these facts, the old approach of reacting rather than preparing and preventing had to be changed if results were to be improved. This is why a new Animal Health Strategy was issued in 2007, containing all the planned activities and objectives to be reached in the following 6 years. The cornerstone of this new strategy was the creation of a “horizontal” norm providing general rules for all in the fields of animal health, welfare and nutrition, a new Animal Health Law.

The conception of this new Animal Health Law, together with its scope, structure and state of the art of the document’s drafting process are described in the next chapter (Chapter II).

Research was another cornerstone of the new AHS. Several tools were put in place to allow the Strategy to improve the activities in this area: the network of National Reference Laboratories, the European Agencies on scientific risk assessment and the new FP7. Research will have the possibility of becoming a real pillar for the new Animal Health Strategy. Research prioritisation was recognised to be a fundamental issue to be covered. The first step to be carried out in a prioritisation study is the identification of research gaps. At the end of this report, a chapter (Chapter III) is dedicated to the research gaps that emerged from both the whole analytic and legislative workflow, beyond the issuing of the new animal health law, and from dedicated EU projects or stakeholders’ surveys.

Chapter II:

The new Animal Health Law: drafting process and state of the art.

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Introduction

The historical process that raised the need for the development of a new Animal Health Law has been reported in Chapter I.

Chapter II will detail the scope of the norm, focusing on the general principles that underlie it and on its contents and will describe its complex and long drafting process.

The creation of a new “horizontal” norm, covering all areas of animal health, including the link of animal health to animal welfare and to existing food safety and hygiene rules for food and feed, was considered as the more relevant tool for the practical application of the new Animal Health Strategy. It was still unclear what kind of legislative act should be put in place (e.g. regulation or directive). Nevertheless, it was thought to be the central link among all the other activities foreseen within the AHS, and most of the other Strategy outcomes were linked to it.

This norm is meant to be issued with the aim of simplifying and clarifying the animal health framework while reflecting stakeholders' expectations in reducing administrative burdens. As a final outcome, this norm is supposed to help the sector in becoming more resilient, thanks to active prevention measures and more flexible risk management, and in allowing it to react and overcome the current economic crisis.

Several innovative approaches were followed in the drafting process of the AHL, as compared to the norm previously issued in this area. The focus on broad stakeholder and Member States involvement in the preparation process, the principle of sharing responsibilities and the convergence of EU norms to international standards are only some of the innovative traits that characterise the new AHL.

The drafting process of the document is taking a long time and is still currently on-going. The data presented here have been gathered through a deep search and analysis of the publicly available documents and through interviews with persons that were involved, with different roles, in the process and can be therefore considered reliable. However, some slight changes, in particular for what concerns the norm structure, might occur prior to the final entry into force of the norm. Nevertheless, due to the relevance of its contents, and to the innovative approach that was and will be followed for the preparation of this rule, the authors decided to dedicate a Chapter of this report to it.

The information that will be provided in this Chapter is relevant for all professionals working with animals, as well as for a broad range of other stakeholders (including, to some extent, the Competent Authorities of the Member States). This section will be equally important for the public and private bodies involved in the funding of research, who might find here the main areas considered relevant for the European Commission in the field of animal health in its broader sense.

General principles and scope of the AHL

Until present, the legislation acting on the field of animal health was scattered among many legal measures with a different subject-matter. Most of them were “vertical” norms, meaning that they targeted a particular issue (e.g. the control of one specific disease), and none of them provided for a general framework laying down general rules applicable in all fields concerning AH. The new Animal Health Law will be highly innovative in this sense, being a “horizontal” norm. To develop it, a similar approach will be followed as for the General Food Law (Regulation (EC) 178/2002), which provides the main principles on the protection of human health and the protection of consumers in relation to food,. These two norms (the General Food Law and the AHL) will be of equal value but they will target different areas, being complementary. The Food Law, in fact, is not dealing with animal health unless it is concerning food safety, while the AHL will not consider the health threats that are transmitted through the food chain, even if they can represent a risk for public health.

Some general principles underlie to the creation of the new Animal Health Law. Firstly, the norm will reflect the priorities of “Smart Regulation in the European Union¹⁷”, a set of measures planned to achieve the aim, set out by the Europe 2020 Strategy¹⁸, of smart, sustainable and inclusive growth. Strengthening the voice of citizens and stakeholders, through a high and early involvement in the drafting process, will be one of the pivotal points. It will ensure to take into account stakeholder concerns and to increase their awareness of the rights and obligations deriving from EU norms, contributing to improve also the transparency of the overall process. Attention will be paid in order to finally get outcome-based rules and to avoid excessive prescriptiveness. The issue of a simplified norm, leading to a reduced administrative burden, will be another driving force of the drafting of the AHL. Lastly, the concept of shared responsibility, as introduced by the new Animal Health Strategy, will be another pivotal theme of the new norm. Therefore, the engagement of all involved parties, from the European Commission to the Member States to the stakeholders, in the formulation and implementation of EU policies will be encouraged.

The aim of this norm will be to implement the commitments and visions provided for in the new Animal Health Strategy, setting a legal basis for a common EU animal health policy and a single, simplified, transparent, flexible and clear regulatory framework for animal health.

The AHL will set the basic principles of animal health, providing rules for the movements of animal and products of animal origin, setting disease control measures, and ensuring the conditions for early detection, notification and surveillance of disease. In addition, this new norm will take into consideration the link between animal health and animal welfare and food safety, also considering the economic, social and cultural issues that those aspects could entail.

The new norm will target all farmed animals (both terrestrial and aquatic), together with pets, hobby, and zoo animals. Wild animals might be mentioned, as far as it concerns their impact on human health or on other animals of the above-mentioned categories, to avoid the spread of diseases.

¹⁷ Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0543:FIN:EN:PDF>.

¹⁸ Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>.

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One of the focuses of the new AHL will be on the convergence of EU standards with the international, and in particular with the OIE, ones. In particular, the setting of general principles for disease categorisation and then prioritisation will be laid down, following the approach that the OIE developed on this concern.

As stated in the 2007-2013 AHS, “prevention is better than cure”. Therefore surveillance, being a key tool to preserve animal health by preventing the introduction of the animal health threats into the EU and enabling their eradication, will be a pivotal principle of the new norm. Through surveillance, better and more effective disease preparedness and safeguard measures can be put in place.

Biosecurity will be another key tool to improve the prevention of diseases. Being available to a wide range of people working with animals, it will be necessary to setup clear roles and responsibilities for all the actors involved in the field of animal health, going from the farmers, through the business operator, to the Competent Authorities. Veterinarians will be acknowledged to have a key role in the investigation of diseases and will act as a link between operators and the Competent Authorities (CAs). Nevertheless, the farmer is meant to become the key figure for the application of biosecurity measures. The new norm, in fact, will put the main responsibility for the health of the animals with the farmer himself, similarly to what happened with food business operators in the General Food Law. The farmers will be asked to put the preventive approach in practice through implementation of biosecurity measures at farm level. The application of these procedures will entail new costs, which will need to be covered not just by the farmers themselves but also through public investment. The funding of these measures, however, will not represent an additional burden for the EU but will result in an overall budget reduction. In fact, although it will cause an increase of the investment in prevention, it will end up in a global lowering of direct costs for the “cure”.

Another key issue of the AHL will be the transport of animal and products, both intra- and extra-EU. To ameliorate it, animal traceability will be improved and provisions on the conservation of species and on the introduction of non-native species will be included in the new norm.

All these elements will constitute a solid framework which will enable quicker response to health threats and the general improvement of animal health, and welfare, status across the EU.

State of the art: drafting process

A pre-feasibility study for the analysis of the impact of an Animal Health Law was performed in 2006, and its results were inserted in the report of the CAHP evaluation. In the Action Plan of the new Animal Health Strategy, details and priorities were already set, as well as the timeframe for the completion of the drafting process. In the same document it was stated that all CVOs would be involved in the whole process and that a Steering group would be created, followed by a wide consultation process. In fact, to provide a transparent and rational basis for political decision-making, an Impact Assessment, to be prepared by the Commission services, was planned. To ensure

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the involvement of all Member States in the process, plenary consultations with them were planned through working groups.

The preparatory work for the creation of the AHL officially started in 2008, when the Commission drafted the first scoping paper and sent it to the CVOs for evaluation. After that, the Steering group was formed. The Terms of Reference¹⁹ for the Steering group stated that its aim would be to assist the Commission in technical and legal matters relating to the content of the new Animal Health Law. This assistance would include both technical and scientific assistance about the legal form of the new norm and about its contents. The group was composed by 8-10 Member States experts, experts from the international organizations such as OIE and other interested stakeholders until reaching a maximum number of 15-20 persons. Other experts might have been invited to attend to group meetings by the Commission, if requested for particular purposes by the group. The first meeting of the Steering group took place in February 2009, to discuss about the scoping paper²⁰.

In this document, issued to provide an overview of the strategies to be followed to achieve the goal of drafting the AHL, four different options were taken into account for setting the general structure of the future Animal Health legislation (see Table 7). The first two options did not contemplate the issue of a completely new norm and appeared inadequate to achieve the objectives set by the AHS, while the choice among the other two options was not easy, and required a deep evaluation.

Table 7: Options provided for the future animal health legislative framework.

Option 1	Keeping the existing bulk of legislation intact.
Option 2	Simplification and adaptation through amendments to the existing acts and possible use of non-regulatory instruments.
Option 3	Animal health law as an instrument of basic principles and rules and additional set of measures as a second level of regulation (“Animal Health Framework”).
Option 4	Comprehensive animal health code that covers a significant part of the existing legal framework of imports, notifications, disease eradication and control as well as horizontal rules of the legislation on veterinary checks and control, animal identification and registration (“Animal Health Code”).

Source: “Working Document on the Structure of the Animal Health Law and Relation to Linked Policy Areas”

Before going into more detail about the proposals concerning the structure of the new norm, it is important to specify which were the arguments to be covered by the AHL, as highlighted by the Steering group discussion about the scoping paper. In fact, four main categories of themes needed to be covered by the new AHL, but the way these themes would be integrated inside the norm

¹⁹ The TOR are available on-line at http://ec.europa.eu/food/animal/diseases/strategy/pillars/docs/tor_ahl_steergroup_en.pdf.

²⁰ The Working Document on the Structure of the Animal Health Law and Relation to Linked Policy Areas issued after the first Steering group meeting is available on line at http://ec.europa.eu/food/animal/diseases/strategy/pillars/docs/steer_group_main_areasahl_180209.pdf.

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would depend directly on the general scheme followed to develop it. The four themes are listed in Table 8.

Table 8: Themes covered by the new AHL.

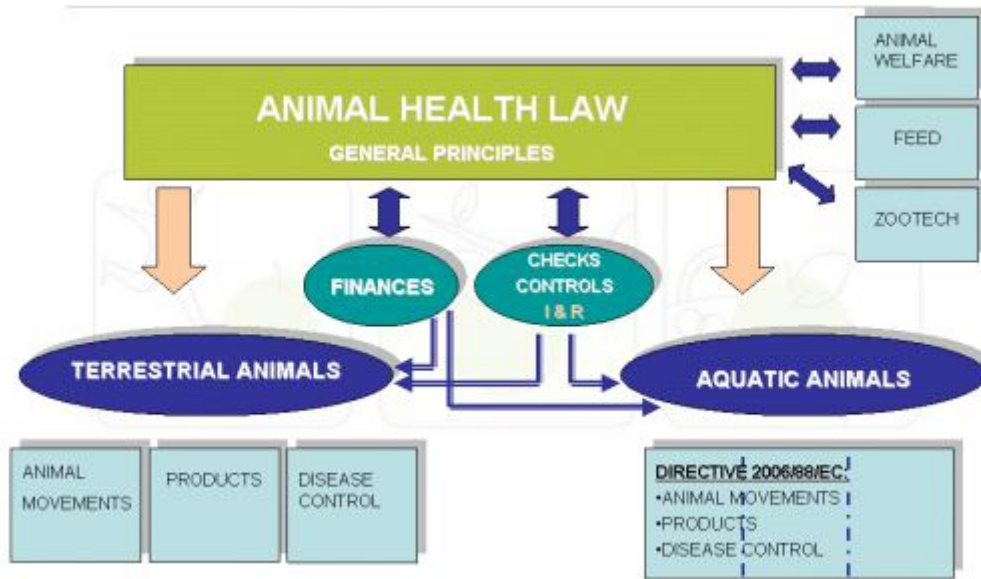
Group 1	General principles, common issues and overlaps.
Group 2	Legislation on veterinary checks (control directives) and on the measures on financial support.
Group 3	Remaining acts which could be divided regarding the type of animals, terrestrial and aquatic. Three main areas: <ul style="list-style-type: none"> - movements and trade in live animals, - movements and trade in animal products, - disease control and surveillance.
Group 4	Related legislation on animal welfare, animal feed and zootechnics.

Source: "Working Document on the Structure of the Animal Health Law and Relation to Linked Policy Areas"

In case an "Animal Health Framework" would have been selected as the best form for the new norm, only the general principles would have been directly included in that law, providing links to all other relevant legislation in the areas of veterinary checks, financial support, and disease control and movements for terrestrial and aquatic animal. Links to related legislation on animal welfare, nutrition and zootechnics would be provided as well (Figure 2).

Figure 2: The "Animal Health Framework" concept and relation to linked policy areas.

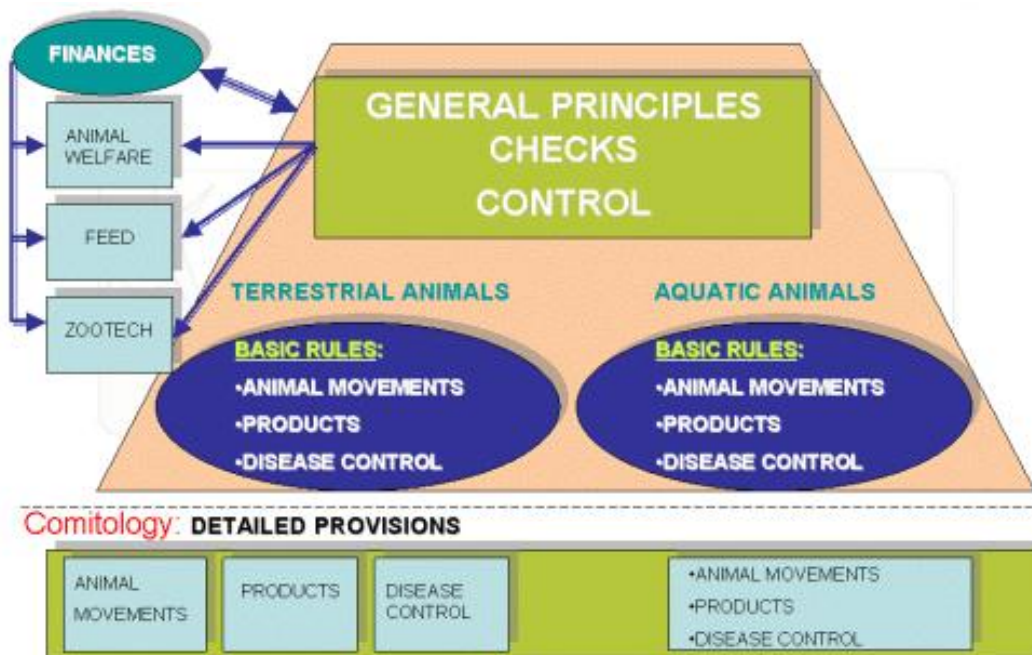
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Source: “Working Document on the Structure of the Animal Health Law and Relation to Linked Policy Areas”.

In case the option 4 would have been selected, and the new AHL would have the structure of an “Animal Health Code”, this norm would have contained directly not only the general principles but the legislation about veterinary checks would have been integrated there as well. Basic rules for terrestrial and aquatic animals (both for animal and animal product movements and for disease control) would have been given in the Code as well, while specific provisions on these areas would have been derived from Comitology. Furthermore, the norms about financing, animal welfare, animal nutrition and zootechnics would have kept their autonomy although principles and interfaces would have found a place in the AHL (Figure 3).

Figure 3: The "Animal Health Code" concept and relation to linked policy areas.



Source: “Working Document on the Structure of the Animal Health Law and Relation to Linked Policy Areas”.

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Option 3 was selected following the consultations with the Member States working group. The norm would now include the framework and basic principles and further specific rules on animal health, as well as the principles for all actors dealing with animal health, and would also include the official activities other than official controls, which would remain under Regulation (EC) 882/2004. The new norm was drafted as a Regulation, hence having the peculiarity, once issued, of entering in force directly for all Member States without need of a transposition into national law.

In 2009 a consultation within the Steering group was performed to identify the issues emerging from the actual legislative framework on animal health, and to be able to identify the areas that needed improvement and the adequate tools to perform these enhancements through the new AHL.

A wide stakeholder consultation was put in place in 2009. A questionnaire was developed and made available to interested parties. All persons involved were asked to evaluate the state of the art of the proposal and to add their comments and suggestions about it. From this stakeholder survey²¹ the Commission services drafted an Impact Assessment report about the implementation of the new AHL. The results of the consultation show a general support of stakeholders on the approach proposed by the Commission on the majority of the aspects covered by the AHL. Nevertheless, some discrepancies of opinions among stakeholders were observed on certain themes (e.g. finding of the training, tasks of veterinarians EU-wide, compulsoriness of biosecurity) and therefore needed to be discussed further to obtain an homogenous and agreed norm.

The drafting process of the Animal Health Law is contained in the programming document²² of the Animal Health Strategy (Fig 4). However, since the preparation of the norm took longer than originally planned, the information available on this website is not updated and stops at 2010.

Figure 4: Programming document.

2. A Modern Legal Framework			
Activities	Milestones	Leadership	Orientative date for completion
A single and clearer regulatory framework			
4. An EU Animal Health Law	CVOs - preparatory work		Done (Feb 2008)
	<u>Steering Group (Scoping paper)</u>	SANCO D1	2nd semester 2008
	<u>Consultation process</u>		2009
	<u>Regulatory proposal (IA)</u>		CLWP 2010

Source "Programming Document", last access 18th March 2013.

A first draft of the norm was circulated in late 2010 among all MS participating in the revision committee, to obtain amendments and comments. Later on, during the following years, the MS plenary working group met regularly to agree on the more significant issues to be covered and to

²¹ Summary results of the consultation, based on the responses to the questionnaire, are available at http://ec.europa.eu/food/animal/diseases/strategy/pillars/docs/sum_results_consultation_en.pdf.

²² Available at http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_en.htm.

keep on defining the norm. In the meanwhile, the Commission kept the CVOs updated and the Legal Office through internal meetings. Several drafts have been circulating among the members of the working groups until now. Currently, the state of advancement of the work is good and it's legitimate to suppose that from now on no more fundamental changes will be made by the working group nor by the Commission. The new norm has been developed by the European Commission using the delegation procedure foreseen under art. 290 of the Treaty of Lisbon and recently implemented²³. This procedure foresees that both the European Parliament and the Council might use their right of opposition, denying the entry into force of the Regulation if they have complaints about it. Some changes might then occur at this very stage. However, it is not possible at the moment to know if they will occur nor to which extent or how they might impact on the norm. The AHL contents description, shown in the following chapter, therefore, does not take this possibility into account.

Structure and contents of the new AHL

Up to now, the Animal Health Law is meant to be issued as a Regulation, acting as a general framework in the field of animal health in its broader sense.

The legislators put a lot of effort in designing a norm being at the same time proportional and assuring a common playground for all Member States, while guaranteeing that all necessary action were covered all over the EU. Hence, some of the rules included in the AHL (e.g. the ones on trade) are well-detailed in order to avoid different interpretations, and then implementation, among MS or Competent Authorities, contributing to reduce the risk of having market distortion. In the meanwhile, some other rules needed flexibility to ensure the efficacy of the implementation of the norm across Europe. Therefore, the Member States were given the right to adapt, to some extent, some of the rules to their national (or even local) situation, to make the norm more fit for purpose in different scenarios.

The norm is subdivided in seven main parts (Table 9), each of them addressing particular issues.

Table 9: Parts of the new AHL.

Part I	General Rules
Part II	Notification, Surveillance, Eradication Programmes, Disease Freedom
Part III	Disease Preparedness, Awareness and Control
Part IV	Requirements Concerning Registration, Approval, Traceability and Movements
Part V	Entry into the Union and Export
Part VI	Emergency Measures

²³ The Communication from the Commission to the European Parliament and the Council on the implementation of Article 290 of the Treaty on the Functioning of the European Union is available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0673:FIN:EN:PDF>.

Part VII	Final and Transitional Provisions
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In Part I the general rules and principles will be given. The request for listing and prioritisation of diseases, that would allow the allocation of resources on a scientific and evidential basis, will be included in this section. There, for the first time, a clear definition of role and responsibilities of all people working with animals (not only veterinarians but also business operators, farmers, pet keepers, etc..) will be given, and the need for all these actors to have a basic knowledge of animal health, links between animal health and animal welfare and related matters will be stated.

In Part II the roles of all actors involved in the surveillance in the EU will be set and clearly detailed. The new approach is conceived in a manner to allow a better cost-efficient use of resources, together with guaranteeing the efficacy of surveillance actions. The use of compartmentalisation will be enhanced, widening the list of diseases where this measure might be implemented and introducing in the meantime a certain degree of flexibility in disease control measures.

Part III will deal with disease preparedness, providing for the preparation of contingency plans in the Member States and setting up the regulatory framework for vaccinations. A new method for the provision of antigen, vaccination and reagent will be given: the UE will be responsible for this, implementing this duty in a more coherent and consistent way. The importance of the responsible use of medicinal products for disease prevention and control and the use of the epidemiological approach to face disease spread will be also stressed.

Part IV will deal with animal traceability. Animal identification and registration is recognised to be crucial for preventing the spread of disease. Due to the different production methods, this section will deal separately with terrestrial, aquatic, and other animals. For the first two categories the norm will promote a wider use of traceability, via electronic identification, and the simplification of the procedures through the use of technology. The third title of the norm will be issued in order to be prepared in case new health threats might emerge from these other animals.

Part V will set the standards and requirements that will be necessary for allowing the entrance of animals and products of animal origin in the European Union. In this same section, provisions for the export will be defined. For both import and export, the provisions contained in the AHL will not divert from the rules that are already in place and that are considered effective.

Part VI will deal with emergency measures, which are a crucial part of disease management. The procedures to be followed in case of an emergency will be detailed but, also in this case, the new norm won't contain any relevant change as compared to the existing legislation.

The last part, Part VII, will contain the final and transitional provisions.

Conclusion

The simplification and harmonisation of the norms is a strong priority nowadays in the EU in all fields. The general legislative framework concerning animals, and not just animal health, is now changing following this drive. The Regulation (EC) 882/2004 is under revision, to adjust some areas in order to simplify and clarify the existing framework and consolidate the integrated approach. During the revising process, efforts have been made to make it more consistent with the new AHL and with the new Plant health norm. Lastly, also the possibility of issuing a revised EU legislative framework for animal welfare, as foreseen in the Animal Welfare Strategy 2012-2015, is currently debated²⁴. The drafting of the AHL is therefore part of a more complex ploy, that will impact on the work of professionals working with animals across the EU.

As emerged in this Chapter, the drafting process of the new Animal Health Law has been long and involved a really broad range of stakeholders. The process is not completed yet and several years are still needed to have the norm applied in the EU. The new norm, as it is in its current state, may have very important strong points, but in some areas some improvement might still be needed. For example no appropriate source of financial support were identified yet to allow farmers to apply the biosecurity measures. Nevertheless, the need exists for the people working in the livestock sector, and more in general in the animal sector, to start taking into account the new drivers that emerged from the writing process.

Several really relevant innovations will arise from the new AHL, such as the focus on prevention, the assignation to farmers of the main responsibilities concerning animal health, the improvement of traceability and the agreement with other relevant standards. Starting to take this into account will be important for a large number of professionals and stakeholders, both belonging to the public and private sector.

Farmers and Competent Authorities, in particular, may take profit from this first overview on the new norm. In fact, these two actors will be the ones most involved in the new AHL implementation. Farmers will need to acknowledge that they play a pivotal role in the field of animal health, being the first responsible for their own animals. This role will also entail them with more duties, so it is important to build the understanding that this will represent a positive opportunity in the long run for the whole animal sector. Competent Authorities will also need to start knowing the new norm, in order to be ready to have it implemented as soon as it will be applied, and will need to foster the preventive approach on the protection of animal health.

Lastly, this study of the animal health law proposal might be of help as well to public and private bodies involved in the funding of research. Several new drivers for the protection of animal health emerged from this drafting process, which highlighted which will be the main tools in place for this purpose in the new norm.

²⁴ An open debate for stakeholders and Member States was held on the 22nd of February 2013 in Brussels on this issue. The agenda of the event is available at http://ec.europa.eu/dgs/health_consumer/information_sources/docs/ahw/agenda_22022013.pdf.

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In the next Chapter, the research drivers that could be derived from the whole process will be identified and detailed, in order to provide a valid playground to funding bodies to set the priority areas for the financing of research on animal health and welfare in the EU.

Chapter III:

Analysis of future research drivers emerging from the new Animal Health Law and other relevant EU actions

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Introduction

The process underlying the drafting of the new Animal Health Law was long and complex. During those years of preparatory work, while studying the best way to improve the animal health status inside the EU, several problematic areas were identified. Gaps of knowledge relies sometimes at the basis of these problems. The filling of these gaps, with appropriate scientific research, would guarantee the finding of better knowledge-driven solutions and a more fruitful animal health policy in the European Area.

A very important contribution to the identification of research gaps in the field of animal health and welfare was provided by the continuous inputs of the EU Standing Committee on Agricultural Research (SCAR), and in particular by its Collaborative Working Group on European Animal Health & Welfare Research²⁵ (CWG). This CWG group, that met regularly since 2005, has the scope to improve focused network of research funders, enhancing collaboration on research prioritisation and procurement and creating the necessary critical mass and focus to deliver the animal health and welfare research needs of both policy makers and European livestock industry. In order to accelerate the CWG work, the EMIDA (Coordination of European Research on Emerging and Major Infectious Diseases of Livestock) ERAnet was launched. An overview of the main gaps identified during this project is presented in this Chapter.

In Chapter I, it emerged clearly that the Animal Health Strategy 2007-2013 has been one of the main driving force for the issuing of the new AHL. Nevertheless, in order to reach its objectives of better animal health and welfare conditions across the EU, the Strategy promoted a number of other actions. Several projects (e.g. DISCONTTOOLS) were launched with the aim of identifying research gaps on the field of animal health and welfare, indicating how important this issue was considered by politicians and Community technical experts. All of these actions operated in the same field but from different perspectives, obtaining sometimes different outcomes. In this Chapter, a general description of the main actions that were carried out to identify gaps on animal health and welfare is performed. Then, the identified results have been aggregated here to provide more complete and broadly accepted outcomes.

On the other hand, the AHS was also asking for a development of animal health policy based on extensive stakeholder consultation. Taking into consideration the perspective of stakeholders will represent an added value to the ANIHWA purposes. In particular, since farmers will be the main actors in the new AHL framework, their view on future research drivers cannot be ignored. Then, a section of this Chapter is dedicated to the knowledge gaps on animal health and welfare identified by the Copa-Cogeca (Committee of Professional Agricultural Organisations – General Confederation of Agricultural Co-operatives in the European Union).

Lastly, knowing which disease are circulating across Europe would be relevant in order to better know which threats are likely to emerge in the next future and develop the right tools to face them. That is why a preliminary study of the disease notified to the World Organisation for Animal Health (OIE) in the last four years (2009-2012) was performed, in order to identify those that are more likely to become a priority for Europe in the next years, and is presented in this Chapter. These data,

²⁵ CWG Website available at <http://www.scar-cwg-ahw.org/>.

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combined with sound prioritisation policies, might help to minimise the impact of emerging disease by increasing prevention, on-going surveillance and preparedness to potential threats and emergencies.

The preliminary study carried out for preparing this report is meant to provide assistance to the work of the other ANIHWA WPs. Firstly, it will be a valuable tool to help WP4 in the decision of the themes to be covered by the second ANIHWA joint call, that will be launched in October 2013. Moreover, the collected data might represent a first basis for the WP3 research gaps identification and will give some preliminary information to WP5 for the preparation of the ANIHWA SRA on animal health and welfare.

Research drivers emerging form the drafting of the new AHL

The process that led to the drafting of the new Animal Health Law was described in Chapter II. As it can be noticed, several innovations are supposed to derive from the AHL once it will enter into force. This is due to the new driving forces that acted during the drafting of the norm. Since these drivers will be leading most of the actions aiming to protect animal health in the EU, the delivery of innovation in these sectors would have a major impact on the overall situation. That is why it was decided to identify and to describe these drivers in this section.

Prioritisation of diseases is an important theme to be covered under the new AHL. Some criteria for the ranking of diseases will be provided in the Regulation but then research will be needed to define the priority diseases list.

Biosecurity is another keyword of the new AHL. The new norm will ask the farmers to put in place biosecurity measures in order to prevent the spread of infectious disease, being in charge of covering at least part of the costs deriving from them. Practical and affordable tools to be used on field in order to ease the application of these principles would then have a major impact on the animal producing sector.

The responsible use of medicinal products for disease prevention and control will be highlighted in the new norm. More knowledge about efficacy and side effects of available drugs, also taking into consideration animal welfare and environment implications, or the development of new products might play a beneficial role. New knowledge of and developments in disease control tools should be taken into account also for the drawing of contingency plans.

Traceability is another important drive that emerged. Efficient traceability is a key element of disease control policy. Improving the efficacy of identification and registration systems will then result in an improved effectiveness of disease control.

This short list of research drivers, together with the ones that will be following in the next sections, would allow to draft a priority list of knowledge gaps that will help in the prioritisation of research funding.

The ETPGAH Strategic Research Agenda and Action Plan

The Strategic Research Agenda (SRA) is one of the main outcomes of the ETPGAH platform, that was launched with the aim of boosting research by developing methodologies to prioritise requirements and develop more effective funding on animal health in the European Union. The SRA provided a comprehensive list of recommendations for research and further action to meet those aims. As previously mentioned, the indications that were contained in the SRA served as a basis for the setting up of research themes to be covered by the FP7, and are likely to be taken into account for the definition of the next framework programme (Horizon 2020) first priorities.

The SRA covered 6 key issues:

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- Prioritisation of animal diseases;
- Performing of gap analyses;
- Ensuring of high quality relevant fundamental research;
- Identification the enabling factors to improve the rate of Technology transfer;
- Consideration of regulatory issues;
- Keeping of a Global Perspective.

For each of those themes, the SRA delivered recommendations providing the strategic direction for the development of new tools to address animal health, focussing on the control of the major diseases and zoonoses.

In order to implement the Agenda and achieve the main objectives of the strategy, the ETPGAH Action Plan²⁶ was published in 2007. This document was intended as a tool to explain the research and information-gathering exercises that needed to be completed and to show the specific steps that needed to be taken to deliver the recommendations in the SRA.

The Action Plan followed the same structure of the SRA. It contained all the recommendations of the Agenda, divided among the 6 key issues, and grouped in sub themes. For each of them it identified the objective, deliverables and tasks to be reached, establishing a degree of priority as well as possible sources of funding. The Action Plan also recognised that, among the key issue, the first priority would have been the identification and prioritisation of disease, followed by the identification of research gaps to better target future researches.

A prioritisation of all recommendations was given in the Action Plan, ranking them from “High and Immediate priority” to “Medium and long term priority”. The high priority recommendations regarding research were selected for the aim of this report and are listed in Table 10. Those recommendations that, even if recognised as of high priority, are not directly linked to research, are out of the scope of this report and then are not listed in the table. Several high priority recommendations was referring to different aspects of the prioritisation of diseases. Therefore, since the scope of this Report is to provide general future research drivers and not to define detailed knowledge gaps, it was decided to merge all of them in one driver.

Table 10: Main research drivers derived from the ETPGAH Action Plan.

Research Drivers
- Methods for animal diseases and zoonoses prioritisation;
- Methods to identify new and emerging diseases and predict when they may become a threat to Europe (e.g. in relation to global warming and climate change);
- Wildlife diseases which might impact on human and animal health, and new screening test for wildlife infectious agents;
- Fundamental research: Host/Pathogen interactions, Fundamental Immunology, Epidemiology, Genomics and Integrated Biology.

Source: ETPGAH Action Plan

²⁶ Available at www.etpgah.eu/component/downloads/downloads/61.html.

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The inputs provided by the Action Plan were given to inspire both European and national research programmes and public/private research partnerships, improving the degree of cooperation and the alignment and coordination of the plans. The drivers identified were indeed used to launch project calls in several research programmes. In particular, several FP7 projects were funded in the last six years on these areas.

The establishment of ERAnets was proposed as an instrument to avoid duplication and to enhance integration and coordination of research programmes. In particular, the promotion of networking and coordination of national programmes in relation to animal health and welfare through an ERA-Net was stated to be of particular importance. Therefore, the launch of ANIHWA itself might be considered as a consequence of the ETPGAH Action Plan.

In the ETPGAH Executive Board (EB) meeting²⁷, held in September 2011, a close collaboration between ANIHWA and ETPGAH was proposed, to reach an alignment of the Action Plan to be developed by the new ERAnet and that of the ETPGAH. The scope of this report is also to contribute to this venture, providing preliminary data that might be used by the other WPs. Overall, this will enhance the active cooperation among the different partners working on the project.

After the delivery of the Action Plan, the ETPGAH EB kept on meeting periodically to discuss about how to update and review the Agenda concerning the new drivers for research. All participants agreed that it would be valuable to review the Agenda every 5 years, also defining what has been done and what still remains to be done. Although funding were no more foreseen to sustain this activity, a SRA revision work is now on-going but not yet completed. Inputs from the EMIDA 15 years SRA, issued in late 2011, are being used as a basis to develop this revision of the ETPGAH Agenda.

In addition to the drivers already listed in the Action Plan and reported in table 10, some new ones were identified during the ETPGAH EB meetings held in the last 2 years:

- the **One Health concept**, to link healthy plants/animals/food/humans;
- **sustainability of the bio-economy**, to link economic, ecological and socially sustainable growth.

The EMIDA project Strategic Research Agenda.

As mentioned in the previous chapter, the ETPGAH Action Plan suggested priorities and activities to be performed to reach the set objectives. Several FP7 projects could be considered as a direct consequence of it and some of them had as aim the identification of research gaps or the setting of new action plan for EU research. One of them was the EMIDA ERAnet, that run from April 2008 to December 2011.

The EMIDA project aimed at building on and accelerate the work of the SCAR Collaborative Working Group in developing a durable focused network of national research in the field of animal

²⁷ Minutes of this meeting are available at www.etpgah.eu/component/downloads/downloads/69.html.

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health across the EU. The scope included emerging and major infectious diseases of production animals, including fish and bees.

One of the project specific tasks was to undertake a 10-15 year forward-look exercise to identify requirements for animal disease research and to develop criteria for priority setting. Then, the production of a common strategic research agenda based on shared priorities was foreseen.

The EMIDA SRA was delivered on December 2011²⁸. To ensure the consideration a complete vision in which animal health threat would have been the priority in the next 10 to 15 years, the process to develop the Agenda followed several subsequent steps. Firstly, a literature review was carried out to map current research gaps already identified. Later on, a Delphi²⁹ study was launched to gather and collate the point of view of a board of experts on the future knowledge needs for the emerging and major infectious diseases of livestock. Lastly, a multidisciplinary consensus workshop among experts in the various animal health field was organised. As a basis for discussion during this Strategic Research Agenda Workshop (STRAW), the outcomes of the two previous activities (both the literature search and the Delphi) were used. The results of the three studies provided the foundation upon which to build the Agenda.

From the STRAW, ten research drivers emerged and were ranked in order of priority, from the perspective of both the EU on a global scale and for bio-climatic sub-regions. Nevertheless, some interactions and overlapping were present among the identified research areas. In order to avoid overlapping and to make a clearer distinction among the identified themes, a regrouping was made in the SRA, leading to the identification of a total of six research drivers. These drivers, ranked on the basis of the pan-European focus, are listed in table 11. Even if priority on the EU global level were very similar to the sub-regional ones, some slight difference were present in their ranking. In the EMIDA SRA a list of the regional priorities is provided but it will not be discussed here since it is out of the scope of this ANIHWA report.

Table 11: Pan-European research drivers as identified by the EMIDA SRA.

Pan-EU Priority	Research Drivers
High	Surveillance system and risk analysis;
High	Control measures and biosecurity;
High	Ecosystem change, vector-borne disease and preparedness (in the field, laboratories and veterinary services);
Medium	Host-pathogen interaction that serves the development of diagnostic tools and vaccination;
Lower	Antimicrobial resistance;
Lower	Zoonoses.

Source: EMIDA Strategic Research Agenda

²⁸ Full document available at <http://www.emida-era.net/upload/pdf/EMIDA%20SRA%20final%2020111227.pdf>.

²⁹ A description of the Delphi method is provided in the EMIDA SRA.

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Furthermore to derive more specific research topics, and to validate the consensus on the results obtained, a comparison with results emerging from other on-going studies were performed (e.g. DISCONTTOOLS). The final results of this foresight work have been aggregated and reported in table 12.

Table 12: Pan-European research priorities identified in the EMIDA SRA.

Research Drivers	Research priorities
1. Surveillance system and risk analysis	<i>Risk based improvement of surveillance;</i>
	<i>Improvement of risk analysis.</i>
2. Control measures and biosecurity	<i>Biosecurity measures on all level, including wildlife issues;</i>
	<i>Development of diagnostic tools and control methods for diseases of neglected species;</i>
	<i>Vaccination and vaccination strategies;</i>
	<i>Development of novel control methods for endemic diseases.</i>
3. Ecosystem change, vector-borne disease and preparedness	<i>Better understanding of vector borne diseases and health effects of ecosystem changes;</i>
	<i>Improvement of preparedness for emerging and exotic diseases by improvement of diagnostic tools and by an epidemiological approach of risk pathways identification.</i>
4. Host-pathogen interaction that serves the development of diagnostic tools and vaccination	<i>Vaccine development;</i>
	<i>Antiviral development;</i>
	<i>development of detection tests.</i>
5. Antimicrobial resistance	<i>Development of alternatives to antimicrobials;</i>
	<i>Molecular and cellular basis of antibiotic and anthelmintic resistance.</i>
6. Zoonoses	<i>Unidentified/new, emerging, neglected and endemic zoonoses.</i>

Source: EMIDA Strategic Research Agenda

The identified research drivers might serve as a basis to start the development of the ANIHWA SRA, that will broaden the scope of EMIDA to animal welfare.

The DISCONTTOOLS project: gap analysis on disease control tools

Both from the ETPGAH and from the Animal Health Strategy 2007-2013, a strong request to prioritise animal related threats and identify the “gaps” in existing control tools for surveillance,

diagnosis, vaccination and treatment emerged. In fact, disease prioritisation was recognised to be the first priority in the Action Plan. As a response, the DISCONTTOOLS project was launched on March 2008. This FP7 project, ended on February 2013, aimed at providing mechanisms for focusing and prioritising research, to reach the development and delivery of new and improved vaccines, pharmaceuticals and diagnostic tests. A broad number of stakeholder were partners of the project, ranging from the industry to the research community, to regulators, users etc.

The DISCONTTOOLS project focussed on 51 diseases. For each of them, an expert group was formed, gathering specialist from both inside and outside the EU. These groups met periodically during the lifespan of the project to provide an agreed description of the disease and of the state of advancement of the control tools to face it. Moreover, each expert group was asked to “score” the disease they were working on the basis of scoring models that were developed in an earlier stage of the project. Two different models were developed. The first model aimed at scoring the relevance of one disease compared to another, taking into account criteria such as the negative impact they may have on animal health, welfare or trade. The second model allowed to score the gaps of knowledge that exist in relation to disease control tools, taking into consideration three main categories: diagnostic, vaccines and pharmaceutical tools. For both models, a score was assigned to each evaluated criteria. The overall score of one disease was then comparable with the score of the other diseases, allowing a ranking on the basis of their relevance or on the need of knowledge still present according to the disease control tools. The two scoring models followed two different scoring systems, that will be described more in detail later on. Once an agreement was reached among the experts on the disease description and scoring, the disease was included in the “disease database”.

The database is now publicly available online³⁰. It is an interactive tool that allows not only to retrieve information about the contained diseases but also to make comparisons among them on a variety of criteria. Among its functionalities, the database allows to obtain the list of priority diseases, that can be calculated considering a pool of all the criteria provided in the database or only specific ones (e.g. species involved or zoonotic potential), depending on the purpose of the analysis to be performed. The possibility is also given to obtain an overall ranking of the diseases gap knowledge as well as a rank only on the basis of one of the three categories of control tools (e.g. vaccines), to highlight which diseases that more strongly need further research in a given area. It is also possible to analyse diseases by sub-groups. Three main disease groups were created (epizootic diseases, zoonotic diseases and food producing animal complexes), and are pre-set on the online database to allow a more focussed analysis for thematic area.

Therefore, the disease database could be considered as a tool that allows the prioritisation of future activities in order to fill the gaps of knowledge on vaccines, pharmaceuticals and diagnostic tests. These information are meant to be inspiration for the drafting of future research Agendas in the EU, to focus funding on priority areas. These information are certainly relevant for the ANIWA scope too. For the purpose of this report, some analyses of the data contained in the disease databases were performed and are shown in this chapter. The aim is to obtain research drivers for the launch of the second ANIHWA call as well as to provide some inputs for WP3 and WP5 of the ANIHWA project.

³⁰ The database can be consulted on-line at <http://www.discontools.eu/Diseases>.

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Among the 51 available diseases, 5 are out of the scope of the ANIHWA project, either because the target species are mainly not livestock (e.g. leishmaniasis) or because they are more likely to be food-borne diseases (Bovine Spongiform Encephalopathy, campylobacteriosis, cryptosporidiosis and salmonellosis). Then, these diseases will not be considered in this analysis.

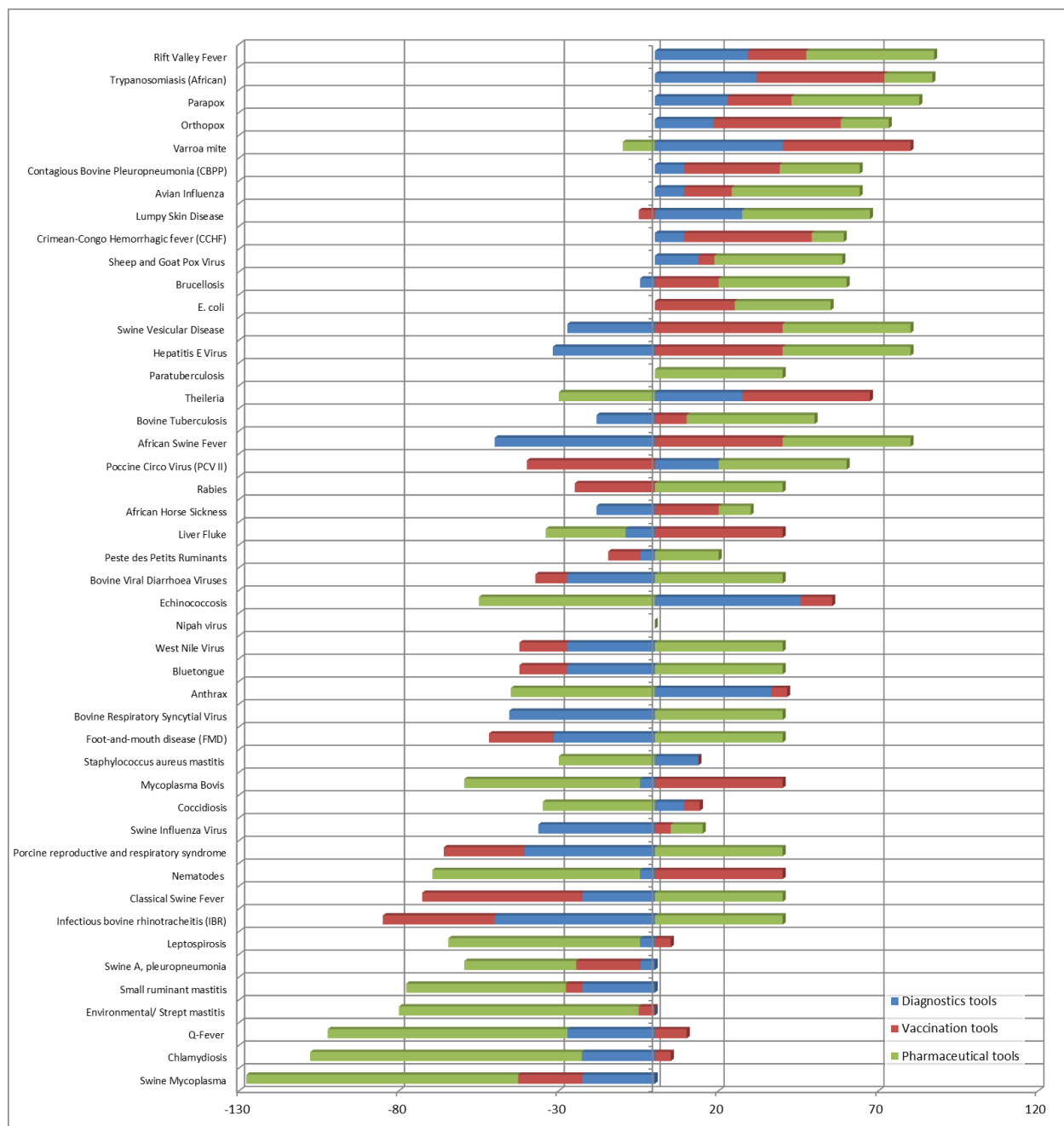
A first scan was performed on the remaining 46 diseases to analyse the gaps that are present for vaccines, pharmaceuticals and diagnostic tests. The results of this first scan are showed in figure 5.

Ranking scores are based on the “product gap analysis scoring model”, developed during the project³¹. Briefly, the scoring system for gap analysis was structured as follows. Several criteria were considered for each of the three tool categories (diagnostic, vaccines and pharmaceuticals), such as availability, quality, affordability and efficacy. The scores for each criteria ranged from -2 to +2, with negatives scores applied when products were already fully developed and available. Then, multipliers were applied to each criteria, on the basis of the relevance of the given criterion on the overall score. The overall scores might have a positive or a negative number, diseases with a positive overall score being the ones having more urgent need of new knowledge.

Figure 5: Gap analysis in vaccination, pharmaceutical and diagnostic tools for 46 of the DISCONTTOOLS listed diseases.

³¹ The product gap analysis model is available on-line at http://www.discontools.eu/upl/1/default/doc/1236_GapAnaScoring-V3-1.pdf.

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Source: DISCONTTOOLS disease database.

Figure 5 shows the diseases listed in relevance order for research gaps. At the top of the list are shown the diseases needing more new knowledge (for either vaccines, therapeutics and diagnostic tests) while at the bottom we find the one having the appropriate tools already available. From that figure it can be observed that, if for several diseases the appropriate tools are already available (e.g. swine mycoplasma or chlamydiosis), for others important gaps of knowledge still exist (e.g. Rift Valley Fever). Vaccination tools (red bar) appear to be, on a general level, the more impelling needs at the moment, having a positive mean score that is about the double of the pharmaceuticals tools' one. Diagnostic tools (blue bar) emerged as the tools category for which new research is less likely to be needed, on the overall of all diseases, having a negative mean value. Nevertheless, big differences can be observed among diseases. Therefore, some more insight studies are needed in order to provide more reliable and usable research drivers.

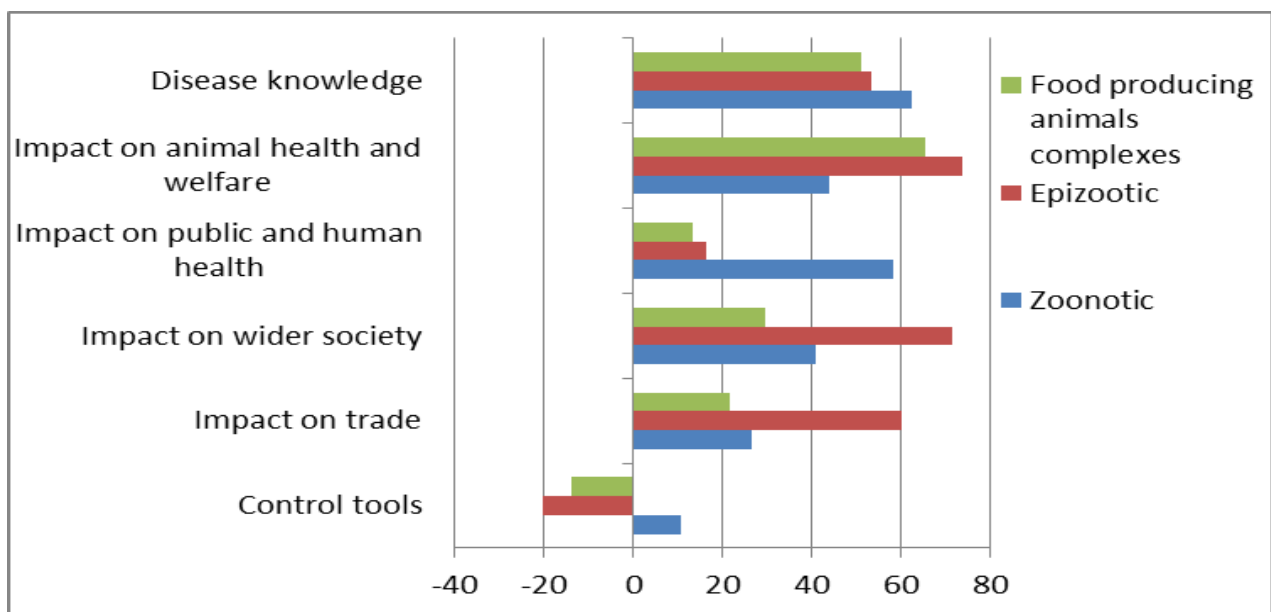
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In addition to the ranking of diseases according to present knowledge gaps, the DISCONTTOOLS database allows to perform prioritisation of the diseases on the basis of their relevance (e.g. general characteristics of the disease, impact on animal health and welfare, impact on humans and on trade). For this purpose, another scoring model was developed³².

The scoring system used for prioritisation was different from the one used for gap analysis. Six categories of criteria were given (disease knowledge, impact on animal health and animal welfare, impact on public and human health, impact on wider society, impact on trade and control tools), each one composed by several scoring criteria. For each criterion within each category (with the exception of the “control tools”) scores from 0 to 4 were given. A score of 0 indicated the non-relevance of the disease for the specified criterion (e.g. a non-transmittable disease was scored 0 for the “speed of spread” criterion) while a score of 4 indicated high relevance (e.g. a disease having rapid transmission between holdings without animal movements was scored 4 for the “speed of spread” criterion). For each criteria then, based on the relevance of it on the overall importance of the disease, a multiplier was applied (e.g. all diseases characteristics had a multiplying factor of 2.5 while the ones referring to the impact on animal health and welfare had a 8.33). The criteria regarding “control tools”, on the other hand, had the -2 to +2 score already described and, due to the relevance of such area, had a multiplier of 16.66. Therefore the impact of lack of control tools plays a main role on the overall score, and this is one of the reasons why some of the highly rated diseases are the same that the ones identified as having major gaps.

Going back to the analysis to identify drivers for ANIWA, a priority analysis of the diseases divided into the 3 groups assigned by DISCONTTOOLS (epizootic, zoonotic and food producing animal complexes) was performed in order to reduce the field of interest (Figure 6).

Figure 6: Mean score per criteria for each disease category.



Source: DISCONTTOOLS disease database.

³² The disease prioritisation model is available on-line at http://www.discontools.eu/upl/1/default/doc/1234_PrioV3-1-20110303.pdf.

Epizootic diseases are the ones having higher mean scores on the criteria “impact on animal health and welfare”, “impact on trade” and “impact on wider society”. Zoonosis, on the other hand, are more relevance from the point of view of the “impact on public and human health” and “disease knowledge” and need more effective “control tools”. Food producing animal complexes have the lowest score for most categories, mainly due to their lower impact on human health, trade and wider society. From this first analysis it could be suggested that future research should focus on **epizootic** and **zoonotic diseases** rather than on food producing animals complexes.

Another way of deriving driving research from the DISCONTTOOLS outcomes could be to rank all diseases on the basis of their relevance and select only the priority ones. For this analysis and to reduce the list of the original 46 diseases, the top 12 diseases were arbitrarily selected, and a more in depth study of them was performed. The list of the 12 priority diseases is given in Table 13. Again, diseases out of the ANIHWA scope were not considered.

Table 13: Priority diseases: top 12 list and overall score.

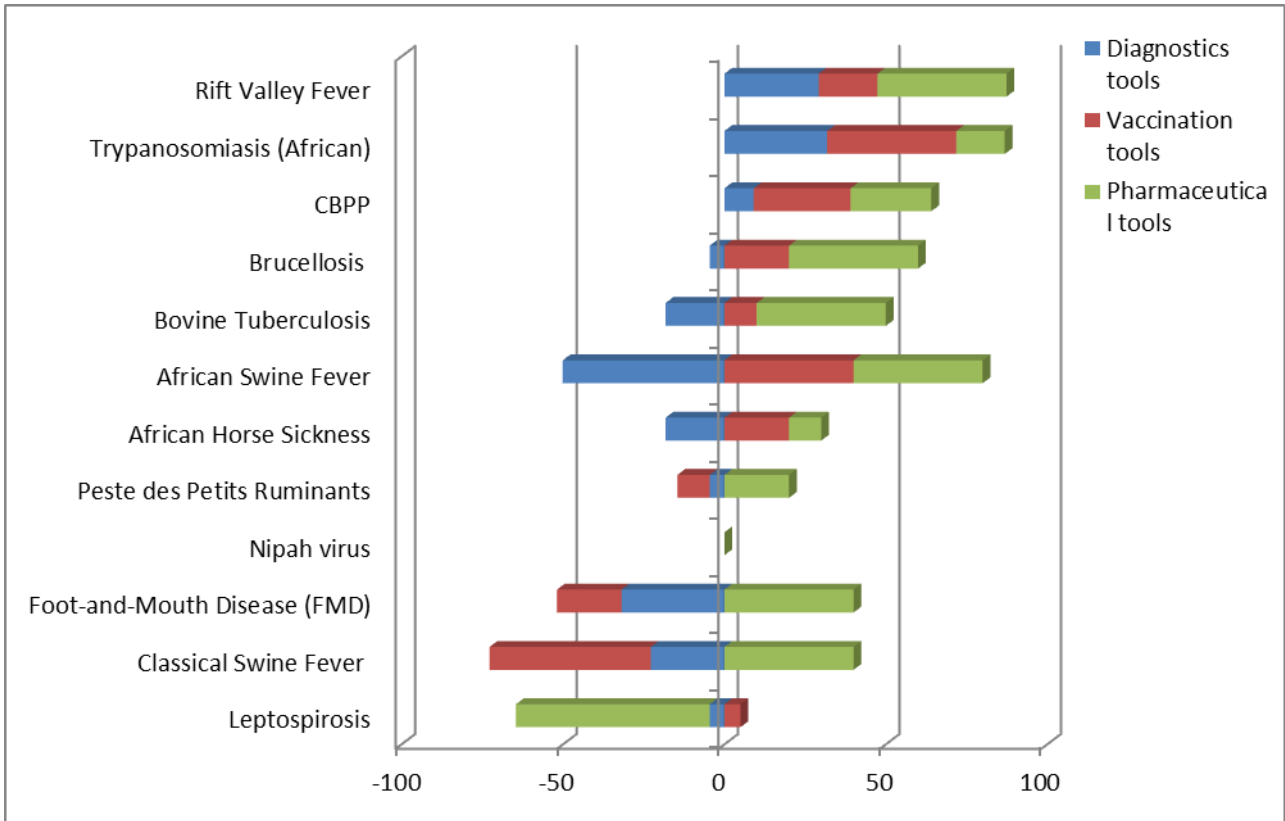
Rank	Disease	Category	Score
1	Nipah virus	Zoonotic	463,94
2	Peste des Petits Ruminants	Epizootic	384,49
3	African Swine Fever	Epizootic	372,83
4	Rift Valley Fever	Epizootic	365,25
5	Bovine Tuberculosis	Zoonotic	358,59
6	Foot and Mouth Disease (FMD)	Epizootic	310,34
7	Trypanosomiasis (African)	Zoonotic	296,16
8	African Horse Sickness	Epizootic	293,68
9	Contagious Bovine Pleuro Pneumonia (CBPP)	Epizootic	268,69
10	Leishmaniasis	Zoonotic	261,54
11	Brucellosis	Zoonotic	254,44
12	Leptospirosis	Zoonotic	249,88

Source: DISCONTTOOLS disease database.

Interestingly, no “food producing animals complexes” are present among the 12 more relevant diseases, that are in majority belonging to the “epizootic” group, then confirming previous analysis. To get an insight of which are the main areas that still need research for those diseases, a gap analysis on the selected list was performed (Figure 7).

Figure 7: Gap analysis for the 12 top priority diseases.

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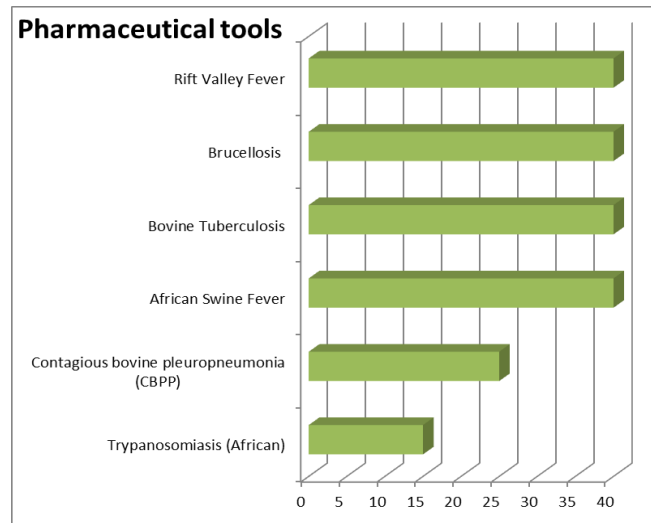
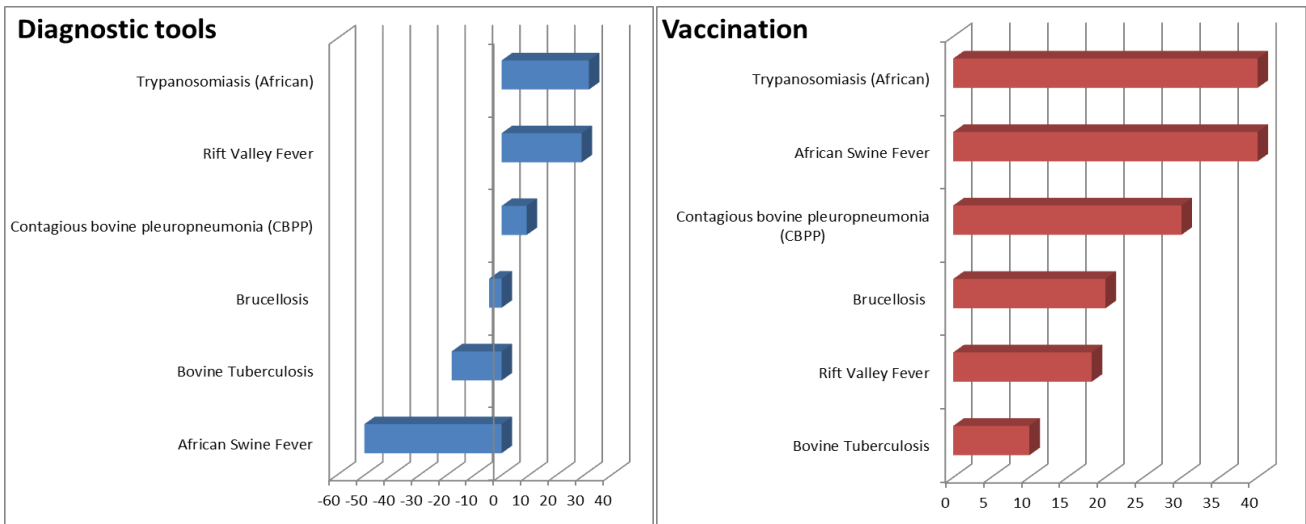
Source: DISCONTTOOLS disease database.

Although several areas still need improvement for the vast majority of the selected diseases, different needs are present according to the disease considered. This figure, anyhow, allows to identify among the more relevant diseases, which are the ones having also a higher need for new knowledge. To deepen this study of research drivers, the number of analysed diseases was halved.

Diseases included in this analysis were: Rift Valley Fever, trypanosomiasis, Contagious bovine pleuro-pneumonia (CBPP), brucellosis, bovine tuberculosis and African Swine Fever. Half of them belong to the zoonotic group while the other half to the epizootic. To detect more in detail the area needing improvement, three separate gap analysis were carried out, one for each type of tool, considering each of the six diseases. Results are shown in Figure 8.

Figure 8: Gap analysis for diagnostic tools, vaccination and pharmaceutical tools for the 6 top priority diseases.

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Source: DISCONTTOOLS disease database.

The development of new diagnostic tools appear to be a priority only for some of the diseases (Rift Valley Fever, trypanosomiasis, CBPP, and brucellosis) while all of them would need further development of **vaccines** and **pharmaceutical tools**, even if, for some of them, those will be less urgent (e.g. vaccines for bovine tuberculosis or pharmaceuticals for trypanosomiasis) as compared to the other.

As a last step of this prioritisation effort performed in this ANIHWA report, it was decided to further reduce the number of diseases to 3 for each of the gap categories, to ensure the detection of the more urgent needs (e.g. to be covered by the next ANIHWA call). This selection might have been made previously on the top 12 priority list, without passing through the overall gap analysis, but the results would have been different and less accurate. The ranking for general priority needs, in fact, highlights for which diseases there is a lack of mean of control, that is an information that is lost when the analysis is performed only on one of the three kind of control tools. For example, if no vaccines are available for one specific disease, the availability of effective therapeutics is likely to be more relevant than in case an effective vaccines exists. Having an idea of the overall level of

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need for one disease hence contributes to give a priority rank for the development for at least one of the tools to control, or detect, it.

Then, from this analysis of the DISCONTTOOLS disease database, it can be concluded that the more urgent needs of new research on the field of disease control tools are:

- new **diagnostic tools** for **trypanosomiasis, Rift Valley Fever, and CBPP**;
- new **vaccines** for **trypanosomiasis, African Swine Fever, and CBPP**;
- new **pharmaceutical tools** for **Rift Valley Fever, brucellosis, and bovine tuberculosis**.

Copa-Cogeca strategy: which improvements to AH and AW?

The involvement of stakeholders in the decisional processes and in the determination of EU actions regarding animal health and welfare has been a key issue of the last years' policy in Europe. Several stakeholders were involved in the evaluation process of the last CAHP and played an important role in the definition of the Animal Health Strategy 2007-2013, as well as in the Animal Welfare Strategy 2012-2015. The inclusion of major stakeholders in the decision-making process on significant policy issues, as well as in the definition of a research action plan, were foreseen in the AHS. That is why in this study about the drivers for research it seems appropriate to take into consideration the stakeholders point of view.

Among the vast range of stakeholders having an interest and playing a role in the identification of drivers for future research, the Copa-Cogeca is one of the most relevant. The Copa (Committee of Professional Agricultural Organisations) and the Cogeca (General Confederation of Agricultural Co-operatives in the European Union) are the more ancient European representative organisation for the agricultural sector, being funded respectively in 1958 and 1959. The two organisations merged already in 1962 and from then on they reinforced their position as Europe's strongest farming representative bodies, arriving today to represent 76 organisations from the EU Member States. This broad membership allows Copa-Cogeca to represent both the general and specific interests of farmers and of the entire agricultural and fisheries cooperative sector in the European Union. Therefore, the view of this organisation on animal health and welfare should be taken into account in the EU.

Copa-Cogeca contributed to the evaluation of the Animal Health Strategy 2007 - 2013³³, participating to the request for a simplified animal health legislative framework and asking for more efforts on biosecurity improvement. In the same document, it was asked to the European Commission to provide a more planned and complete involvement of key stakeholders in "peace time", to improve the cooperation between the parties.

In the last ten years, the Copa-Cogeca published several position papers on the issue of animal health and welfare (AHW) and, more recently, also specifically on the theme of research in the

³³ Full document available at <http://www.copa-cogeca.be/Download.ashx?ID=216359>.

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agricultural field (RES). Among the numerous papers published, two are mainly of interest for the purpose of this survey.

The first one, published in December 2011, expressed the “Copa-Cogeca’s views on research and innovation in the field of animal health and welfare in the European Union” (AHW(11)8502). One of the main aims of that document was to make the European research and innovation agenda for animal health and welfare more efficiently implemented at farm level. The positive role of the existing European platforms (e.g. EPTGAH), of the Standing Committee on Agricultural Research, and of the existing research programmes around Europe was recognised. The proposal for a European Innovation Partnership (EIP) on Productivity and Sustainability in Agriculture, as foreseen in the Europe 2020 strategy, was also very welcomed in order to improve implementation of research findings on the field. Nevertheless, several areas of improvement for the AH and AW research agenda, such as the improvement of communication and coordination of activities and research results, were identified. Some research gaps on animal health and welfare issues were also identified, and will be described and listed later on.

The second paper, published one year later, contained the initial thoughts of Copa-Cogeca about the future role of farmers and cooperatives in shaping research for the agri-food sector. The document, titled “Research and Innovation as the driving force for sustainable, productive and competitive European agriculture” (RES(12)5658³⁴), states that the agricultural situation in the EU is changing and that this sector is facing big challenges nowadays, such as the ones deriving from climate change. In this framework, population demand for food is increasing, making the challenge even harder. Then, Copa-Cogeca identified some actions to be taken to enable farmers to remain economically viable and to meet society expectations. One of these actions is to improve research and innovation in the agricultural field. The organisations then commit itself to help in identifying new research requirements, also to ensure that the new proposals will be applicable at the farm level. There again, a list of research gaps were developed.

Furthermore, for certain aspects, two additional documents have been considered to be relevant to this mapping exercise: the Copa-Cogeca’s views on the responsible use of antimicrobials in food producing animals (AHW(12)1244³⁵) and the reaction of European farmers and European agri-cooperatives to the EU strategy for the protection and welfare of animals 2012-2015 (AHW(12)1243³⁶).

The study and analysis of the aforementioned Copa-Cogeca documents allowed to draft a categorisation of the animal health and welfare gaps in “research drivers”. Six main drivers were identified: Sustainability and climate changes, Control of infectious diseases, Genetics, Animal Welfare, Development of technological tools and Development of practicable solutions. The knowledge gaps that were identified with this study are presented in table 14 and assigned to one of the identified drivers. Nevertheless, since some of these gaps appeared to be linked to more than one driver, when it occurred it was decided to repeat them in the table.

³⁴ Full document available at <http://www.copa-cogeca.be/Download.ashx?ID=957611>.

³⁵ Full document available at <http://www.copa-cogeca.be/Download.ashx?ID=909106>.

³⁶ Full document available at <http://www.copa-cogeca.be/Download.ashx?ID=907972>.

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Table 14: Research drivers on animal health and welfare identified by Copa-Cogeca

Research Drivers	Knowledge gaps
Sustainability and climate changes	<ul style="list-style-type: none"> - study on the control and reduction of greenhouse gas emissions in livestock farming; - study on the possibility of controlling the spread of zoonoses in the environment (e.g. vector-borne infections in restored wetlands); - development of strategies to face climate change leading to heat stress.
Control of infectious diseases	<ul style="list-style-type: none"> - study on the way of infection and on the development of new vaccines to improve animal welfare and productivity; - development new tools for early diagnosis of FMD and other new or emerging virus (e.g. BTV, Schmallenberg virus); - development of standardised procedures and farm tools for early, rapid diagnosis and control of diseases; - development of early warning models; - development of valid biosecurity measures.
Genetics	<ul style="list-style-type: none"> - study of more resistant breeds; - analysis of defence mechanisms of more resistant breeds; - development of new animal health traits; - development of new animal behaviour/welfare traits; - improvement of genetic for dairy cow to enhance fertility and to ease the management of dry cows.
Animal welfare	<ul style="list-style-type: none"> - development of objective and practical welfare indicators which could be used on voluntary farm management systems; - development of new animal behaviour/welfare traits; - optimisation of behaviour/welfare characteristics.
Development of new technologies	<ul style="list-style-type: none"> - evaluation of the application of new technologies, such as remote detection tools, to help in the management of animal diseases; - development new tools for early diagnosis of FMD and other new or emerging virus (e.g. BTV, Schmallenberg virus); - development of innovative antimicrobials and alternative solutions for the care of animals; - development of specific antibiograms/sensitivity tests as basis to the use of third and fourth generation cephalosporins as well as fluoroquinolones on flocks or groups of animals; - development feeding strategies to improve the fertility of dairy cows and to better manage dry cows.
Development of practicable solutions	<ul style="list-style-type: none"> - development of standardised procedures and more on farm tools for early, rapid diagnosis and control of diseases; - development of objective and practical welfare indicators which could be used on voluntary farm management systems; - further evaluation of trade-offs between changes in farming systems in order to comply with animal welfare requirements and impact on disease control, environment, water, biodiversity and climate change policy; - evaluation of the application of new technologies, such as remote detection tools, to help in the management of animal diseases.

Source: position papers AHW(11)8502, RES(12)5658, AHW(12)1244 and AHW(12)1243.

ANIHWA partner countries: preliminary analysis of the notified outbreaks 2009-2012.

Knowing which emerging diseases are entering in one territory could help to identify areas where to focus research to provide more appropriate tools to face outbreaks in the near future. In order to identify the major diseases that have recently occurred in ANIHWA countries, one of the main information systems used for the notification of animal diseases was scanned for information. This is the World Animal Health Information System (WAHIS), belonging to the World Organisation for Animal Health (OIE). The aim of this system is to ensure a rapid exchange of information between competent national authorities in charge of animal health and to improve the monitoring of outbreaks. The data and information provided by Members and held into WAHIS are accessible via the World Animal Health Information Database³⁷ (WAHID), a public web interface to the system. A second disease notification system is existing in Europe, the Animal Disease Notification System (ADNS), that belongs to the EU. However, the OIE database was preferred for retrieving data since not all the ANIHWA countries report through the ADNS

The data about all outbreaks incurring in the ANIHWA partner countries in the period 2009-2012 were retrieved through WAHID and analysed. A general overview of the collected data is given in Annex. In this section of the Chapter it was decided to focus the attention on the top diseases that were notified in the selected countries over the given period, to identify trends and new threats.

In some cases, different captions were used to identify a same infectious agent among the notifications gathered. It was the case, for example, of the Schmallenberg, that was mentioned sometimes as “Schmallenberg virus” and other times as “Schmallenberg disease”. In order to ease the interpretation of the data, all notifications regarding a same infectious agent were aggregated a same category, with the exception of the ones regarding Avian Influenza. For this disease sub-categories were left for different serotypes, since different research gaps might exist for different types. In case of Ostreid herpes virus 1, suspected cases were aggregated to the confirmed ones.

The diseases were ranked on the basis of the number of outbreaks in the ANIHWA countries per each year. It was then decided to select the 7 more frequently occurring to perform a more detailed analysis. These are reported in Table 15. More detailed data about the geographical distribution of these outbreaks is presented in Annex. From this first screen it can be noticed how outbreaks of some diseases were present each year, from 2009 to 2012 (e.g. **Bluetongue** and **Newcastle disease**). On the other hand, some diseases were present and then disappeared from the list during the time (e.g. Avian Influenza) while some other appeared during the time span (e.g. Schmallenberg and Rabies). Also, different trends in the number of outbreaks might be observed, that in some cases is decreasing (e.g. West Nile Fever) while in other it increased in the last years (e.g. Bluetongue). It is interesting to see how the listed diseases cover a broad spectrum of target species, including not just mammals and birds but also molluscs (Herpesvirus OsHV-1) and bees (European foulbrood of honey bees).

³⁷Available at http://www.oie.int/wahis_2/public/wahid.php/countryinformation/countryreports.

Table 15: Top 7 diseases in ANIHWA countries 2009-2012.

Year	Disease	Outbreaks
2009	Bluetongue	104
2009	Equine encephalosis	42
2009	Pandemic A/H1N1 virus	39
2009	Influenza A (H3N2)	26
2009	Newcastle disease	20
2009	Herpesvirus OsHV-1	30
2009	Foot and Mouth Disease	14
2010	West Nile Fever	138
2010	Newcastle disease	90
2010	Equine infectious anaemia	48
2010	Aujeszky's disease	22
2010	Herpesvirus OsHV-1	39
2010	European foulbrood of honey bees	17
2010	Bluetongue	8
2011	West Nile Fever	94
2011	Newcastle disease	78
2011	Anthrax	28
2011	Low pathogenic avian influenza (poultry)	26
2011	Foot and mouth disease	21
2011	Equine infectious anaemia	14
2011	Bluetongue	12
2012	Schmallenberg virus	3494
2012	Bluetongue	94
2012	Lumpy skin disease	78
2012	Newcastle disease	27
2012	Rabies	16
2012	West Nile Fever	14
2012	Equine infectious anaemia	8

Source: OIE WAHID.

Bluetongue was the more often notified disease across the ANIHWA countries in 2009 and then decreased in the two following years, while re-increasing its incidence in 2012. In the two year period 2010-2011, West Nile Fever was the most frequently reported disease, always followed by Newcastle disease. On 2012, Schmallenberg virus accounted for the vast majority of the notification, accounting for more than 90% of the overall.

The data shown before regards the overall analysis of the situation in the ANIHWA countries. Due to the vast geographical area covered and to the range of climatic zones, different diseases are more likely to be a priority for one area than another. In order to investigate the extent of these variation a further analysis was performed.

It was decided to divide the ANIHWA countries into two categories, on the basis of the geographical localisation. It was then formed a group of Northern countries (Belgium, Czech Republic, Denmark, Finland, Germany, Ireland, Lithuania, Netherlands, Norway, Sweden, UK) and another with Southern countries (Austria, Cyprus, France, Greece, Israel, Italy, Spain, Switzerland).

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France has been included in the Southern ones due to the junction to the Mediterranean Sea. Diseases were ranked per number of outbreaks for each year in both areas: the overall results are shown in Annex. In order to focus on priority diseases, in each area the 3 more frequently occurring diseases were selected (Table 16).

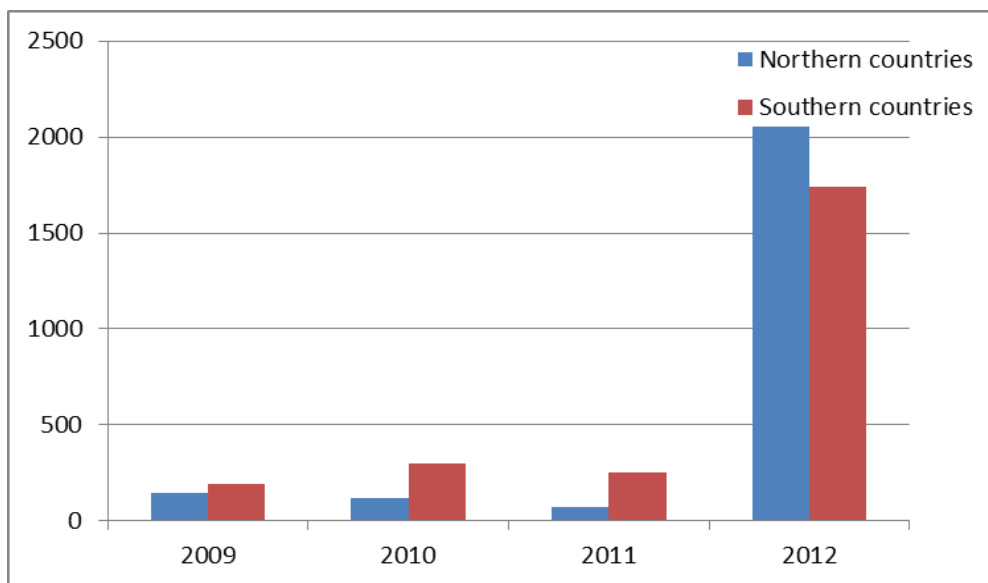
Table 16: Top 3 diseases divided per geographical area.

North Disease	Year	South Disease
Pandemic influenza A/H1N1	2009	Bluetongue
Influenza A (H3N2)	2009	Equine encephalosis
Herpesvirus OsHV-1	2009	Newcastle disease
Equine infectious anaemia	2010	West Nile Fever
Herpesvirus OsHV-1	2010	Newcastle disease
European foulbrood of honey bees	2010	Equine infectious anaemia
Low pathogenic avian influenza (poultry)	2011	West Nile Fever
Equine infectious anaemia	2011	Newcastle disease
Classical swine fever	2011	Anthrax
Schmallenberg virus	2012	Schmallenberg virus
Equine infectious anaemia	2012	Bluetongue
Brucellosis (<i>Brucella abortus</i>)	2012	Lumpy skin disease

Source: OIE WAHID.

As it was foreseen, the identified diseases are different in the two areas. In addition, it emerged that while Northern countries top list is quite different from the global one, the first three diseases in the Southern countries group are exactly the same as the ones of the list for the whole area. It was then decided to compare the total number of outbreaks in the two areas, to explain this finding. The results are shown in Figure 9.

Figure 9: Comparison of number of outbreaks between Northern and Southern countries per year.



Source: OIE WAHID.

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The number of outbreaks notified in Southern countries was always accounting for the majority of cases, with the exception of 2012 where it was slightly lower than in Northern countries. This discrepancy might be due to the proximity to the Mediterranean basin, that represents the door of access to the EU for emerging diseases that are present in Africa and Middle East. Also the climate itself plays a role on this. Most of the top 3 disease in the last four years in Southern countries, in fact, are **vector-borne diseases**, conversely to what happens in the Northern area.

Two kind of conclusions might be derived by these latter analyses. On one side, considering only the disease outbreaks in the whole EU area information about what is relevant for Northern countries might be underestimated. On the other hand, since climate is changing worldwide, the conditions allowing the establishment of vectors in areas that used to be free are becoming a common issue. Vector-borne diseases might then represent a future challenge also for countries that are listed as Northern ones.

A more detailed research about which diseases are emerging was necessary. These preliminary scans, in fact, while giving some data about which disease might be target for more detailed studies in the near future, still provides little information about the emerging diseases. Indeed, it is not specified if these notification was regarding a first detection of a disease in a territory or if it was a signalling of some disease being already present. A refining of the analyses was then performed, in order to select only the diseases that were notified as “first occurrence”, “emerging disease” of “new strain” across all countries. The diseases belonging to each of the three categories are listed in Annex. A ranking was performed on the basis of the total notifications and it was decided to arbitrarily select only the 3 more recurring ones for each year (Table 17).

Table 17: Top 3 emergent diseases in ANIHWA countries 2009-2012.

Year	Disease	Reason for notification	N°
2009	Pandemic influenza A/H1N1	Emerging disease	49
2009	Equine encephalosis	Emerging disease	42
2009	Herpesvirus OsHV-1	Emerging disease	30
2010	West Nile Fever	First occurrence	138
2010	Herpesvirus OsHV-1	Emerging disease	44
2010	Equine infectious anaemia	First occurrence	7
2011	West Nile Fever	First occurrence	38
2011	Bluetongue	New strain	2
2011	Koi herpesvirus disease	First occurrence	2
2012	Schmallenberg virus	Emerging disease	3494
2012	Koi herpesvirus disease	First occurrence	6
2012	Herpesvirus OsHV-1	Emerging disease	3

Source: OIE WAHID.

Some interesting observations emerged from this analysis. In fact, although several similarities are present between the list of the emergent disease as compared to the global one, some important differences are there as well. **West Nile Fever** and **Schmallenberg virus** still cover a predominant role, being the more incident one in 2010-2011 and 2012 respectively. Bluetongue, that was one of the main disease in the previous list, is almost disappeared in the new one, indicating that it can no

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more be considered as an emerging disease in Europe. Lastly, it can be observed that almost half of the list concerns aquatic animal viral diseases (**Oyster Herpesvirus type 1** and **Koi herpesvirus disease**) and it might indicate that more attention should be paid in the future toward this area.

Conclusions

Several different research drivers emerged from the analyses carried out for the preparation of this report. A summary of the main ones that emerged from the drafting process of the new Animal Health Law, from the analyses of recent EU actions aiming to gap identification, and from stakeholder opinions can be found in Table 18.

Some future drivers were identified by more than one analysing process, and are listed there:

- **Disease prioritisation;**
- **Biosecurity;**
- **Host/pathogen interaction;**
- **Zoonotic diseases;**
- **Control of infectious diseases (development of new pharmaceuticals/ vaccines);**
- **Climate change;**
- **Sustainability.**

Nevertheless, some differences can be noticed among the different lists. It should be considered that these drivers were selected by different organisations, sometimes having slightly different purposes and that applied different methodologies to obtain their results. Merging together these information allows to obtain a quite complete overview of the research needs in the ANIHWA partner countries. Moreover, since the aims and processes underlying these gap analyses were described in this report, funders could decide to select only the drivers identified by a particular project or organisation, on the basis of their specific needs.

The collected material allows also a more detailed gap identification, providing a preliminary list of diseases that are of increasing interest in the European area. Both the study performed on the DISCONTTOOLS project and the analysis of recent notification through the WAHID, in fact, produced a ranking of diseases. Nevertheless, it must be acknowledged that the more relevant diseases that emerged from the two studies differs to some extent. In fact, the DISCONTTOOLS list of 51 diseases do not include all the emerging ones that caused outbreaks in Europe in the last 4 years (e.g. Schmallenberg virus, that was discovered in 2011, when the list was already prepared). On the other hand, no notification were issued in this same time span regarding the diseases that were identified as priority by our analyses through the DISCONTTOOLS disease database. Defining which of those will be the more urgent priority in the ANIHWA partner countries would require a more detailed risk analysis, that is not the purpose of this report. Nevertheless, the preliminary data provided here could be considered as a starting point for the selection of priority disease.

Overall, this report, and Chapter III in particular, is meant to be a tool to assist the other ANIHWA WPs work. These preliminary data, in fact, might represent the basis for further gap analysis and for the definition of the NAIHWA research agenda. This collaborative approach will stimulate the exchange of information among the different partners, allowing to obtain more complete and shared foresight of research drivers in the European area.

Table 18: Overview of the identified research drivers.

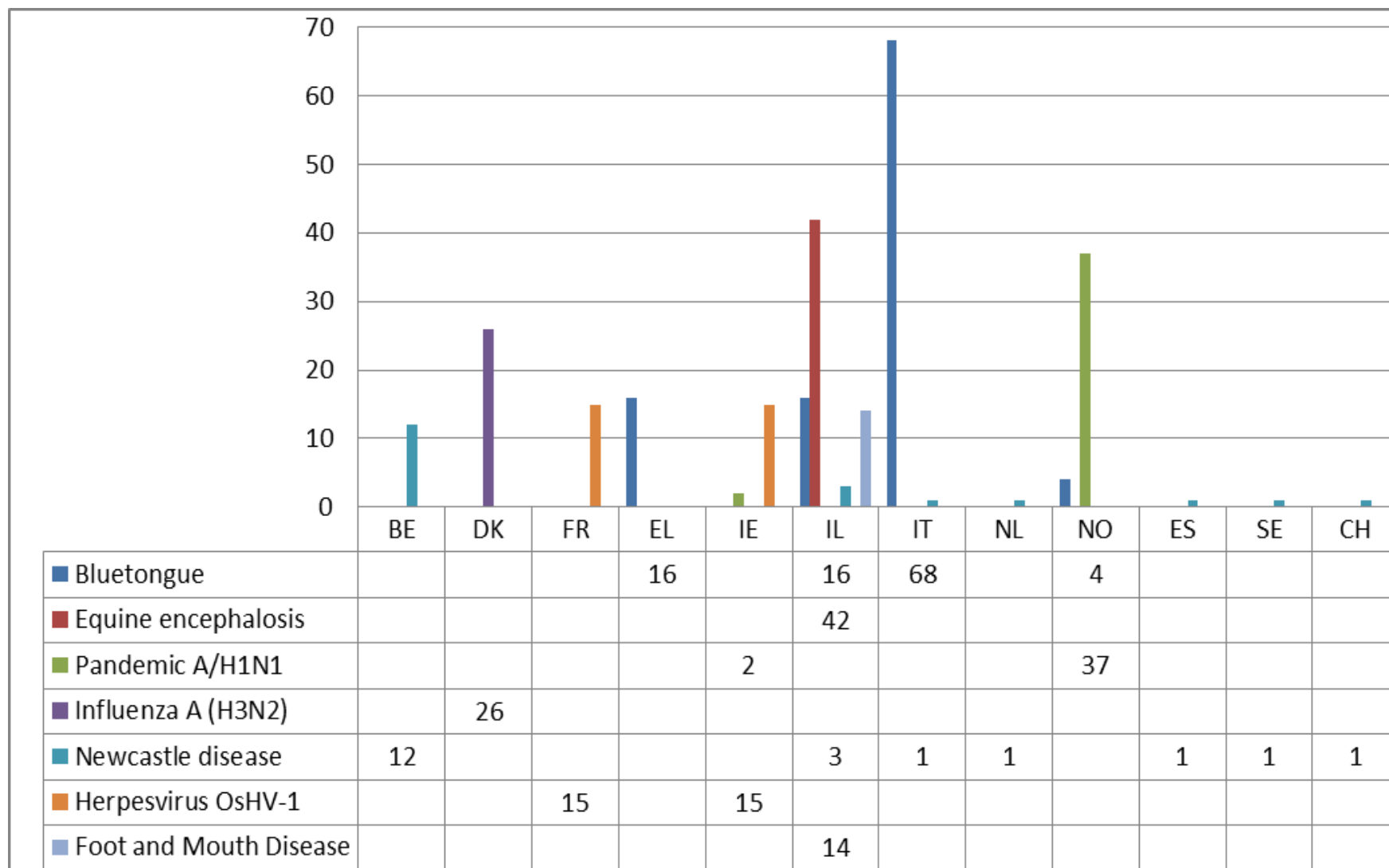
AHL	ETPGAH	EMIDA	DISCONTTOOLS	Copa-Cogeca
Prioritisation of diseases	Prioritisation of diseases	Surveillance system and risk analysis	New vaccines	Sustainability and climate changes
Biosecurity	Identification of emerging disease (e.g. in relation to climate changes)	Control measures and biosecurity	New pharmaceutical tools	Control of infectious diseases
Responsible use of medicinal products	Wildlife diseases	Ecosystem change, vector-borne disease and preparedness	Epizootic diseases	Genetics
Animal traceability	Host/pathogen interaction	Host/pathogen interaction	Zoonotic diseases	Animal welfare
	Fundamental Immunology	Antimicrobial resistance		Development of new technologies
	Epidemiology	Zoonoses		Development of practicable solutions
	Genomics			
	Integrated Biology			
	One Health			
	Sustainability of bio-economy			

Annex

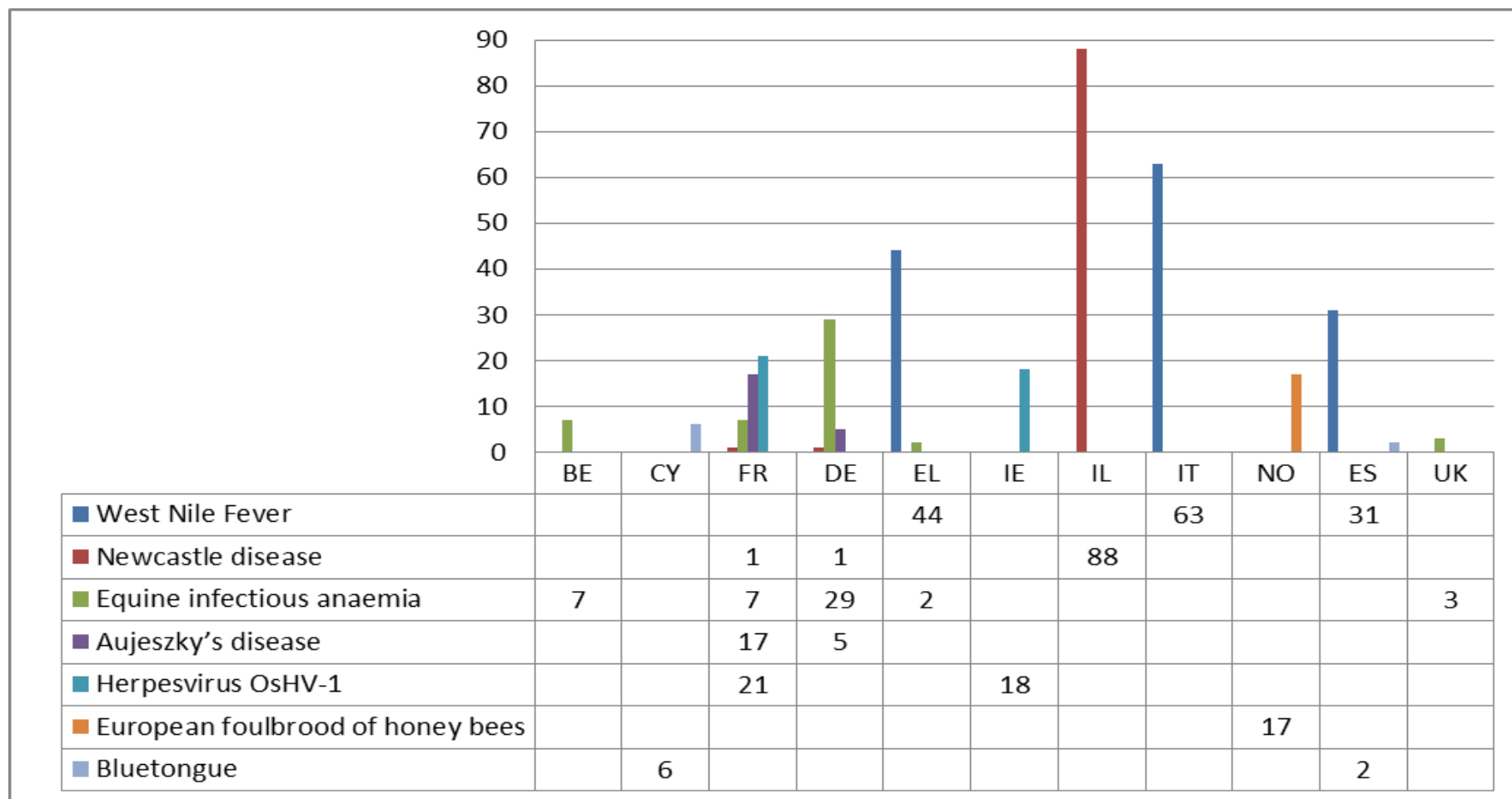
Notified diseases in ANIHWA countries in 2009-2012 period.

2012	2011	2010	2009
American foulbrood of honey bees	American foulbrood of honey bees	Aujeszky's disease	Anthrax
Anthrax	Anthrax	Bluetongue	Bluetongue
Aujeszky's disease	Avian infectious bronchitis	Bovine spongiform encephalopathy	Bovine spongiform encephalopathy
Avian infect. laryngotracheitis	Bluetongue	Brucellosis (Brucella abortus)	Brucellosis (Brucella suis)
Bluetongue	Bovine spongiform encephalopathy	Brucellosis (Brucella suis)	Classical swine fever
Brucellosis (Brucella abortus)	Brucellosis (Brucella suis)	Contagious equine metritis	Contagious equine metritis
Brucellosis (Brucella melitensis)	Classical swine fever	Crayfish plague (Aphanomyces astaci)	Crayfish plague (Aphanomyces astaci)
Brucellosis (Brucella suis)	Crayfish plague (Aphanomyces astaci)	Enzootic bovine leukosis	Equine encephalosis
Contagious equine metritis	Dourine	Equine infectious anaemia	Equine infectious anaemia
Echinococcosis/hydatidosis	Echinococcosis/hydatidosis	Equine viral arteritis	Equine piroplasmosis
Equine infectious anaemia	Equine infectious anaemia	European foulbrood of honey bees	Foot and mouth disease
Equine rhinopneumonitis	Equine piroplasmosis	Herpesvirus OsHV-1	Herpesvirus OsHV-1
Equine viral arteritis	Equine rhinopneumonitis	Highly path. avian influenza	Highly path. avian influenza
European foulbrood of honey bees	Foot and mouth disease	Inf.bov.rhinotracheit. (IBR/IPV)	Inf.bov.rhinotracheit. (IBR/IPV)
Foot and mouth disease	Herpesvirus OsHV-1	Infection with Batrachochytrium dendrobatidis	Infection with Bonamia ostreae
Fowl typhoid	Highly path. avian influenza	Infection with Bonamia exitiosa	Infectious salmon anaemia
Herpesvirus OsHV-1	Infection with Bonamia exitiosa	Infection with Marteilia refringens	Influenza A (H3N2)
Highly path. avian influenza	Infection with Marteilia refringens	Low pathogenic avian influenza (poultry)	Koi herpesvirus disease
Infectious salmon anaemia	Infection with ranavirus	Newcastle disease	Low pathogenic avian influenza (poultry)
Koi herpesvirus disease	Koi herpesvirus disease	Pandemic influenza A/H1N1	Newcastle disease
Low pathogenic avian influenza (poultry)	Low pathogenic avian influenza (poultry)	Rabies	Pandemic influenza A/H1N1
Lumpy skin disease	Myxomatosis	Spring viraemia of carp	Rabies
Myxomatosis	Newcastle disease	West Nile Fever	Spring viraemia of carp
Newcastle disease	Peste des petits ruminants		Viral haemorrhagic septicaemia
Porcine reproductive/respiratory syndr.	Pullorum disease		
Rabbit haemorrhagic disease	Rabbit haemorrhagic disease		
Rabies	Rabies		
Schmallenberg virus	Sheep pox and goat pox		
Scrapie	Spring viraemia of carp		
Tularemia	West Nile Fever		
Viral haemorrhagic septicaemia			
West Nile Fever			

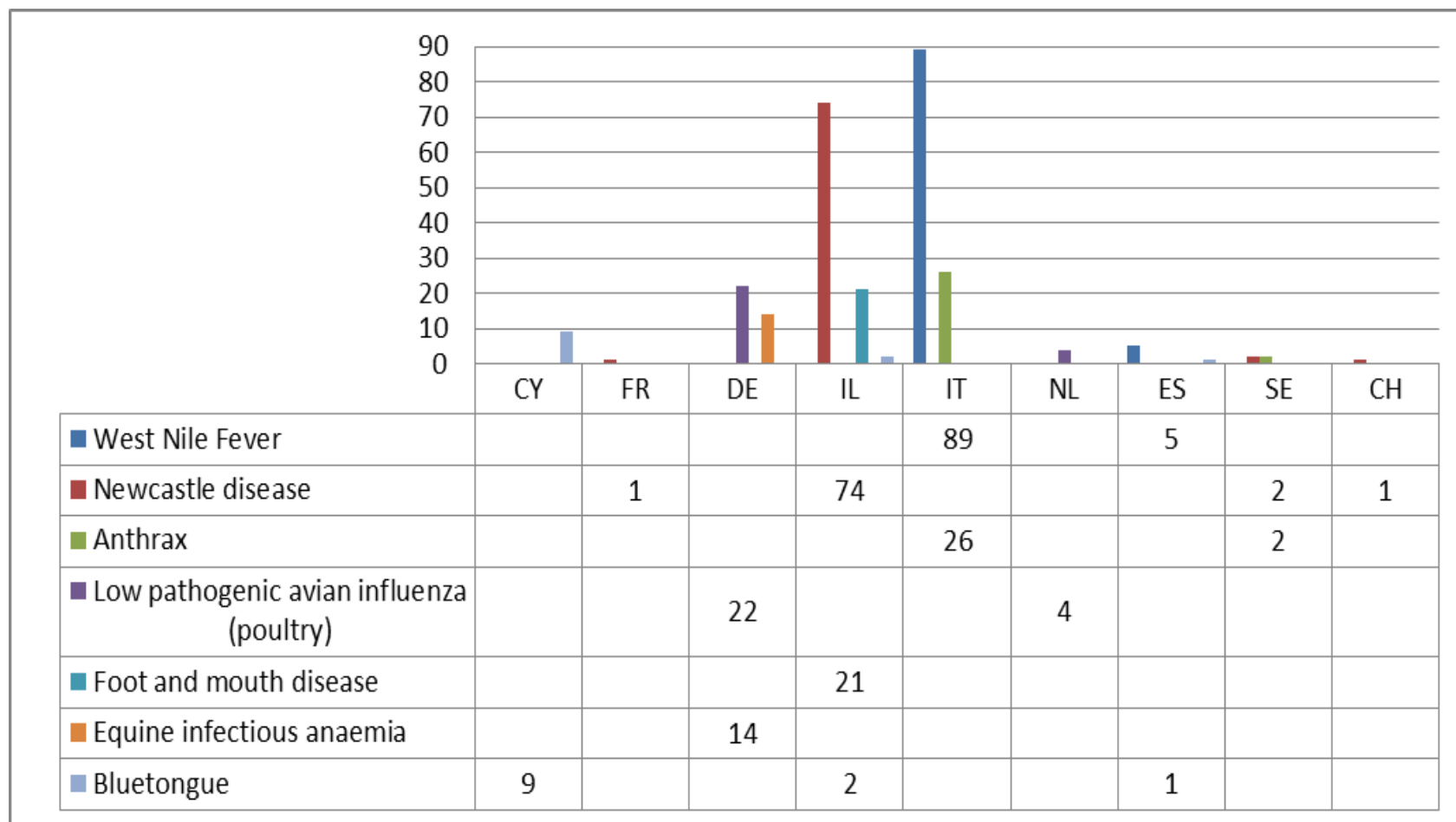
Number of outbreaks for top 7 diseases per country: 2009.



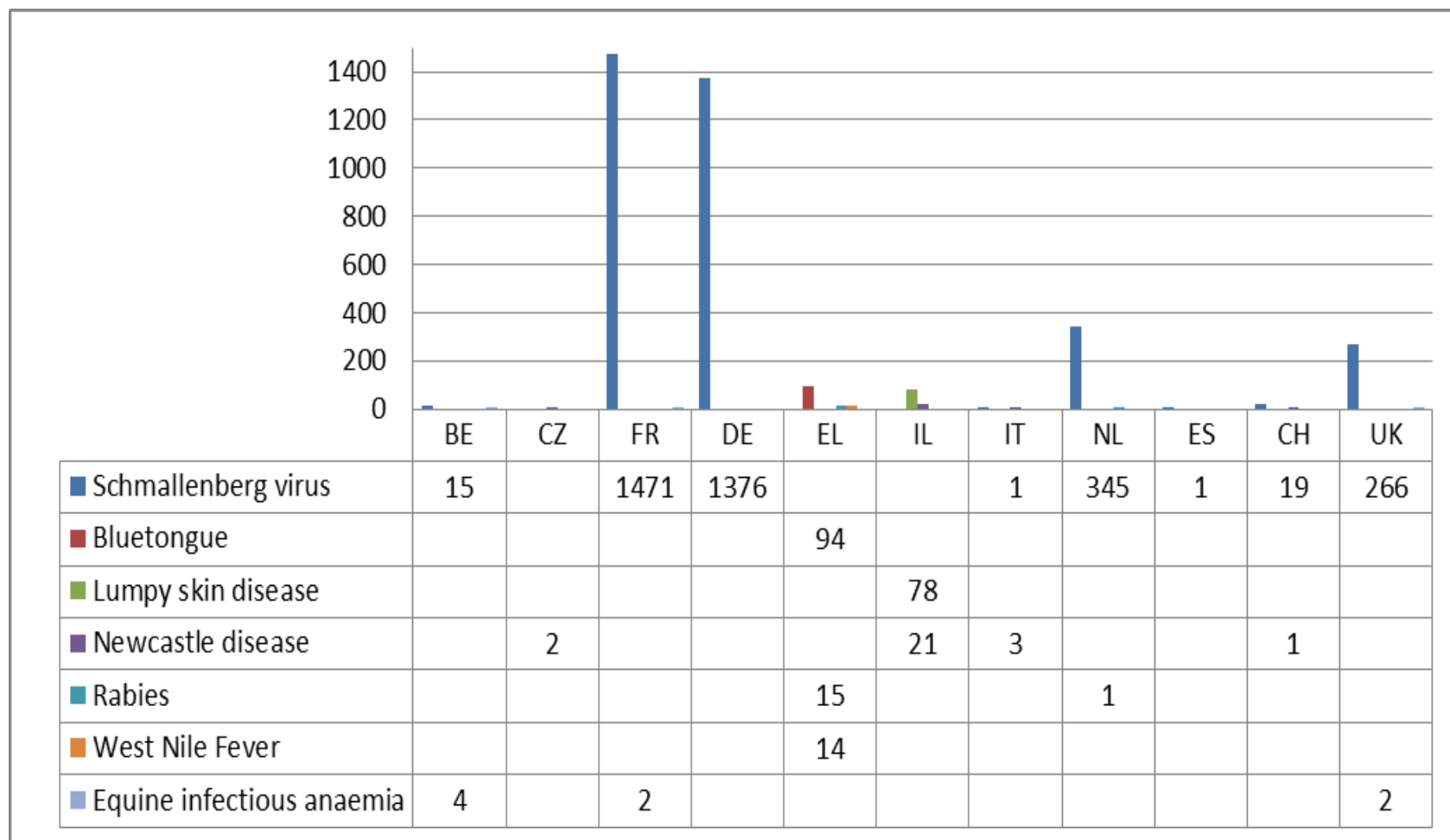
Number of outbreaks for top 7 diseases per country: 2010.



Number of outbreaks for top 7 diseases per country: 2011.

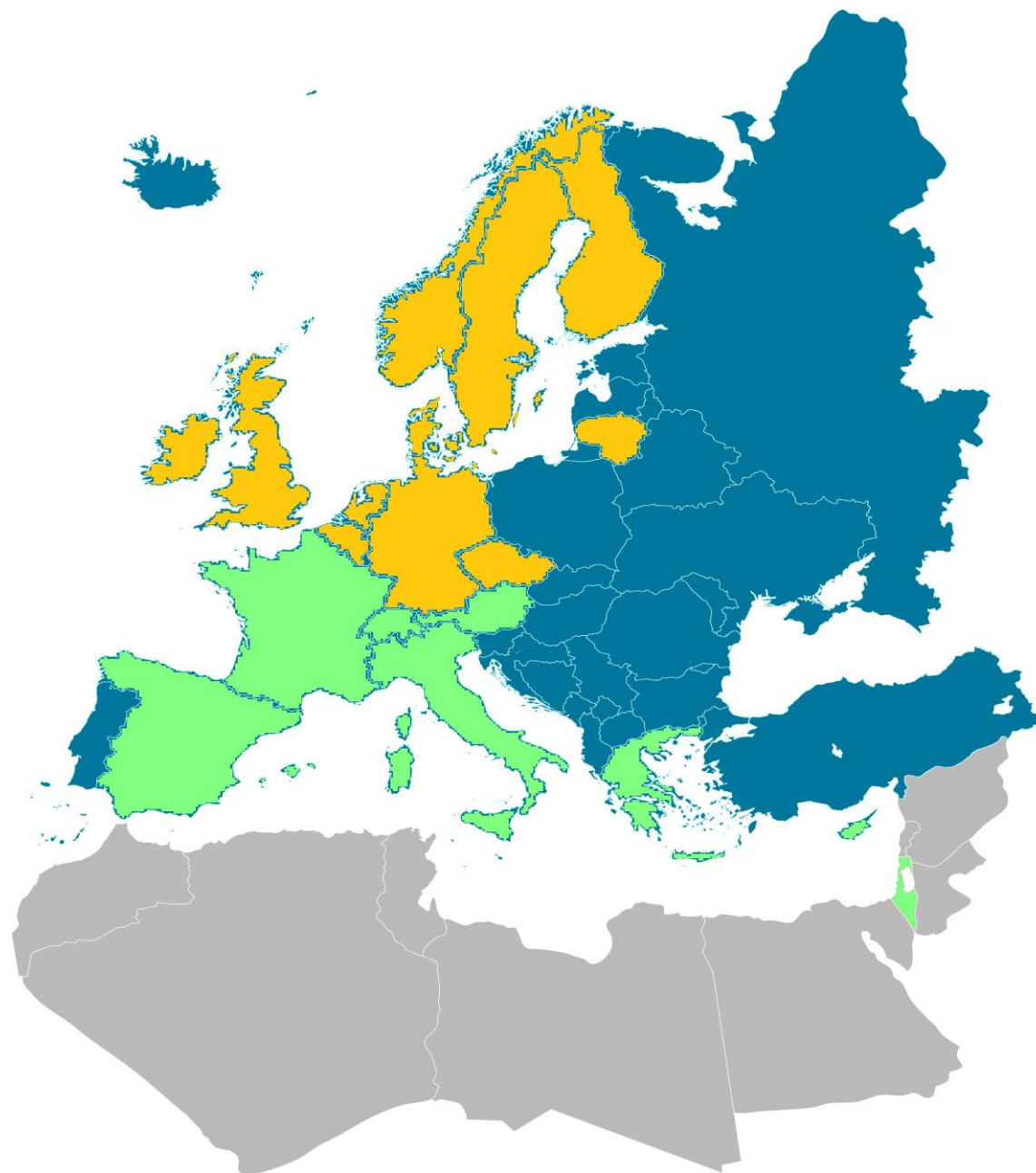


Number of outbreaks for top 7 diseases per country: 2012.



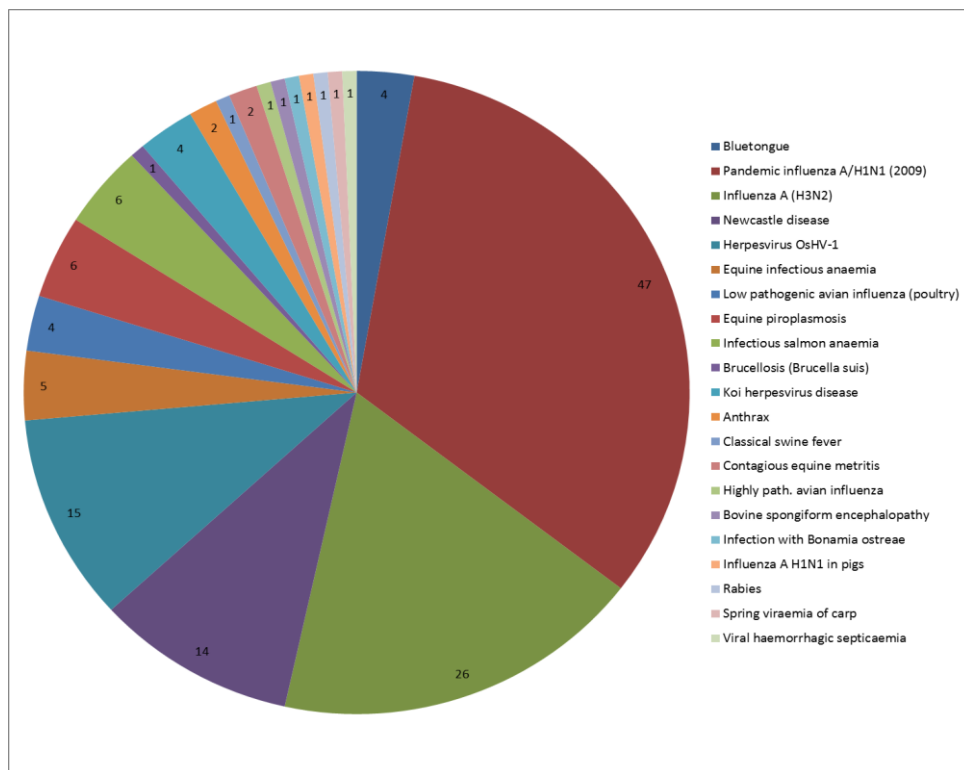
Geographical distribution of the outbreaks: Northern vs Southern ANIHWA countries.

COUNTRY	GROUP
Belgium	North
Czech Republic	North
Denmark	North
Finland	North
Germany	North
Ireland	North
Lithuania	North
Netherlands	North
Norway	North
Sweden	North
UK	North
Austria	South
Cyprus	South
France	South
Greece	South
Israel	South
Italy	South
Spain	South
Switzerland	South

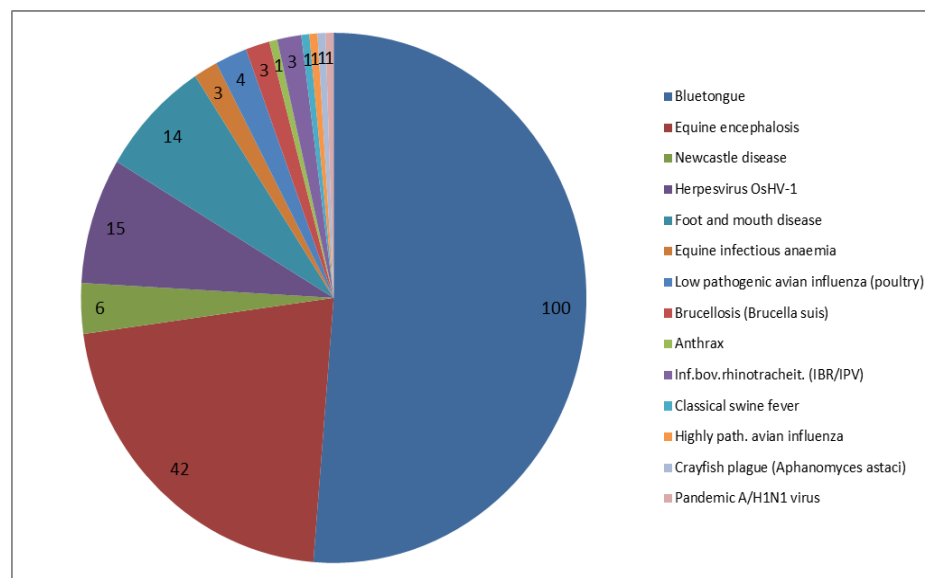


Number of outbreaks 2009

Northern countries

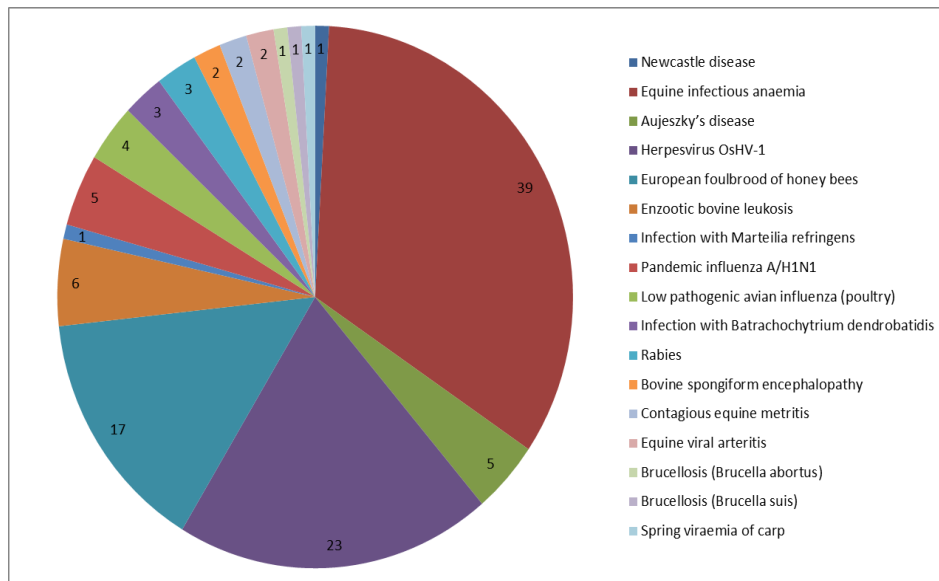


Southern countries

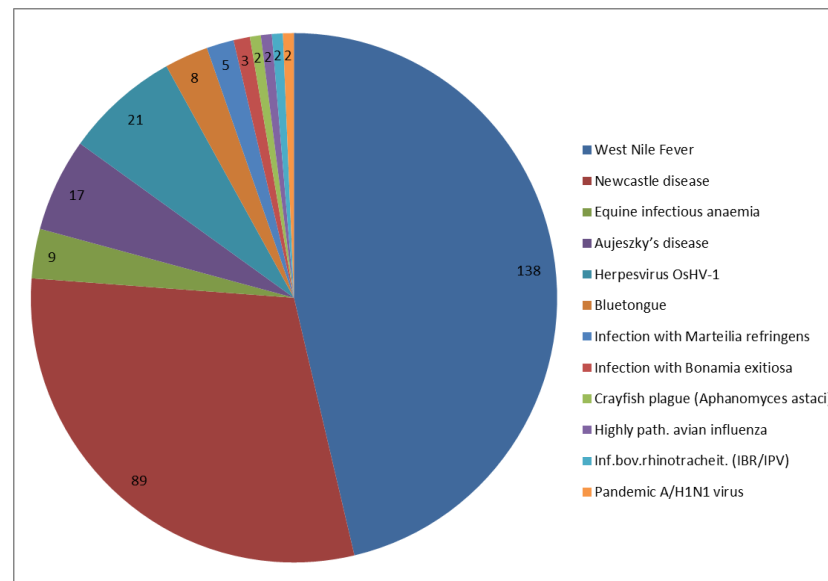


Number of outbreaks 2010

Northern countries

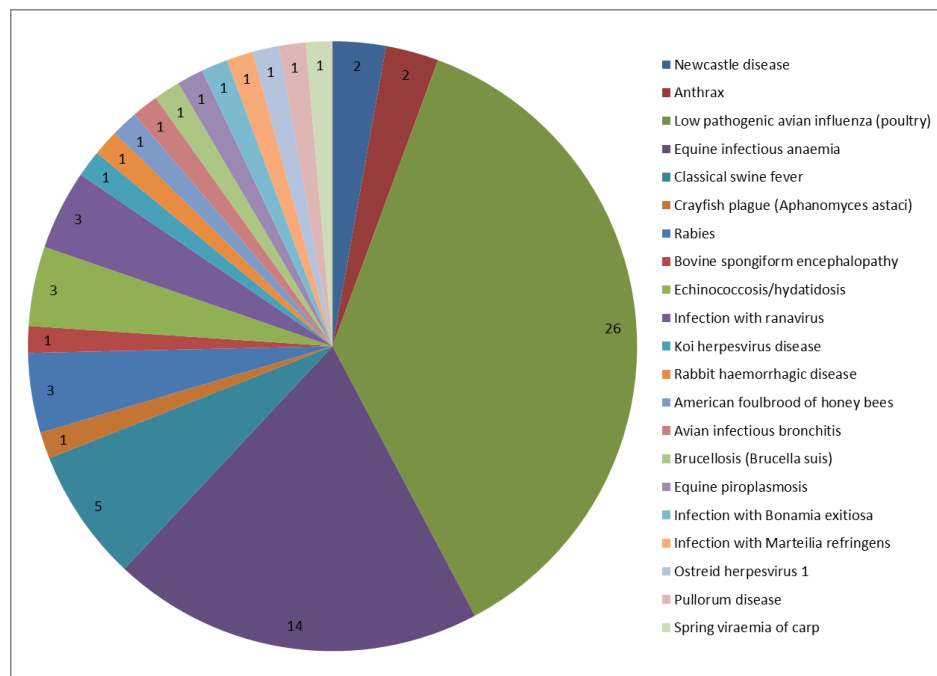


Southern countries

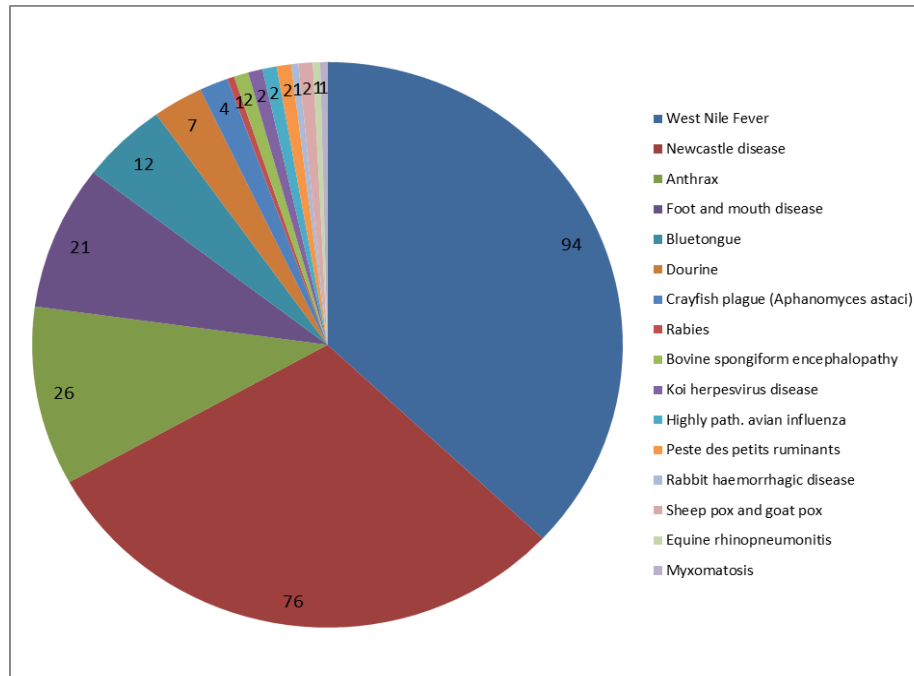


Number of outbreaks 2011

Northern countries

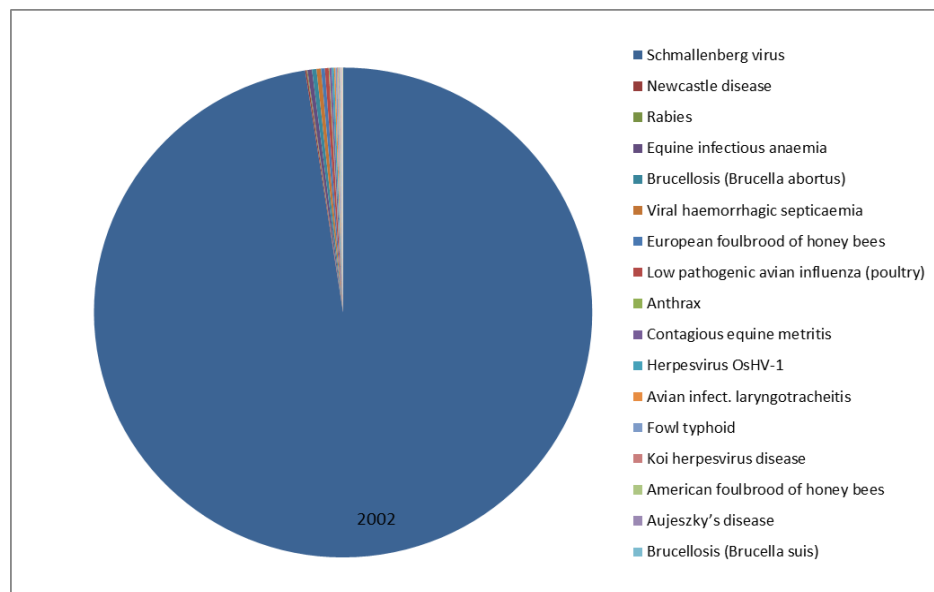


Southern countries

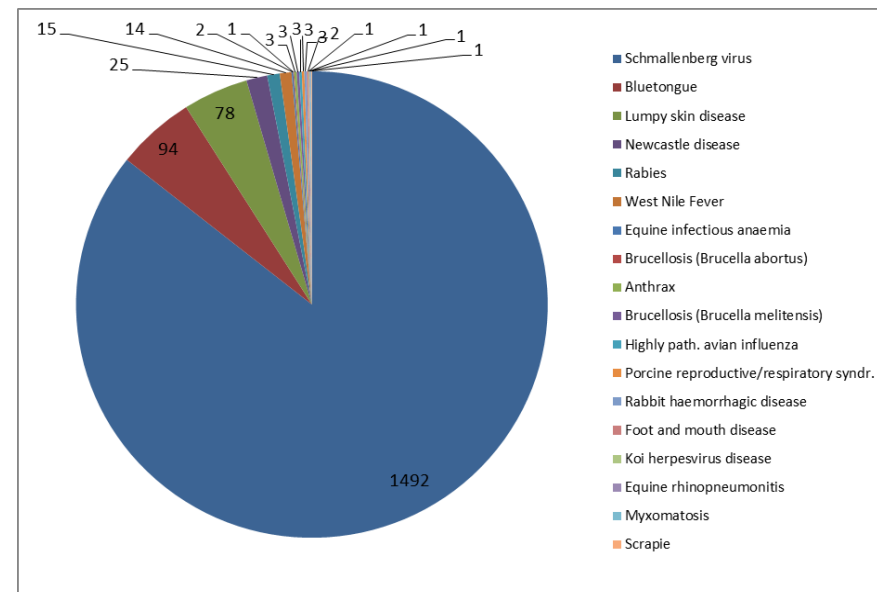


Number of outbreaks 2012

Northern countries



Southern countries



Notification of emerging diseases in the ANIHWA countries: 2009-2012.

Country	Year	Disease	N°
IL	2009	Equine encephalosis	42
NO	2009	Pandemic influenza A/H1N1	37
DK	2009	Influenza A (H3N2)	26
FR	2009	Herpesvirus OsHV-1	15
IE	2009	Herpesvirus OsHV-1	15
UK	2009	Pandemic influenza A/H1N1	7
IE	2009	Pandemic influenza A/H1N1	2
FI	2009	Pandemic influenza A/H1N1	1
DE	2009	Pandemic influenza A/H1N1	1
IT	2009	Pandemic influenza A/H1N1	1
FR	2010	Herpesvirus OsHV-1	21
IE	2010	Herpesvirus OsHV-1	18
UK	2010	Herpesvirus OsHV-1	5
DK	2010	Pandemic influenza A/H1N1	4
FI	2010	Pandemic influenza A/H1N1	1
FR	2010	Pandemic influenza A/H1N1	1
IT	2010	Pandemic influenza A/H1N1	1
NL	2011	Herpesvirus OsHV-1	1
FR	2012	Schmallenberg virus	1471
DE	2012	Schmallenberg virus	1376
NL	2012	Schmallenberg virus	345
UK	2012	Schmallenberg virus	266
CH	2012	Schmallenberg virus	19
BE	2012	Schmallenberg virus	15
IL	2012	Herpesvirus OsHV-1	2
IT	2012	Schmallenberg virus	1
ES	2012	Schmallenberg virus	1
UK	2012	Herpesvirus OsHV-1	1

Notification of first occurrence of diseases in the ANIHWA countries: 2009-2012.

Country	Year	Disease	N°
IE	2009	Equine piroplasmosis	6
NO	2009	Bluetongue	4
CZ	2009	Low pathogenic avian influenza (poultry)	1
IT	2009	Crayfish plague	1
NO	2009	Infection with Bonamia ostreae	1
ES	2009	Low pathogenic avian influenza (poultry)	1
IT	2010	West Nile Fever	63
EL	2010	West Nile Fever	44
ES	2010	West Nile Fever	31
BE	2010	Equine infectious anaemia	7
EL	2010	Infection with Marteilia refringens	5
SE	2010	Infection with Batrachochytrium dendrobatidis	3
IT	2010	Crayfish plague	1
ES	2010	Infection with Bonamia exitiosa	1
SE	2010	Infection with Marteilia refringens	1
IT	2011	West Nile Fever	38
FR	2011	Koi herpesvirus disease	1
EL	2011	Myxomatosis	1
NL	2011	Equine piroplasmosis	1
NL	2011	Infection with ranavirus	1
ES	2011	Koi herpesvirus disease	1
UK	2011	Infection with Bonamia exitiosa	1
UK	2011	Infection with Marteilia refringens	1
UK	2012	Viral haemorrhagic septicaemia	6
CZ	2012	Newcastle disease	1
DK	2012	Tularemia	1
IT	2012	Koi herpesvirus disease	1
NO	2012	Infectious salmon anaemia	1

Notification of new strain of infectious agent in the ANIHWA countries: 2009-2012.

Country	Year	Disease	N°
IL	2009	Bluetongue	6
EL	2009	Bluetongue	3
EL	2009	Bluetongue	3
FI	2009	Rabies	1
IL	2009	Bluetongue	1
IL	2009	Bluetongue	1
ES	2009	Highly path. avian influenza	1
SE	2010	Rabies	3
IL	2011	Bluetongue	2