European Technology Platform for Global Animal Health

Strategic Research Agenda








Contents

Executive Summary

The European Technology Platform for Global Animal Health (ETPGAH) was launched in December 2004. Following a meeting of all the stakeholder organisations in February 2005 the Platform was formally established with a Steering Council and an Executive Board under the chairmanship of IFAH-Europe (the International Federation for Animal Health - Europe). Since then a Strategic Research Agenda (SRA) has been developed by all the stakeholders. It should also be recognised that this SRA complements the Vision document of the Platform published in 2005.

The overall concept of the Technology Platforms is that stakeholders, led by Industry, get together to define an SRA on a number of strategically important issues. These have a high societal relevance where achieving Europe's future growth, competitiveness and sustainability objectives are dependent upon major research and technological advances in the medium to long term. The SRA has important consequences for animal health research and is in line with the Lisbon agenda which aims to make the EU an important science and technology driven society by 2010. More information can be found in the published Vision document of the European Technology Platform for Global Animal Health (http://www.ifah.be/Europe/euplatform/platform.htm).

The SRA describes the research that is recommended in order to realise the aim of the platform, namely: "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." The agenda is intended to recommend research in its broadest sense thus it encompasses reviews of available information, analysis of markets and attitudes, and the development of useful tools as well as the more traditional areas of veterinary science.

The current focus of the Platform is the development of vaccines, pharmaceuticals and diagnostic tests for major animal diseases. The development of pharmaceuticals is especially important where the limited availability of innovative pharmaceuticals for animal health is endangering the efficient control of a number of animal diseases. The importance of aquaculture and the diseases of fish is recognised, although the initial focus for the Platform has been land-based animals. As many of the same principles apply, it would be feasible to develop this SRA further to include fish diseases should the stakeholders so wish. There are many challenges which must be overcome in order to take maximum advantage of the advances in science and technology if new products are to become available.

Europe has a relatively good scientific research base to take advantage of the new technologies, but is much weaker in translating scientific discoveries into products that can be used in an operational situation. This needs to be overcome. There is an urgent need to boost research by developing methodologies to prioritise requirements and develop more effective funding, so that new or improved veterinary medicines – vaccines and pharmaceuticals – and diagnostic tests can be delivered. Closely associated is the effort required to enhance and enable the effective transfer of innovations and breakthroughs from the research base into the development, manufacture, authorisation and distribution of new and safe products for practical use.

Stakeholders have defined the SRA setting out their common views on the necessary short, medium and long-term research, development and delivery needs for Global Animal Health over a period of 10 years. This will establish a framework for guiding research over this period. In achieving this, the anticipated changes in animal health and production worldwide must be taken into account. The SRA must also be aligned to competitiveness and other Community policies and strategies. The SRA must also be closely linked to the Community

Animal Health Policy Strategy which is currently under development and due for completion by 2007 covering the period 2007 to 2013.

The SRA considers the research necessary to ensure breakthrough and innovation in the development of new tools to control animal diseases. It also considers the research requirements to resolve the problems in manufacture, production and registration of new products. This involves identifying the research required to develop new methodologies and tests for demonstrating the safety, quality and efficacy of new products thereby enabling their rapid registration and approval by the regulatory authorities. As well as the specific research requirements, a number of critical factors linked to the successful transfer of technology from the research base to the development phase and subsequent manufacture are identified. It is these enabling factors which need to be enhanced before Europe will be in a position to compete successfully.

The SRA details the long-term priority requirements for research and will need to be complemented by an action plan which will identify potential funding from public and private sectors. The SRA also addresses the key issues of European competitiveness, although the immediate purpose is to develop vaccines, pharmaceuticals and diagnostic tests to prevent and control disease by using new technologies and making the most effective use of technologies currently available.

This approach has been developed with all stakeholders. Three expert working groups were established to consider and develop the SRA recommendations in the areas of fundamental research, horizontal issues and regulatory issues. Extensive consultations have taken place through the use of broadly based working groups and through the stakeholder forum which was established to take account of stakeholder views, to facilitate input to the discussions and to generate and incorporate ideas into the SRA.

The SRA is organised around 6 themes to reflect the issues which impact on the successful transfer of ideas into deliverable products. In each of the themes a number of recommendations for research or other actions are suggested. The 6 key interacting themes are:

- To prioritise animal diseases
- To conduct a number of gap analyses
- To ensure high quality relevant fundamental research
- To identify the enabling factors to improve the rate of Technology transfer
- To consider regulatory issues
- To maintain a Global Perspective

The first stage in developing the SRA is to define a rational methodology to prioritise diseases within Europe and worldwide. This is crucial to set the priority framework for research into the new or improved tools for disease control and to ensure the most effective use of resources and research capacity. Prioritisation is an important component of the SRA. It is difficult to allocate diseases into a simple classification as the large number of variables made a prioritisation method difficult to develop and agree over a short period of time. This will take time and effort. Some principles are defined, a preliminary assessment of disease priorities is undertaken and a number of areas for future research are recommended. A formal and transparent mechanism is needed which can act as a guide to the scientists who will need to develop concept papers and prepare for the work.

Nevertheless an attempt at producing an interim list of priority diseases has been made with a preliminary gap analysis aimed at considering all available information on the interim prioritised diseases listed in Chapter 2. The objectives are to determine the gaps which currently exist in the knowledge and understanding of the diseases, gaps in the availability of products and the weaknesses of existing products. The availability of new technology was considered and further analysis is required to ensure that newly developed technologies are being used to maximum benefit. Finally the gaps in research activity within the EU were considered. A strategic approach should target all the gaps in a co-ordinated manner. The range of partners in the ETPGAH could then ensure that a co-ordinated approach, rather than individual actions, brings added value to the process.

Action is needed to develop programmes to fill gaps whilst at the same time developing research collaboration and synergies to avoid duplication of research effort. A formal mechanism to identify research gaps is essential for success. Much of the current public research funding is targeted at problem resolution or at providing the evidence on which to base policies. Consequently, funding for innovation is lower than appropriate, resulting in difficulties in filling knowledge gaps. Furthermore, no single group has an overview to ensure an integrated and coordinated Research and Development (R&D) programme across Europe. Provision of such an overview would reduce duplication of effort, lead to a more effective use of resources and limited funds, encourage synergies, and enable major gaps in research to be identified and filled. A series of recommendations are made to develop the methodologies and to ensure that the research activity across Europe is coordinated.

Fundamental sciences are critical to the SRA since they act as the building blocks for the new technologies. Without these basic data the development of new and improved tools to control diseases is unlikely to be successful. A strong base of fundamental science is essential if progress is to be made and if the competitiveness of European industry is to be improved. Funding is vital for the fundamental sciences and it would be appropriate to consider specific programmes for each discipline. A series of recommendations are made. One of the most important is that a European Central Institution for Epidemiology and Infectious Diseases should be recognised to have responsibility for training epidemiologists, to create a critical mass for the future, and for acting as a repository for a range of databases on disease information.

The enabling factors to the better identification, development and use of innovation are an important component of the SRA. Five potential barriers to the efficient transfer of technology to enable development of new products are identified: quality management, intellectual property rights, facilitation of technology transfer, education and training, and infrastructure. It is essential to minimise or overcome the effects of these barriers if the EU is to remain competitive and to produce innovative and new products. Many enabling factors are involved in the successful delivery of new products. Perhaps one of the most important is the urgent need to establish a method for Europe to identify innovation, ensure the scientists involved understand the need to acquire patents and to fill the critical gap which currently exists between the science and the major pharmaceutical companies. A series of recommendations for action and research are made to improve the potential and reality of technology transfer.

Much has been achieved in Europe over the past 25 years to establish the standards for the supply and safe and effective use of veterinary medicines. The development of the regulatory controls now applied has resulted in the improvement of medicinal products and food safety, and developed the harmonisation of regulatory approach throughout the 25 Member States. Research and good scientific data underpin the regulatory processes across the world and provide the technical solutions to respond to the regulatory hurdles. The new legislation recently enacted in the EU could have a major impact and lead to considerable improvements in the regulatory process. The recommendations in the SRA are intended to identify the research needed to develop possible solutions to improve the regulatory process further thereby continuing the achievements of the past 25 years.

Societal studies are also needed to

assess the impact of new technologies or alternative eradication programmes with the use of veterinary medicines and to evaluate the most effective ways to present the new technology to the public. An assessment of the risks and benefits of new products along with an evaluation of the risk communication and science strategies available to present the new technologies to the public would be valuable.

Finally, from a global perspective it is vital to work in partnership with countries outside of the EU. The global nature of many of these problems, and the scale and complexity of new product development means that solutions will not be very effectively produced or very robust if developed exclusively for and/or in Europe. The scale and complexity of vaccine and diagnostics development is such that alliances with non-European countries and international organisations such as the World Organisation for Animal Health (OIE) and the Food and Agriculture Organisation (FAO) will be essential. In the context of the priority diseases identified in this SRA and based on the gap analysis and the research needs for each of the priority diseases, the input of developing countries should be included in the proposals below. In general projects should be promoted in partnership with developing countries.

The recommendations in the SRA fall into three categories. First, the short term analyses which need to be completed in order to confirm the priority areas on which to focus research funding to meet the aims of the Platform. Although detailed analyses are recommended it is important to ensure that funding is primarily directed to research which will deliver products. Second, the areas identified for funding. And third, the enablers which need to occur in parallel to ensure the successful outcomes from the funded research. The SRA provides a comprehensive list of recommendations for research and further action to meet the aim of the technology platform. The implementation of the SRA will require funding.

The next stage is to consider the full range of recommendations, classify them into one of the three categories above and identify which groups or organisations will take ownership and responsibility for progress. Linked to this is funding, and contact is required with the funding organisations in order to develop an action plan for a 5-year period; the strategy itself will cover the next 10 years. It is also anticipated that the recommendations in the SRA will be taken into account by the EU Commission when developing the work programme for the EU Framework 7 Programme.

The Steering Council of the European Technology Platform for Global Animal Health working closely with all the stakeholders and funders will develop the action plan for the SRA to ensure that wherever possible the recommendations are implemented. In addition close contact will be maintained with other technology platforms with similar interests, especially those involved in the knowledge-based bio-economy and others such as innovative medicines.

Summary of Recommendations

Prioritisation of Animal Diseases/Infections

1. Create a risk based, disease specific, prioritisation model to evaluate Global Animal Health Priorities (endemic, exotic, emerging diseases) and the risk they could pose for the European Union in order to assist in allocating research funding and implementation of control measures. (para 2.6.1)

2. Use the model to identify and formally prioritise animal diseases of major socio-economic animal or public health importance for Europe. (para 2.6.2)

3. Identify the threats to Europe from pathogens which are not considered important at present (i.e. horizon scanning) and conduct full risk assessment of potential threats from new and emerging diseases in particular those outside the EU boundaries. (para 2.6.3)

4. Develop and use a predictive model to identify when a disease agent becomes a threat and assess the potential EU and global costs (taking into account the Lisbon Agenda). (para 2.6.4)

5. Target research funding to the diseases in the defined priority areas i.e. major disease, those for surveillance and neglected zoonoses, unless specific cases can be made for the funding research into other diseases. A case may be made to fund research into diseases or species currently considered as MUMS (minor uses/minor species) diseases within the EU, but which may constitute a significant threat to the EU (e.g. Bluetongue) or may be considered major species in less developed regions (e.g. goats, buffalo). (para 2.6.5)

6. Develop research with appropriate funding into surveillance methodologies to ensure new and emerging disease both in Europe and on its borders are detected rapidly. (para 2.6.6)

7. Direct research funding into wildlife diseases, especially in relation to zoonoses, which may have an impact on human and animal health. (para 2.6.7)

8. Initiate research programmes for the priority diseases in cooperation with the developing countries in order to develop sustainable strategies for control. (para 2.6.8)

Gap Analysis

9. Develop and implement the methodology for a gap analysis based on the proposals in the SRA and use this methodology to undertake a comprehensive gap analysis for each of the priority diseases on a regular basis of 2-3 year intervals. (para 3.8.1)

10. Define gaps in existing control tools for surveillance, diagnosis, vaccination and treatment and consider the research required to develop new or improved targeted tools for each of the priority diseases. (para 3.8.2)

11. Target research to increase the knowledge base of the priority diseases in order to develop vaccines, diagnostics and pharmaceuticals to overcome the existing shortcomings in tools for the control of priority diseases focusing on those areas where there is a justified need. (para 3.8.3)

12. Review new technologies and assess their value for the future development of the tools to control priority diseases. (para 3.8.4)

13. Map global research and development for the priority diseases and catalogue the current research programmes against the research organisations both within the EU and globally in order to build a database of research throughout the EU and to maintain and publish such a database. (para 3.8.5)

14. Catalogue and create a database of the available products worldwide for the control of major disease and evaluate their potential for use in the EU in addition to mapping the animal health companies producing veterinary

medicines and diagnostic tests worldwide. (para 3.8.6)

15. Research and develop a comprehensive, risk-based sourcing strategy for vaccines, pharmaceuticals and diagnostic tests to meet EU animal health priorities linked to the priority diseases. (para 3.8.7)

16. In the case of products for MUMS conditions, conduct a gap analysis to identify those conditions for which relatively little research would be required to fill a data gap and thereby allow authorisation of a veterinary medicine within the EU. (para 3.8.8)

Fundamental Research

17. Take a strategic overview of the fundamental sciences in the EU to assess whether there is sufficient capacity and expertise to deliver the science necessary to support research and new technologies needed to develop new tools to control diseases. (para 4.8.1)

18. Develop an EU wide strategy to enhance the capacity and expertise in the fundamental sciences and consider whether specific science and education programmes are needed to develop and maintain expertise in each speciality area. (para 4.8.2)

19. Target research funding to those areas of fundamental science critical to the development of prioritised vaccines, pharmaceuticals and diagnostic tests. (para 4.8.3)

20. Strengthen collaboration between the research organisations working on the fundamental sciences. (para 4.8.4)

21. Establish and support a European Centre for Epidemiology and Infectious Diseases. (para 4.8.5)

Enabling Factors

Quality Assurance.

22. All laboratories and organisations that conduct research that might ultimately lead to the authorisation of a veterinary medicine should operate to appropriate quality standards that are independently audited by national quality assurance organisations. These standards might include ISO9001, ISO17025, GLP, GCP, GMP or other, national quality standards. (para 5.2.1)

23. Build a requirement for quality management into the research funding contracts between the funders and the research organisations. (para 5.2.2)

24. Consider the alternative quality standards necessary to ensure quality control for research into the development of the tools for disease control. (para 5.2.3)

Intellectual Property Rights

25. Educate scientists and researchers on the importance of patents and developing their ideas to the proof of concept stage. (para 5.3.1)

26. Include funding to permit the filing of patents as part of the overall research funding for a project. In the US funding is provided to patent nearly all ideas. (para 5.3.2)

27. Provide funding to enable advice to be obtained from patent attorneys, marketing experts and technical experts in order to correctly file a patent application. (para 5.3.3)

28. Advise on the use of licensing and sub-licensing once patents are obtained. (para 5.3.4)

Overcoming Barriers to Technology transfer

29. Ensure that contracts issued by funders include funding and

clauses to ensure the application for patents and the funding to bring the project to the proof of concept stage. (para 5.4.1)

30. Educate and inform research scientists on the value of developing their ideas to the proof of concept stage. (para 5.4.2)

31. Develop and establish a Europe-wide system to identify innovation and enhance transfer to commercial companies for development. Also establish the criteria for the selection of innovative ideas for further development. (para 5.4.3)

Networks and Centres of Excellence

32. Conduct a review of the existing networks of excellence and integrated projects to evaluate their effectiveness and contribution to the research programmes in relation to the development of new or improved vaccines, pharmaceuticals or diagnostic tests. (para 5.5.1)

33. Develop a mechanism to involve all stakeholders and in particular industry in the work of the networks of excellence and in the development of their research programmes. (para 5.5.2)

Education and Training

34. Evaluate options to foster mobility between academia and industry and vice versa. (para 5.6.1)

35. Map existing activities and skills within Education and Training to include the identification of European Centres of Excellence and develop programmes and implementation plans for the critical areas especially the skills gaps relevant to the priority disease areas. (para 5.6.2)

Infrastructure

36. Conduct an inventory into the availability of Containment Category 3 and 4 animal accommodation throughout the EU for animal challenge experiments and disease investigation. (para 5.7.1)

37. Develop arrangements to ensure that the most effective use is made of existing high containment laboratory facilities for exotic disease research, including ways in which industry can gain access to these facilities at a cost they can afford. (para 5.7.2)

38. Develop a clear set of harmonised guidelines for the handling of various pathogens in containment facilities. (para 5.7.3)

Regulatory and Societal Issues

Regulatory Issues

39. Undertake an assessment and comparison of the different drivers for regulation of veterinary medicines as compared to human medicines in order to design specific research programmes to better support the specific requirements of the veterinary regulatory environment. (para 6.3.1)

40. Conduct research into the value, use, impact and lessons learned from the practical experience of technical guidelines and monographs in order to ensure that guidelines and monographs remain appropriate to developing scientific knowledge. (para 6.3.2)

41. Develop an effective risk-based methodology to define the risks and benefits in the use of veterinary medicines with the intent to use the model to make risk-benefit based decisions and determine the testing required for new products to underpin this approach. (para 6.3.3)

42. Initiate coordinated action to identify the research needed to reduce animal testing by either using alternative methods or by reducing the testing required. (para 6.3.4)

43. Evaluate the harmonisation and consistency of the regulatory approach between EU member states. Identify scientific issues acting as a barrier to implementation of such harmonisation and define research designed to resolve the issues. (para 6.3.5)

44. Identify and evaluate the quality of data required by the regulatory process to approve a veterinary medicine. Define the most appropriate level to satisfy the needs of the system. (para 6.3.6)

45. Evaluate the relevance and importance of the environmental assessment process and define the quality of data required for veterinary medicines of differing types. To what level of detail should environmental risk assessment be established to be effective and what further research would assist in improving the importance, relevance and value of environmental assessments for veterinary medicines? (para 6.3.7)

Diagnostic Tests

46. Support projects for the establishment of international sample panels / or standard sera, that can be used in test validations. They should be available for all diagnostics producers. (para 6.4.1)

47. Encourage and finance joint projects between institutes and the industry. (para 6.4.2)

48. Establish links and promote the information flow between institutes and vaccine and diagnostics producers especially for the marker vaccine development area. (para 6.4.3)

49. Support projects shared with "Central and Reference laboratories" for the validation of diagnostic products in different geographical locations to facilitate the "Fit for purpose" recognition. (para 6.4.4)

50. Develop and introduce quality standards regarding diagnostic producers, concerning the implementation of an industrial standard that sets the conditions of the production of quality veterinary diagnostics. (para 6.4.5)

Societal Acceptance of Technology

51. Establish a research programme into consumer perception and expectations of new technologies and the consequent acceptance of new veterinary medicines. (para 6.5.1)

52. Review existing research findings on social perceptions of new technologies and new veterinary medicines. (para 6.5.2)

53. Study factors which affect consumer behaviour in relation to food safety. (para 6.5.3)

54. Develop a risk communication strategy to educate the public on GM vaccines and pharmaceuticals and identify the most effective ways to communicate the information. (para 6.5.4)

Community Animal Health Policy

55 Maintain contact with the CAHP Evaluation Team in order to contribute to their review of the research requirements for the CAHP. (para 6.6.1)

56 Ensure that the work of the Platform contributes and supports the CAHP through the strategic research agenda. (para 6.6.2)

Global Perspectives

57. Introduce joint research programmes with institutes in non-EU countries, for important diseases that do not occur in the EU in order to conduct risk analysis, undertake epidemiological research, investigate outbreak scenario's and evaluate intervention and control strategies. (para 7.4.1)

58. Validate tools developed using modern biotechnology to control animal diseases representing a sanitary risk for Europe and other countries in cooperation with developing countries. (para 7.4.2)

59. Provide sustainable support for research through international cooperation in order to improve knowledge and information for animal diseases and zoonoses. (para 7.4.3)

60. Promote partnerships and provide finance for joint research and development projects with developing countries in order to assist with capacity building by improving training, infrastructure and technical and scientific capabilities for control of diseases. (para 7.4.4)

61. Develop and fund collaborating centres linking EU and developing country institutes. (para 7.4.5)

1. Introduction

1.1 Introduction

The European Technology Platform for Global Animal Health (ETPGAH) was launched in December 2004 with the encouragement and guidance of the European Commission in order to bring together companies, research institutions, the financial world and regulatory authorities to define a common research agenda.

1.2 Aim of the Technology Platform

The aim of the ETPGAH is:

"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."

1.3 Deliverables from the European Technology Platform for Global Animal Health

Whilst the overall platform objectives are detailed in the ETPGAH Vision document, a number of specific disease control objectives are identified. These are to:

- Protect Europe from the incursion of epidemic animal diseases and zoonoses
- Deal rapidly and effectively with disease outbreaks in Europe should they occur
- Assist in speed of access to market, facilitation of world trade and the alleviation of poverty by reducing the impact of these diseases in developing countries. Reduce worldwide levels of disease and thereby indirectly protect Europe from disease spread by people or trade

In order to meet the vision and the above objectives the major deliverables from the platform must be to:

- Bring more focus into research towards new tools for dealing with animal diseases
- Increase the translation of technology into applications, which are efficacious in the control of animal disease
- Bring the developed tools faster to the market
- Remove unnecessary legal and re-gulatory hurdles, which limit disease control options and decrease competitiveness of the industry
- Enable disease control authorities both within the EU and other countries to provide a swift and efficient reaction to new disease outbreaks
- Streamline research, development and regulatory efforts in order to ensure consumer safety without compromising the efficiency of product development
- View projects in the context of feasibility, applicability, need and availability of existing products within the time frame of the SRA

1.4 The Strategic Research Agenda (SRA)

The SRA describes the research which is recommended in order to realise the Vision and to ensure the objectives of the Platform are met. Whilst Europe has a relatively good scientific research base to take advantage of new technologies, it tends to be much weaker in translating scientific discoveries into products, which can be used in an operational situation. This needs to be overcome. The SRA considers the research necessary to ensure breakthrough and innovation in the development of new tools to control animal diseases. It also considers the research needed to resolve the problems in manufacture, production and registration of the new products. This involves identifying the research required to develop new methodologies and tests for demonstrating the safety, quality and efficacy of new products thereby enabling their rapid registration and approval by the regulatory authorities.

Stakeholders define the SRA setting out their common views on the necessary short, medium and long-term research, development and delivery needs for Global Animal Health over a period of 10 years. This will establish a framework for guiding research

over this period. In achieving this, the anticipated changes in animal health and production worldwide must be taken into account. The SRA must also be aligned to competitiveness and other Community policies and strategies, in particular the Community Animal Health Strategy which is currently under development and due for completion in 2007.

The SRA is focused on the challenges to be overcome in facilitating and accelerating the development and deployment of new tools for disease control which include vaccines, pharmaceuticals and diagnostic tests. The full spectrum of research, from fundamental and applied research through to effective production and delivery of new products, is addressed along with efficient knowledge transfer along the whole chain. Fundamental science is essential to develop the knowledge base, and applied science to use this knowledge to introduce innovative products and processes.

The initial discussions on the SRA at the stakeholder forum in February 2005 identified three main themes: Research, Technology Transfer, and Horizontal issues. Cross cutting issues, which would need to build into a matrix with the three themes, included sustainability, competitiveness, security from bio terrorism, public health including food safety, food security and market access. Three working groups of experts were established in order to develop the SRA. Each group had specific terms of reference and met twice during 2005. The presentations and minutes of the working groups are on the Platform web site and readily available to all stakeholders. The work of these groups provided the basis for the recommendations in this SRA. Details of membership of the working groups is in Annex 1.

1.5. Key Issues for the SRA

Key scientific and technological challenges have been identified by the working groups. These challenges were further defined, developed and extended in more detail along with contributions from stakeholders. The working groups considered the challenges and gaps in knowledge that exist in their sectors with respect to the development of vaccines, pharmaceuticals and diagnostic tests. This clarified the key issues which need to be addressed over the next 10-15 years.

In order to deliver the objectives of the Platform, the SRA is organised around a series of 6 key interacting issues which are:

- To prioritise animal diseases/infections
- To conduct a number of Gap analyses
- To ensure high quality relevant fundamental research.
- To identify the enabling factors to improve the rate of Technology transfer
- To consider regulatory issues
- To maintain a global perspective

2. Prioritisation of Animal Diseases/Infections

2.1 Introduction

The first stage in developing the SRA is to define a rational methodology to prioritise diseases within Europe and on the global scene. This is crucial to set the priority framework for research into new or improved tools for disease control and to ensure the most effective use of resources and research capacity. Prioritisation is an important component of the SRA and begins with the definition of diseases progressing to the technologies available to resolve problems associated with each disease.

2.2 International Criteria

The definition of a serious animal health problem in the EU is one that meets one or more of the following criteria:

- Known disease or animal health problem (including drug resistance and animal welfare) that does not occur (in endemic form) in the EU, and for which it is considered to be in the EU's interest to be free of the disease
- Variant form of an endemic disease, caused by a strain or type of the causal agent that can be distinguished by appropriate diagnostic methods, and which, if established in the EU, would have a serious socio-economic or public health impact (emerging, exotic)
- Disease of unknown or uncertain cause, which may, on the evidence available at the time, be an entirely new disease, or one not included in the priority disease list
- Disease for which authorised veterinary medicines may, on the evidence available at the time, be ineffective, unavailable, unlikely to become available, unsuitable or in the process of becoming unsuitable
- Known endemic disease, but with potential to occur in the form of a severe outbreak requiring an emergency response representing a large-scale epidemic of European significance or serious loss to the market economy
- Disease which meets one or more of the criteria for inclusion in the OIE list

The criteria for inclusion of a disease in the OIE list is based on only one of the following:

- International Spread
- Significant Spread within Naïve Populations
- Zoonotic Potential: Animal pathogens and human pathogens for which animals are asymptomatic reservoirs: has transmission to humans been proven (with the exception of artificial circumstances) and is human infection associated with severe consequence (death or prolonged illness)
- Emerging Diseases: is there rapid spread and/or apparent zoonotic properties

The comprehensive OIE lists of diseases were a starting point for the present exercise. Many of these diseases are not present in the EU but pose a risk of entry through EU borders. For example the table below indicates those disease not recorded in the EU during 2004. The spread of Avian Influenza during 2005 demonstrates how quickly the situation can change with the need for rapid responses supported by the appropriate tools for diagnosis, surveillance and control.

Table 1

Some Animal diseases not recorded in the EU 1 Jan - 31 Dec 2004

African horse sickness	Lumpy skin disease
Avian influenza	Peste des petits ruminants
African swine fever (limited to Sardinia)	Porcine enterovirus encephalo myelitis (formerly Teschen)
Contagious Bovine Pleuropneumonia	Rift valley fever
Dourine	Rinderpest (cattle plague)
Foot-and-mouth disease	Sheep and goat pox (Capripox)
Glanders	Vesicular stomatitis

2.3. Disease Threats

A predictive methodology is needed to identify emerging and new diseases that may pose a problem in the future and for which research is required now or in the future. As a consequence the research capacity in Europe must be sustained above a critical level to ensure an ability to respond rapidly to deal with the new and unexpected diseases. Furthermore, a risk analysis methodology is essential to assess the probability of diseases entering the EU under different sets of circumstances, including by bioterrorism, in order to develop contingency plans for their prevention or control.

The OIE (OIE, Scientific and Technical Review, Volume 23 (2), August 2004) identified the main global threats of emerging and re-emerging zoonotic diseases and pathogens list as follows:

There are overlaps between these groups, particularly between vector-borne diseases and emerging diseases.

- Vector-borne diseases: West Nile fever, Rift Valley fever, Japanese encephalitis and Crimean-Congo haemorrhagic fever, leishmaniasis
- Bacterial zoonotic diseases: bartonellosis, leptospirosis, Lyme borreliosis, plague
- Animal coronaviruses: SARS
- Emerging viral zoonotic pathogens: Hantaviruses - rodent-borne agents belonging to the Bunyaviridae family causing haemorrhagic fever with renal syndrome (HFRS) or hantavirus pulmonary syndrome (HPS)
- Tuberculosis: a re-emerging zoonosis : Mycobacterium bovis

Diseases which pose a potential threat through bio-terrorism should be included in order to provide a complete picture of risks to Europe. These are listed at Annex 2.

2.4. Disease Priorities

Neither the OIE nor WHO list the diseases in any priority order. In preparing priority lists it is important not to lose sight of diseases in companion animals (e.g. leishmaniasis), endemic diseases or disease syndromes (e.g. lameness, mastitis) and diseases where vaccines are not currently the most effective solution to the problem (e.g. internal and external parasites). Developing a common methodology to define priorities would assist in determining the focus for research.

Methodology

Initially a range of major animal diseases, both for EU member states and for other countries with a special emphasis on developing countries, were listed according to their impact on animal and/or human health. A priority list was then produced based on the experience of the working group members. A relatively simple methodology was developed using a small number of criteria as part of the assessment.

A number of different groups of criteria were employed. An initial method used three main criteria based on the economic, zoonotic and developing country impact of the diseases. A second system used 7 criteria each of which was scored between 0 and 5. In this case the criteria were: societal relevance, food safety, direct economic effect (on the animals), trade consequences, risk of EU introduction or prevalence in the EU, zoonotic properties, and importance to developing countries. The diseases were listed and the top 30 considered further.

The list of priority diseases was reviewed and finalised although complete unanimity was not achieved. The 30 diseases or infections were classified into 3 groups as follows:

- Major diseases
- Diseases for surveillance: generally unknown or unexpected diseases that should be put under surveillance in the EU member states or in other countries
- Neglected zoonoses that could deserve more attention

Emerging or re-emerging diseases were also to be considered within all three groups.

Group 1 Major diseases

List of the 15 individual or groups of diseases identified by the working groups as high priority but not in prioritised order:

- African Swine Fever (ASF)
- Pestivirus: Classical Swine Fever

(CSF)
- Rabies
- Avian Influenza (AI)
- Foot and Mouth Disease (FMD)
- Bluetongue
- Parasitic gastro-intestinal/neglected parasitic diseases (many of the latter group also fall into the neglected zoonoses category)
- Contagious Bovine Pleuro-Pneumonia (CBPP)
- Food borne zoonoses (including Salmonella/Campylobacter/E. coli/Cryptosporidium)
- Transmissible Spongiform Encephalopathies (ante-mortem diagnosis)
- Mastitis
- Tick/fly borne diseases
- Q fever
- Mycobacterium (Bovine tuberculosis and Bovine paratuberculosis)
- Zoonoses from non human primates

Group 2 Diseases for surveillance

As well as the priority list of major diseases, a separate list was considered necessary to identify the diseases for which there should be a surveillance programme. This relates to those diseases which pose a risk to Europe and for which tools are needed for optimum detection, surveillance and control. Important diseases with a high mortality rate and a wildlife reservoir, such as Nipah or Ebola, which are exotic to Europe need to be considered. These haemorrhagic fevers are mainly public health risks but the existence of a wildlife reservoir does implicate animal health services. The diseases recommended for inclusion in the surveillance programme are:

- Ruminant pox virus infection
- Rift Valley Fever (RVF)
- West Nile Disease (WND)
- Peste des petits ruminants
- Swine Vesicular Disease (SVD)
- African Horse Sickness (AHS)
- Food borne viral diseases
- Nipah virus

Recent experience has shown that wildlife is a major source of new pathogens that pose a threat to animal and human health. Sophisticated new screening assays such as micro arrays offer opportunities to screen wildlife populations for the presence and distribution of infectious agents that cannot be isolated in culture and/or that are only distantly related to known infectious agents.

New and emerging infections will continue to pose a risk to human and animal populations. There is a need to anticipate and adopt a proactive approach for new virus discovery in order to respond rapidly to new and emerging animal diseases, including zoonoses. It is critical that surveillance for these diseases/infections can be introduced as quickly as possible after their initial detection.

Europe must have the capacity to conduct surveillance and to deal with the above diseases. This involves the collection of the appropriate data, detailed analysis and the rapid dissemination of information to the appropriate authorities. The recipients of the information must have received the most suitable training and must be in a position to take the necessary measure upon receipt of the information.

Group 3 Neglected Zoonoses

The World Health Organisation (WHO) has drawn attention to the relationship between poverty and the emergence or re-emergence of zoonotic diseases, listed below, which are largely neglected:

Table 2
Neglected Zoonoses

Anthrax	Echinococcosis
Bovine TB	Rabies
Brucellosis	Trypanosomiasis
Cysticercosis	(Source WHO)

Consequently diseases in this category are important both for human health but also for their socio-economic effects and thus the potential to alleviate poverty in developing countries. In addition to the diseases listed above by the WHO the following should be included:

- Trypanosomiasis
- Leishmaniasis
- Chlamydia
- Leptospirosis

2.5. Conclusions

The analysis raises many questions concerning the practicality of prioritising diseases and the criteria which should be used. The validity and relevance of the criteria adopted for the

scoring method are crucial if a validated system is to be developed and widely accepted. The methodology has to incorporate a mechanism to reflect the views of governments, political importance and society's perceptions and views of the diseases.

A range of other variables must be considered. These include the variation in importance of a disease in different geographical localities of the EU, the risks or potential risks to Europe and whether the disease is a problem to Europe alone. More information on the socio-economic impact of a disease and the benefits of control is a prerequisite to the priority setting process. This indicates that all the critical criteria must be determined before a successful prioritisation system for all diseases can be developed. A sensitivity analysis for each of the criteria is also required in order to evaluate their individual impact on the overall priority status of each disease.

It is clear that a tool is needed which will allow the transparent classification of disease and that a risk-based animal disease prioritisation model would be a first step. More research is required to define the methodology and to establish the criteria on which to base the prioritisation. It important to define the criteria against which a disease can be assessed in order to allow for a more logical and comprehensive approach to the allocation of resources for research and control measures. Defining the absolute disease priorities may not be as valuable as assessing the research requirements against a set of criteria which can be refined and developed over time. The advantage will be a transparent and reproducible mechanism with inbuilt flexibility to evaluate new and emerging diseases when necessary. Priorities may change and the methodology must also be flexible to respond effectively.

It is difficult to allocate diseases into a simple classification: the large number of variables made a prioritisation method difficult to develop and agree over a short period of time. In the short term, a skeleton model is provided but in the longer term a model needs to be established which takes account of the overall risk level of a given animal disease, the availability of suitable products or technology, the feasibility of control, the impact on economies, human health, food safety and public/consumer perception, etc. An initial proposal is that information should be collected under 4 main headings: "epidemiology", "impact", "control" and "other". A score of between 0 and 5 would be allocated to each of the parameters based on the actual situation. This would also identify those areas where information is unavailable to complete the scoring process thereby identifying areas for research. Further details of the suggested criteria are in Annex 3.

Without a specific priority setting process there will be a lack of clarity over priorities for research funding and the successful outcomes from the research. The aim of the proposed model is to develop a consistent means to prioritise animal disease risks of major importance for the EU. The model will provide the criteria against which new and emerging diseases can

be assessed and this in turn should enable research to be focused in a manner which will allow the objectives of the ETPGAH to be met. Consequently resources should be directed primarily towards the priority diseases although it must be accepted that disease prioritisation can also change with events both within and outside the EU. It will have the added advantage of providing researchers with the information on those diseases considered to be a priority and where funding is most likely to be available.

2.6. Research Agenda: Prioritisation of Animal Diseases/Infections

The use of a predictive model will enable organisations to determine their funding policies and review the situation on an annual basis to determine whether priorities have changed and whether new or emerging diseases will necessitate the redeployment of resources. Overall, for the Strategic Research Agenda, there is a requirement for coordinated action.

The main recommendations are:

2.6.1 Create a risk-based disease-specific prioritisation model to evaluate global animal health priorities (endemic, exotic, emerging diseases) and the risk they could pose for the European Union in order to assist in allocating research funding and implementation of control measures.

2.6.2 Use the model to identify and formally prioritise animal diseases of major socio-economic, animal or public health importance for Europe.

2.6.3 Identify the threats to Europe from pathogens which are not considered important at present (i.e. horizon scanning) and conduct full risk assessment of potential threats from new and emerging diseases, in particular those outside the EU boundaries.

2.6.4 Develop and use a predictive model to identify when a disease agent becomes a significant threat and assess the potential global costs (taking into account the Lisbon agenda).

2.6.5 Target research funding to the diseases in the defined priority areas, i.e. major disease, those for surveillance, and neglected zoonoses, unless specific cases can be made for funding research into other diseases. A case may be made to fund research into diseases or species currently considered as MUMS (minor uses/minor species) diseases within the EU, but which may constitute a significant threat to the EU (e.g. Bluetongue) or may be considered major species in less developed regions (e.g. goats, buffalo).

2.6.6 Develop research with appropriate funding into surveillance methodologies to ensure new and emerging disease both in Europe and on its borders are detected rapidly.

2.6.7 Direct research funding into wildlife diseases especially in relation to zoonoses, which may have an impact on human and animal health.

2.6.8 Initiate research programmes for the priority diseases in cooperation with the developing countries in order to develop sustainable strategies for control.

3. Gap Analysis

3.1. Introduction

Gap analysis, which can vary in complexity and sophistication, is the methodical identification and investigation of specific gaps between the current position and the ideal future situation. Equally it can also identify the needs and the resources available. It is recognised that ideal solutions for the control of disease may not be achievable but an assessment of the improvements that are possible still needs to be undertaken. A number of relatively simple gap analyses were conducted during the development of the SRA. The main objectives were to identify the gaps in key areas and then to consider how the gaps could be filled by the development of the SRA.

Issues are considered under 5 headings:

- Gaps: Disease Knowledge
- Gaps: Product Availability regarding vaccines, diagnostic tests and pharmaceuticals
- Gaps: Sourcing of Products.
- Gaps: Technology Usage
- Gaps: Research Activity

3.2 Gaps: Knowledge of the priority diseases

In the first instance a relatively basic analysis was undertaken to identify the gaps in the current knowledge of host-pathogen interaction, epidemiology, immunology, and control methods for the diseases in the three priority categories recorded in chapter 2. The table below summarises the findings.

Table 3

Gaps in Knowledge of Priority Diseases

Infection	Host pathogen interaction	Epidemiology	Immunology	Prevention diagnosis therapy		
				Vaccine	Diagnostics	Therapy
ASF	+	–	–	+	.	.
				+		
CSF	+	–				
Rabies				DC		
Influenza	+	–	–	+	–	+
FMD			-			
Bluetongue			-			
Parasite gastroenteritis	+	drug resist	+host resist.	+	.	+
West Nile disease	+	–	–		–	
Rift Valley fever	+	–	–	+	?	.
CBPP	+		–	+		+
Foot-Rot		–		+	–	.
Salmonella	+	–	–	+	–	.
Campylobacter	+	–	–	+		.
TSE	+	–	–			

Peste des petits ruminants	-	-	-	+	+	
Mastitis	–	–	–	+	+	+
Tick borne disease	-	-	-	+	+	+
Swine vesicular disease	–	–			+	
Q fever	–	–	–	+		+
Trypanosomiasis	–	–	–	+	+	+
Chlamydiosis	–	–	–	+	+	+
Leishmaniasis	–	–	–	+		+
Brucellosis	-	-	-	+	+	-
Swine osteodystrophy	-	-	-	+	-	
T3	–	–	–	+	+	-
Para T3	–	–	–	+	+	-

Key: + gaps identified, +/- partial gap, - no gap identified.

This table is a beginning but it is clear further work is required to reflect priorities and to analyse the gaps in more depth, for example the importance of investing in FMD epidemiology studies compared to AI, TSE, CBPP etc. Also, no distinction is made between the need for vaccines (for example AI for ducks) and need for information on vaccine use (for example FMD).

Whilst the preliminary analysis attempted to identify the overall gaps, a more detailed analysis of the priority diseases is required to investigate specific issues under each of four headings (host-pathogen, epidemiology, immunology and control). In the case of the host-pathogen interaction, the key issues relate to vectors, reservoirs and the interaction between them at macro and molecular levels. For the other three areas the issues were considered in conjunction with the detailed analysis of individual diseases on the priority list. Using this analysis the research requirements for the diseases could be determined in relation to host-pathogen interaction, epidemiology, immunology and control. The methodology for the analysis is in Annex 4.

As a result, a further gap analysis was developed which extended the process beyond the original four main headings. The purpose of the more complex analysis was to identify the most effective way in which to identify the gaps and research requirements. This was achieved by developing a matrix with the priority diseases on one axis and the research requirements on the other. The potential areas for research were extended to include: mapping of research and products, disease prioritisation, sourcing strategy, response capacity, new product needs, evaluation of existing products, knowledge of the disease, research into control methods, and technology transfer. The proposals for further development of this analysis are in Annex 5 using FMD and AI as examples at present.

The societal benefits of veterinary medicines at consumer level should also be assessed and incorporated into the cost and benefits for disease control in animals. For example, the benefits of salmonella vaccine in poultry which reduces food contamination and ultimately human infection should be quantified. There are still gaps in the fundamental understanding of the zoonoses, in particular basic epidemiology, immunology and potential control measures such as competitive exclusion, the use of bacteriophages, and breeding for disease resistance.

By developing this type of analysis, it is possible to produce a summary for each disease identifying the main areas of need in relation to specific measures such as surveillance, treatment, vaccines and diagnostic tests. As a more refined methodology is developed, it can be used to determine the research priorities with more accuracy.

3.3. Gaps: Product availability re vaccines, diagnostic tests and pharmaceuticals

It is generally considered that there is a need to constantly improve vaccines, diagnostics and pharmaceuticals with the objective of getting as close to the ideal as possible. However, this is not always economic or feasible and it may prove appropriate to use less than ideal products which deliver the best affordable controls.

The aim of the ETPGAH is to facilitate and accelerate the development and distribution of the most effective tools for the control of the major diseases, and where these do not exist or are inadequate to identify the gaps in the knowledge base and to search for solutions. Thus the gap analysis for each of the priority disease will help to answer a number of questions:

- What is currently available for effective controls and is it fit for purpose?
- What new tools are needed?
- Is the research near to a breakthrough and does it have the potential to deliver the products?
- What are the costs and timescales for delivery of the new tools?

The table below provides an example of such a preliminary indicative analysis for Avian Influenza. Further work is required to complete the analysis and to undertake a similar analysis for each of the diseases on the priority list.

Table 4

Indicative Example - Avian Influenza: Product analysis

Product analysis	Avian Influenza	Comments
Vaccine needed	Yes	Prophylactically for outdoor poultry, zoos, other collections In the face of an outbreak to reduce spread Reduce requirement for stamping out policy As a contingency against bioterrorism
Vaccines available	Yes	Worldwide, a number of inactivated vaccines produced by major companies as well as local producers A fowlpox vectored vaccine used in Mexico, Guatemala, Salvador, and Vietnam In China, classical and reverse genetics inactivated vaccines as well as fowlpox vectored vaccine
Vaccine authorised in Europe	Yes	Vaccines have recently been authorised. Use permitted under direction of the CVO. Provision made in new Directive for captive birds
Marker Vaccines available	Yes	The use of inactivated vaccine with heterologous neuraminidase (N) subtype allows the detection of infection by testing antibodies against the N subtype of the circulating strains. Unfortunately these tests are not currently commercially available. For vectored vaccines, commercial ELISA and AGP detecting NP and M antibodies can be used
Marker vaccine in Europe	Yes	N variants used in a number of countries
Live or dead Application	Dead Injection	All dead vaccines or live vectored By injection with repeated doses needed. Slow and difficult for mass vaccination Fowlpox recombinant only for day old chicks or chickens not previously vaccinated or infected with fowlpox
Immune development	-	Variable onset of protection depending on the vaccine type (faster for vectored-vaccine). Little knowledge on duration.

Immune development		Variable onset of protection depending on the vaccine type (faster for vectored-vaccine). Little knowledge on duration.
Recombinant/GM Vaccines	Yes	Fowl Pox vectored H5 from H5N8 ILT and NDV vectors reported Reverse genetics used to generate low path vaccine strains that contains a modified hemagglutinin antigen used to produce inactivated vaccine that match highly pathogenic field strains.
Effectiveness	Yes/No	Efficacious to interrupt transmission once onset of immunity is established (14-28 days for inactivated vaccines)
Commercial potential of vaccines in Europe	Maybe	If outbreaks occur, use may be limited to certain categories of poultry in some countries. Commercial and regulatory barriers and may have an impact
DIVA tests	Yes	Can be used based on different antigenic types
Current Therapy	No	Main barrier to antivirals in animals is cost. Also supply limited – keep for human use Although antivirals may be effective they cannot be used due to the potential for resistance in animals and humans
Future therapy	Possible	New developments may allow the use of new therapies to reduce virus infection attachment or excretion. Scope for future research needed
Requirements for product development	Yes	Compatible with mass application Mucosal vaccines Efficacious against different strains Efficacious in different poultry species (chicken, ducks, turkeys geese) Develop effective adjuvants Rapid development of immunity Ability to prevent spread Differential Tests Rapid pen-side DIVA tests available Cell culture vaccine Ability to change strains according to the epidemiological situation with rapid regulatory review
Time to develop new vaccines		Regulatory issues Scale up issues – need high yield, low pathogenic strains Biosecurity issues in manufacturing plants
Cost of development		

3.4 Gaps: Sourcing of Products

The list of available products needs to be reviewed. Worldwide there are more veterinary medicines available than presently authorised in the EU. Some are authorised for a single target species but in case of an outbreak might be used for other species under the cascade. This is a legislative provision which allows a veterinarian to use a medicine to treat an animal even if there is no veterinary medicinal product authorised for use in the species and condition presented. If a marketing authorisation is not economically feasible for the private sector, public funded research should develop data to allow use of a medicinal product in an emergency treatment programme.

Currently, there is no updated, exhaustive catalogue of animal health companies/manufacturers within and outside the EU nor is there a complete

central list of their products. This already exists to some degree for Biologicals and is published by the Institute for International Cooperation in Animal Biologicals. Only some countries have specific sourcing policies for selected products/tools which would be used in the primary or secondary response to address animal health emergencies of major importance in the EU.

A compounding issue is that the main focus of private sector activity will be dependent on the commercial potential of any products. Well-known areas with a commercial potential include salmonellosis and campylobacteriosis whereas those without commercial potential cover diseases such as FMD and CSF. Other diseases may be marginal and of doubtful commercial potential including ASF, CBPP and Flaviviridae. These areas are unlikely to attract private sector interest and the development of useful tools may have to rely on governments to fund research and purchase pharmaceuticals, vaccines or tests. Thus financing the development of diagnostics and products where there is little or no commercial potential is a major issue and deserves unique attention. This is essential.

A similar concern exists for the availability of veterinary medicines for minor species or for minor use in major animal species. In the USA a specific programme has been successfully funded and progressed to deal with this problem. This may have applications to the European situation not only for the minor species but also

the development and delivery of vaccines and tests for diseases which either do not occur in Europe or are of rare occurrence. Changes to the regulatory environment have been recently enacted across the EU in order to promote the availability of MUMS products and the success of these will need to be evaluated before further changes are introduced.

There are a number of sourcing strategies for veterinary medicines, in particular vaccines, in the European Union:

- Suitable products already available in the European Union: identify and source within EU
- Procedures available to manage the risk of unauthorised vaccine/product to allow import and assure supervised use under special authority
- Import master seed, antigen or other starting material from other countries, test against European standards and protocols and produce finished vaccine/product in the EU
- Develop a European "master seed" or starting material stock and

manufacture to European standards
- Sponsor research into development of vaccines/products where currently no vaccine/suitable product is available, where this is technically feasible, industrially viable and where the resulting new product is eligible to be a first line of defence tool
- Create Public Private Partnerships to develop and bring to market veterinary medicines currently not available or needed in the future in the EU

3.5 Gaps: Technology

The rapid advance in new technologies and techniques can be used to develop the tools for the control of animal diseases. Important recent developments in molecular biology which have the potential to be used for animal disease control include:

- Amplification systems PCR (conventional, nested, real-time, hand held, self sustainable)
- Chip technology/ DNA arrays
- Genetically engineered vaccines
- DIVA (marker vaccines)
- Nucleic acid vaccination
- Rapid sequencing (molecular epidemiology)
- Biosensors
- Remote sensing
- Nanotechnologies

In the case of vaccines, improving the level of immunisation will come from the combination of different approaches: new vector systems for expressing candidate immunogens, new adjuvants, combination of vaccine antigens and immuno-modulators and new delivery systems. Specific areas where there are potential applications include:

- Genomic research towards protective antigens
- Molecular epidemiology and evolution / prediction of (re)emergent pathogens
- Antigen delivery systems
- Antigen presentation systems (adjuvants and other technologies)
- Manufacturing processes (towards simplification)
- Comparative vaccinology (advantages / disadvantages of new applications versus existing applications)
- Stem cell technology
- Biotech / GMO products for mass application and food animal application
- Research towards new applications and research towards the use of existing applications in new areas.

New generation vaccines developed through biotechnology include subunit, live recombinant, live vectored and polynucleotide vaccines, any of which may have potential for further development in the case of the priority diseases. The use of DNA arrays and DNA chips have the potential to improve diagnostic testing and allow the rapid, high throughput, reliable use of diagnostic tests with the benefits that will be derived for surveillance, detection and control of diseases.

By evaluating the appropriateness of the individual technologies for vaccines, pharmaceuticals and diagnostics for the priority diseases, research can be focused on those technologies which will provide the greatest benefits.

3.6 Gaps: Research Activity

The successful development of any product requires the involvement of expertise from many disciplines. These include molecular biology (expression systems, vaccine vectors), veterinary immunology, clinical applications (understanding disease and challenge models), manufacturing and the supply chain. As a result, new vaccines, diagnostics and pharmaceuticals will be the output of well-organised but creative, multi-disciplinary teams working on complex projects. Innovation will result from the multi-disciplinary approach and from industrial / academic collaborations.

The gap between the quality of the fundamental research in the universities and technological centres in the EU and its translation into patents and products is due to a lack of coordinated subjects that are covered in the research institutes. Research projects often have no relationship to diagnostic or protective systems from which potential products can be derived. Efforts should be focused on guiding research by encouraging researchers at universities to work on the diseases considered to be a priority.

At present there is no clear picture or overview available of the totality of current research into diseases

throughout the EU or indeed the world. There is no readily accessible information on research funding by public authorities either at a national or regional level nor by large pharmaceutical or the smaller biotech companies. Information on planned or proposed research is also unavailable. Whilst pharmaceutical companies have extensive research programmes there is the question of competition and intellectual property rights, which may limit the exchange of information.

In the case of products for MUMS conditions, a gap analysis would be worthwhile to identify those conditions for which relatively little research would be required, possibly for existing compounds or products, that would fill a data gap and allow authorization of a veterinary medicine within the EU.

A similar situation exists regarding the capacity to undertake research with a potential lack of expertise and infrastructure in Europe. This is compounded by the fact that no catalogue or database containing comprehensive information is available.

3.7 Conclusions

The most effective methods to identify the gaps and research requirements for the priority diseases were considered. Using a simple matrix with the research requirements on one axis and the priority diseases on the other it is possible to develop a gap analysis to identify research requirements. By extending this to include new product needs and an evaluation of existing products it is possible to identify the challenges to be overcome in meeting the aims of the ETPGAH. In the time available it was only possible to produce an outline. A more comprehensive input is required to develop the methodology and to complete and validate the process for all the priority diseases.

There is a need to evaluate the existing technologies versus new technologies. The right solution or the best solution is not always the newest technological trend, but can be a very classical approach based on proven experience (especially at the manufacturing level). The gap analysis should identify where technological advances will assist the development of diagnostics, pharmaceuticals and vaccines. It is important to develop through public and private partnerships an overview of current research and identify the gaps. Programmes can then be developed to fill these gaps whilst at the same time developing research collaboration and synergies to avoid duplication of research effort. Within the EU, the lack of a formal mechanism to identify research gaps increases the reliance placed on scientific communities, panels and workshops to assess these needs. Assessments are limited and need continuous updating.

No single organisation or group has an overview to ensure an integrated and coordinated R & D programme across Europe. Provision of such an overview would reduce duplication of effort, lead to a more effective use of resources and limited funds, encourage synergies and enable major gaps in research to be identified and filled. The analysis will provide the EU, national governments and other public/private organisations that fund research with the information necessary to target and direct funding to achieve the maximum output for the investment and enable the delivery of new or improved tools for the control of animal diseases. Whilst the gap analysis is important it is crucial to recognise that funding should be directed primarily to research which will deliver products.

3.8 Research Agenda: Gap Analysis

Gap analysis is a process to identify the research requirements for the individual priority diseases. This would then 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. Much of this work can be undertaken either by private or public funding but needs to be published and coordinated to avoid duplication of effort.

The main recommendations are:

3.8.1 Develop and implement the methodology for the gap analysis based on the proposals in the SRA and use this methodology to undertake a comprehensive gap analysis for each of the priority diseases on a regular basis at 2-3 year intervals.

3.8.2 Define knowledge gaps in existing control tools for surveillance, diagnosis, vaccination and treatment and consider the research required to develop new or improved tools for each of the priority diseases.

3.8.3 Target research to increase the knowledge base of the priority diseases in order to develop vaccines, diagnostics and pharmaceuticals to overcome the existing shortcomings in tools for the control of priority di-seases focusing on those areas where there is a justified need.

3.8.4 Review new technologies and assess their value for the future development of the tools to control priority diseases.

3.8.5 Map global research and development for the priority diseases and catalogue the current research programmes against the research organisations both within the EU and globally in order to build a database of research throughout the EU and to maintain and publish such a database.

3.8.6 Catalogue and create a database of the available products worldwide for the control of major disease and evaluate their potential for use in the EU in addition to mapping the animal health companies producing veterinary medicines and diagnostic tests worldwide.

3.8.7 Research and develop a comprehensive, risk-based sourcing strategy for vaccines, pharmaceuticals and diagnostic tests to meet EU animal health priorities linked to the priority diseases.

3.8.8 In the case of products for MUMS conditions, conduct a gap analysis to identify those conditions for which relatively little research would be required to fill a data gap and allow authorisation of a veterinary medicine within the EU.

4. Fundamental Research

4.1 Introduction

The previous chapters concerned priority diseases and gaps in the knowledge and understanding of those diseases. It is important to consider the fundamental sciences which act as the building blocks for new technologies and without which the development of new and improved tools to control diseases will not be successful. A strong base of fundamental science is vital if progress is to be made and if the competitiveness of European industry is to be improved.

Fundamental research is primarily a task of the academic scientific community and forms the basis for future technology. Academic freedom is essential to guarantee the maximum creativity for new developments. However, it should be stressed that the outcome and the applicability of fundamental research is difficult to predict. Sharing research findings and confirmation of such findings is essential, but unnecessary repetition of research should be avoided. Commercial companies play a role in the validation of the applicability of fundamental research concepts.

A number of specific themes are considered:

- Host/Pathogen interactions
- Fundamental Immunology
- Epidemiology
- Genomics
- Integrated Biology

4.2. Host (vector, reservoirs) - pathogen relationships

Current Position

The molecular mechanisms of infectious agent-host interaction from the perspective of the infectious agent and from that of the host can only be identified through fundamental research. Pathogen biology and the host-pathogen interaction at the molecular level also need to be understood. This includes the immune response of the host organism against the infectious agent.

At the host-pathogen (vector, reservoir) level a range of issues need to be addressed in order to elucidate the mechanisms. These relate to virulence, susceptibility, the molecular basis for the host range, and adaptation to new host species, genetics of host and infectious agents, functional genomics, mechanisms of pathogen persistence and targeted therapeutics in relation to pathogenesis and pharmacokinetics.

At the level of the cell-pathogen interaction the focus should be on a range of topics including protein-protein interaction, structural and functional genomics, structural biology, cell biology, mechanism of pathogen persistence at cell level, and therapeutics. The molecular and cellular basis of antibiotic and anthelmintic resistance of pathogens would be important at this level.

The development of novel control strategies is critically dependent on an understanding of host and pathogen biology as well as host-pathogen interactions at a molecular level. This includes the immune response of the host organism against the infectious agent. Different levels of this host-pathogen interaction can be distinguished, i.e. host and pathogen populations including vectors and reservoirs, single animals, tissues, cells and sub-cellular compartments.

The molecular understanding of infectious agent-host interactions (receptors, signalling, susceptibility, resistance) and an understanding of innate immune responses and immune evasion are all important. There are continuing advances in genome sequencing which will allow a better understanding of the molecular basis for disease and host-pathogen inter-actions etc.

Priority areas for Research

Emphasis has to be placed on the elucidation of mechanisms that relate to:

- The molecular basis for host range and adaptation to new host species
- Genetics of hosts influencing susceptibility to disease
- Genetics of pathogens and pathogen populations relating to virulence and antigenic variability
- Mechanisms of persistence (host and population levels)
- Therapeutics (targeting in relation to pathogenesis, pharmacokinetics)

4.3 Fundamental Immunology

Current position

A better understanding of the immune system of the relevant target animal species and the provision of tools to perform fundamental immunological studies is essential to provide a solid basis for the new approaches to the development of veterinary medicines and diagnostic tests. Recent technical advances in the immunological knowledge of several veterinary target species provide hope that adequate and efficient tools will be available within a few years. However, many difficulties remain:

- Different cell systems are involved for each disease
- It may not be possible to extrapolate from one species to another
- It may not be possible to extrapolate one model to a similar model in another species

Applications of immunology for vaccine development and the new tools for vaccine development are linked very closely to modern genomics in particular parasite genome sequences, host genomes and post-genomic technologies. The specific application of immunology to vaccine development falls into a number of categories which include:

- Specific diseases - knowledge of protective immune responses can be used to:
  - ✳ Screen for vaccine antigens
  - ✳ Direct the immune system to respond better to existing vaccines
  - ✳ Inform choice of type and route of vaccine delivery
  - ✳ Provide tools for testing potential vaccine candidates
  - ✳ Evaluate the risk of extraneous agents
- Generic applications – to evaluate:
  - ✳ Efficacy of antigen delivery systems
  - ✳ Biological activity of adjuvants/immunostimulants

Priority areas for research

A focused research approach has to analyse the following topics:

- Mechanisms of adaptive immunity
- Contribution of innate immune responses
- Mechanisms of immunity for different types of pathogens (parasites, virus)
- Mechanisms of immune evasion
- Selection of antigenic variation by host immune responses (prediction)

- Tools for studying immunity in livestock
- Immunology targeted to species of economic interest (ruminants, pigs, chicken,)
- Mechanisms for T-cell mediated immunity
- Molecular basis for susceptibility and resistance (genomic sequences for cattle, pigs, chicken available soon)

Within this group specific priorities are:

- Mine animal genome sequences to expand immunological toolboxes
- Establish reagents and methods to quantify specific T-cell responses
- Develop a better understanding of cells and molecules that mediate innate immune responses
- Exploit functional genomics to provide more comprehensive biological profiles of innate and adaptive immune responses

4.4. Epidemiology

Current Position

Research in epidemiology, in particular for zoonoses, is multidisciplinary. As a consequence progress is largely dependent on scientific progress in molecular biology, vaccinology, immunology, bioinformatics, etc. Work to understand the important infectious diseases has to continue through the funding of epidemiological research for the major economically important diseases, in particular FMD, CSF, ND, as well as knowledge of exotic diseases threatening Europe such as Nipah, Ebola, and vector borne diseases such as West Nile disease. Research to increase knowledge of the causative agents for food borne zoonoses such as salmonella and campylobacter should also continue.

Wherever possible, research in this area should take place in the countries where routine vaccination programmes are in place. Transmission studies under laboratory conditions provide valuable information; however, they are of limited value in predicting the role of vaccination in a field outbreak. Epidemiological research to evaluate the effect of vaccination in countries in the face of field outbreaks is necessary. Field studies provide the EU with epidemiological expertise to assist in the control of the disease and the opportunity to research the role of vaccination.

The development of methods to monitor wildlife and domestic animals for existing and newly emerging infectious diseases is a priority. Additionally disease modelling is required for a better understanding of the consequences of outbreaks and to develop scenarios for their control.

Applied research involves the development of sampling and survey methodology. A multidisciplinary approach must be ensured by access to available databases and pathogens. In other aspects epidemiology research should be carried out by trained decision makers – field workers experienced in interpretation of surveillance data and the ability to develop rapid methods for detection and relevant information.

In Europe, epidemiological research is carried out in national institutions and is mainly organised and funded by the EU Member States. There is no central institution with coordinating responsibilities for fundamental and applied research in the field of infectious diseases and epidemiology. In view of the recent enlargement of the EU there is a requirement for an efficient infrastructure or centralised institution for fundamental and applied research into epidemiology and infectious diseases.

Priority areas for Research

The following recommendations are made:

- Develop methods to monitor wildlife and domestic animals for existing and newly emerging diseases, especially as the number of zoo-notic diseases is expanding
- Use disease modelling for better understanding of the consequences of outbreaks and scenarios for control
- Develop models to simulate outbreaks and assess the impact of different control measures
- Use models to develop cost benefit analysis of the potential control measures
- Ensure appropriate use of applied research e.g. sampling and survey methodology
- Adopt a multidisciplinary approach to ensure access to available databases and pathogens
- Develop disease and vector (if

appropriate) surveillance of diseases inside and outside the EU (including exotic)
- Investigate the role of vaccination in limiting transmission and spread

4.5 Genomics

Current position

Genome sequencing activities are continuing at an ever faster pace. There is a strong acceleration of the access to genome data and, in particular, genomes of pathogens. There are continuing advances in genome sequencing which will allow a better understanding of the molecular basis for disease, host pathogen interactions, etc. Having identified the genome sequences there remain many methods for using the technologies although there are also many limitations.

The expression systems from viral and bacterial vectors provide useful research areas. The major challenge is to identify the relevant gene(s) from large bacterial and parasite genomes and develop methodologies to screen for these genes.

Other activities, such as micro-array transcriptome expression analysis, proteome analysis, and protein interactome analysis are also resulting in the accumulation of large quantities of data. The resulting gap between the accumulation of information from these sources and the ability to conduct its experimental evaluation and practical exploitation continues to increase. As a consequence there is a limitation on the value that can be derived from the genomic information available today.

Priority areas for research

Exploitation of genomics technologies is critical in the following areas:

- Mining of sequence data
  - ✳ Enhance the immunological toolbox (cytokines, chemokines, etc)
  - ✳ Provide tools to study innate immune responses
- Gene expression profiling – whole genome arrays or immunological gene arrays
  - ✳ Dissect specific immune responses (biological profiles)
  - ✳ Evaluate antigen delivery systems and adjuvants
- Large scale sequencing (genomic sequences of livestock)
- Large scale sequencing (wildlife reservoirs, virus detection without isolation)
- New sequencing technologies (Very High Throughput) allowing comparison of strains with different characteristics

4.6 Bio-informatics

Current position

Recent advances and the equipment available for research in this field have allowed the increasingly rapid sequencing of large portions of the genomes of several species and pathogens. Advances in genomics/bioinformatics and expression systems will allow research to handle hundreds of genes. The wealth of information generated from research into genomics, proteomics and metabolomics will need to be analysed, interrelated and interpreted in the context of disease problems which are to be addressed. Such information needs to be placed in appropriate databases that are accessible in a user-friendly manner by the research community.

It is essential to develop bioinformatics facilities and to maintain these in order to allow access through the EU research community to all the sequences and analytical software required for the analysis and exploitation of the information. The mass of information now being produced must be stored, organised and indexed to be of benefit. This will involve a multidisciplinary approach using mathematics, information science, computer technology and software development. The application of information science to biology is the basis of bioinformatics. While the storage and organisation of millions of nucleotides is far from trivial, designing a database and developing an interface whereby researchers can both access existing information and submit new entries is only the beginning.

Priority areas for Research

Bioinformatics is already an integral component of research covering activities from automated genome annotations to the integration of disparate datasets from different system-level activities. These activities will have to be extended and intensified as the rate of data generation has increased to unprecedented levels. To ensure that

this science is applied to the work of the ETPGAH the following are important recommendations:

- Establishment of bio-informatics capability
- Standardisation and linking of structural, genomic, proteomic data etc…
- Establishment of parallel databases for biological data to allow interpretive analyses

4.7 Conclusions

Over the next 10 years it is vital to foster a creative environment for fundamental research and to stimulate investment in research, in particular in the fields of molecular biology, immunology, genomics, bioinformatics etc. It is important to recognise that there is a considerable overlap between many of these disciplines which suggests that the fundamental sciences must be considered in a holistic manner to achieve the best results from research. A sound and stable base for fundamental science is vital if innovation and the development of new tools are to be successful. To achieve this, programmes need to be established which inherently support fundamental research either directly or indirectly linked to the priority diseases.

A multidisciplinary approach should be encouraged involving all those whose input has the potential to identify or develop new concepts and take these through to proof of concept stage. However, not all problems can be solved and the SRA needs to be focused in order to maximise the efficiency of future funding.

It is critical that Europe has the capacity and the expertise to undertake fundamental research in these areas. An EU-wide review of the current state of fundamental science as it impacts on the development of vaccines, pharmaceuticals and diagnostics is required for the major diseases. There has been an erosion of the capacity to undertake fundamental research over the years and some specific areas such as entomology are neglected. It is important to sustain a nucleus of expertise which is capable of responding rapidly to the priority diseases using the most up to date techniques and methods and which has the capacity to respond rapidly to new and emerging diseases.

European research into epidemic diseases is often spread over a relatively small number of public institutes. Research into zoonotic diseases, however, is more fragmented, being spread over many institutes. This becomes a serious problem in terms of resources, particularly the availability of expertise, expensive equipment and facilities needed to maximise utilisation of the new technologies.

The establishment of a European Central Institution for Epidemiology and Infectious Diseases would have responsibility for training epidemiologists to create a critical mass for the future and to act as a repository for a range of databases on disease information. This would be expensive to establish and run. An alternative is to identify all the functions which ideally would be included in the terms of reference for such a centre and to develop a virtual centre which would involve centres of excellence around Europe combined in a way to enable ultra-fast information links and methods for data exchange.

It is vital to fund the fundamental sciences and it would be appropriate to consider specific programmes for each speciality. This could be more the responsibility of the funders from the Member States but an EU overview is essential if the EU is to remain competitive in this field.

4.8 Research Agenda: Fundamental Research

The main recommendations are:

4.8.1 Take a strategic overview of the fundamental sciences in the EU to assess whether there is sufficient capacity and expertise to deliver the science necessary to support research and new technologies needed to develop new tools to control diseases.

4.8.2 Develop an EU-wide strategy to enhance the capacity and expertise in the fundamental sciences and consider whether specific science and education programmes are needed to develop and maintain expertise in each speciality area.

4.8.3 Target research funding to those areas of fundamental science critical to the development of prioritised vaccines, pharmaceuticals and diagnostic tests.

4.8.4 Strengthen collaboration between the research organisations working on the fundamental sciences.

4.8.5 Establish and support a European Centre for Epidemiology and Infectious Diseases.

5. Enabling Factors

5.1 Introduction

A number of barriers to the efficient transfer of technology to enable the development of new products were identified. It is essential to minimise or overcome the effects of these barriers if the EU is to remain competitive and to produce innovative and new products. Six enabling factors necessary for the effective transfer of technology were identified:

- Quality Assurance
- Intellectual Property Rights
- Facilitation of Technology Transfer
- Networks and Centres of Excellence
- Education and training
- Infrastructure

5.2 Quality Assurance

Academic institutes in Europe are not accustomed to working to independently audited quality standards such as Good Laboratory Practice. Compliance with quality standards can be expensive, increase research costs and in many cases is not a requirement imposed or requested by the funding client. The consequence for Europe is a severe gap in the knowledge and understanding by European scientists of the importance of compliance with regulations and standards. It is estimated that in 80% of cases companies need to start work from scratch with compliant materials and approaches.

Even in fundamental research where basic concepts are developed, the work should be undertaken to an appropriate quality standard. Indeed research in Europe which receives public funding should be to GLP or equivalent standards although it is important not to inhibit fundamental research which is the source of innovation. Some of the GLP quality requirements may be very expensive for the research laboratories. It will be important for the industry and the public sector to take account of the additional costs required by GLP when funding research projects. This is closely linked in with intellectual property rights and the need to develop ideas to the proof of concept stage in order to facilitate transfer from the research environment to the production of practical products.

The main recommendations are:

5.2.1 All laboratories and organisations that conduct research that might ultimately lead to the authorisation of a veterinary medicine should operate to appropriate quality standards that are independently audited by national quality assurance organisations. These standards might include ISO9001, ISO17025, GLP, GCP, GMP or other national quality standards.

5.2.2 Build a requirement for quality management into the research funding contracts between the funders and the research organisations.

5.2.3 Consider alternative quality standards necessary to ensure quality control for research into the development of the tools for disease control.

5.3 Intellectual Property Rights

Major problems relating to intellectual property rights (IPR) have been identified. The solution for many of these is outside the remit of the technology platform. In Europe the rules on patents do not allow the issue of a patent if details of the discovery have been published before the date of the patent application. This is different from the US where patents can be issued up to 1 year after publication. The financial benefits of patents to the research worker or to the institute concerned are important considerations. It is emphasised that in many institutes research is of an applied nature and could not be patented. The funding for patenting is often inadequate and the true costs are often significantly underestimated which in turn acts as a disincentive to the universities.

The animal health industry is well aware of the legislation relating to IPR but academics often carry out

research with little understanding of the IPR issues involved or the potential use of their discoveries. It is important to encourage and educate the research scientists to understand the importance of IPR and to assess the potential future use of their discoveries.

The situation varies across research establishments. Some research institutes are geared up to patent ideas but in many cases the universities are not. The problem is that universities in general do not patent their discoveries nor do they develop their ideas to the proof of concept stage. From an industry perspective, new product development involves a great deal of investment and is not practical in many circumstances if IPR have not been established which means that potentially valuable innovations are sometimes lost.

It is clear that this is an important area where improvements are needed in order to enable the development of innovative tools to control disease. IPR should not be seen as a hurdle but rather as an essential prerequisite to the development and use of innovative ideas.

The main recommendations are:

5.3.1 Educate scientists and researchers on the importance of patents and developing their ideas to the proof-of-concept stage.

5.3.2 Include funding to permit the filing of patents as part of the overall research funding for a project. In the US funding is provided to patent nearly all ideas.

5.3.3 Provide advice or funding to enable advice to be obtained from patent attorneys, marketing experts and technical experts in order to correctly file a patent application.

5.3.4 Advise on the use of licensing and sub-licensing once patents are obtained.

In all these recommendations the key component is funding. In research contracts whether for the EU, national governments, or other organisations it must be recognised that additional funding should be incorporated into the contract to allow the development of ideas and to assess and prepare comprehensive patent applications backed by the appropriate expertise and advice.

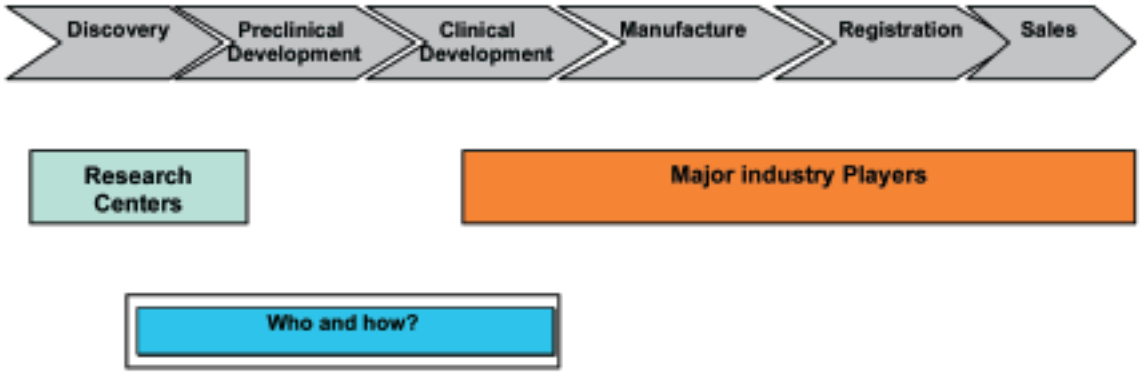
5.4 Overcoming Barriers to Technology transfer

Successful technology transfer relates both to technologies and to potential products. An innovation which will result in more efficient manufacture and production is as important as a new discovery leading to a vaccine, diagnostic test or pharmaceutical product. The fundamental problem is how to identify the innovations with potential for success and how to make progress along the development pathway.

The main hurdles to the transfer of technology fall into three categories. These are finance, understanding of the process by the research scientists and a system that identifies innovation and is able to develop the idea to a stage where it can be manufactured and authorised.

There is an urgent need for the research scientists to understand these processes as many of the scientists do not consider the future development of their discoveries. The need for collaborative work between all concerned must be emphasised. A mechanism is needed which delivers flexibility by allowing scientist to work collaboratively employing other specialised experts as necessary. It is often important to patent new discoveries so that companies are then prepared to take the risks involved in development.

The process and consequent problems can be summarised as follows:



A gap exists between the scientist and the development process. Europe has many of the best scientists but this is not reflected in the number of successful patent applications. Part of the problem is that scientists do not develop their ideas to the proof of concept stage (POC) with the result that the industry is then often unable to develop ideas further, especially as they may not be a sufficiently attractive financial proposition. A minimum requirement is to demonstrate that the invention/product/process does what is claimed and that this is reproducible. This should be sufficient to engage commercial interest for further exploration. Ideally issues of stability, purity, scalability, safety and efficacy should be investigated before the industry becomes involved. However, this is often not within the areas of expertise of the research groups and can be expensive in terms of time and other resources, especially if not covered by research grants. These additional requirements can often be explored as a collaborative arrangement with an industrial partner when the risks can be shared. Research institutes are often not interested in this part of the process for a number of reasons, not least the cost of the process.

Before the gap identified between research and development can be filled there needs to be either a partner with the specific objectives of identifying innovation for further development or one of the larger animal health companies with the resources to take the innovation forward through the development stages. All of this presupposes that there will be a financial potential and return from the discovery. In many areas of animal health this is not the case and alternative funding for the nearer market aspects of the development are needed.

The identification of innovative ideas is crucial to technology transfer as is the exploitation of ideas through the development of new products to a stage where they are delivered to the end users. This is becoming increasingly important as the research funders expect to see concrete developments and products delivered to the market. If the issue of POC is overcome, the successful transfer of technology can be achieved in a number of ways. It is important to create the right environment in terms of quality of research, protection of IP and financial incentives for an entrepreneurial culture to develop such that new research ideas are identified and taken forward through to final product registration. Possible models include:

- The research institute develops the product on its own. This is rarely feasible due to the costs and expertise needed. Some are able to reach the stage of partially acceptable proof of concept and are able to transfer the technology to a company
- A start-up company can be set up to develop the product and either sell the final product after obtaining market authorisations or sublicence or sell to a major company for the final production and marketing
- To develop a Europe-wide organisation with the capability of identifying innovative ideas, establishing criteria to identify ideas with potential for development and providing the link between the research organisations and the major animal health companies. If the innovative

ideas are research results which have been patented, the access to IP would be secured in order to ensure the transfer to a major company

Whilst the start-up company has a number of advantages, it is often linked to only a small number of innovations. The advantage of a Europe-wide organisation is that it can develop a database of research findings along with the criteria to decide which should be followed up with a view to development. Alternatively in some circumstances it may be better to strengthen the interface between the discoverers and the developers and provide additional external funding for the POC studies. The exception would be in areas of low market value where there is limited industry expertise e.g. developing world diseases, where an organisation such as GALV (Global Alliance for Livestock Vaccines) could play a vital role.

Whether the right approach is through the creation of an Europe-wide organisation or through fostering the appropriate entrepreneurial environment could be a topic for further research under the Platform.

The main recommendations are:

5.4.1 Ensure that contracts issued by funders include funding and clauses to ensure the application for patents and the funding to bring the project to the proof of concept stage.

5.4.2 Educate and inform research scientists on the value of developing their ideas to the proof of concept stage.

5.4.3 Develop and establish a Europe-wide system to identify innovation and enhance transfer to commercial companies for development. Also establish the criteria for the selection of innovative ideas for further development.

5.5 Networks and Centres of Excellence

The 6th EU Framework Programme seeks to reduce fragmentation, develop synergies, avoid duplication, and enhance integration and coordination of the programmes of research. With major animal diseases, it is important to strengthen competencies and networking aimed at increasing collaboration between research centres,

reference laboratories and other stakeholders. This is an essential component in strengthening the research area and in ensuring that Europe's position is not undermined.

However, none of the existing networks such as Med-Vet-Net and the integrated projects such as EDEN has the full participation or integration of the animal health or biotechnology industries to assist in coordination and collaboration. The situation with Avian Influenza demonstrates the need for wider dissemination of information as it transpired that a number of networks had already been established but were not common knowledge amongst the working group members. The problem with separation of laboratories from policy makers and industry also posed problems of communication and delivery.

Research should be concentrated in centres of excellence. Research institutions should avoid covering the complete range of subjects and instead should concentrate on specific areas of excellence although this could create the risk of islands of research and reduced knowledge about activities at other centres of excellence. Integration of researchers and good communication links are essential and provisions should be made to encourage this.

In Europe, epidemiological research is mainly organised by EU Member States. In view of the further enlargement of the EU an efficient infrastructure or the use of centralised institutions is needed for fundamental and applied research in epidemiology and the infectious diseases.

The main recommendations are:

5.5.1 Conduct a review of the existing networks of excellence and integrated projects to evaluate their effectiveness and contribution to the research programmes in relation to the development of new or improved vaccines, pharmaceuticals or diagnostic tests.

5.5.2 Develop a mechanism to involve all stakeholders and in particular the industry in the work of the networks of excellence and in the development of their research programmes.

5.6 Education and Training

In the EU the critical mass of expertise and the availability of qualified and skilled researchers is under threat causing a potential impact on the long-term viability of some programmes. For many of the diseases, expertise is limited to a single individual. In some Member States, a worrying decline in the number of veterinary graduates entering research has been identified and this trend is likely to continue. It is important to maintain a nucleus of expertise necessary to respond rapidly to new or emerging diseases or to one of the priority diseases identified in this SRA. To overcome this problem an evaluation is needed of the current position regarding the expertise available in the EU as is an assessment of the career prospects for young scientists in the EU.

Research requires a long-term investment and the benefits may not be appreciated within a short period of time. Without solid research the acquisition of knowledge will decrease. It is essential to provide a sustainable atmosphere for creative fundamental research in particular for the young scientists of today who will become the chief investigators of tomorrow

The main recommendations are:

5.6.1 Evaluate options to foster mobility between academia and industry and vice versa.

5.6.2 Map existing activities and skills within Education and Training to include the identification of European Centres of Excellence and develop programmes and implementation plans for the critical areas especially the skills gaps relevant to the priority disease areas.

5.7 Infrastructure

There is concern over the capacity for research in Europe and indeed worldwide. Currently, there are two main limiting factors in the provision of facilities to perform animal challenge trials for the priority diseases. These are:

i) a lack of suitable premises available to the industry and other users, with appropriate containment facilities, both for early stage research and later stage clinical trials using animals. The facilities required to allow research to be conducted on exotic diseases of livestock in the target species is expensive. These costs are linked to the capital expense of building and equipping the facilities and to the annual running costs for using the facilities. This in turn can delay the development period for a vaccine with a direct impact on the competitiveness of the companies as the product is launched much later than necessary.

ii) A definition of the conditions of use of these specialised premises is needed. The regulatory authorities have not clearly defined which micro-organisms should be handled under which type of containment. There is an urgent need to define clearly and precisely which micro-organisms should have restricted use in contained facilities.

Within Europe an adequate infrastructure incorporating scientific research and diagnostic laboratories and animal facilities is essential. New developments are taking place in a number of Member States to construct containment facilities which are being funded by the Member States. There appears to be little or no coordination on the building of the premises nor does there appear to be any indication of a coordinated or collaborative approach. This area would benefit from greater cooperation in research effort and in the provision and maintenance of the facilities allowing the creation of the required critical mass of infrastructure and to protect the long-term interests of the EU.

The main recommendations are:

5.7.1 Conduct an inventory into the availability of Containment Category 3 and 4 animal accommodation throughout the EU for animal challenge experiments and disease investigation.

5.7.2 Develop arrangements to ensure that the most effective use is made of existing high containment laboratory facilities for exotic disease research, including ways in which industry can gain access to these facilities at a cost they can afford.

5.7.3 Develop a clear set of harmonised guidelines for the handling of various pathogens in containment facilities.

6. Regulatory Issues

6.1 Introduction

Much has been achieved in Europe over the past 25 years to establish the standards for the supply and use of safe and effective veterinary medicines. The development of the regulatory controls now applied has resulted in the improvement of medicinal products and food safety to the extent it provides good assurance to the public. The legislation has also helped to develop the harmonisation of the regulatory approach throughout the 25 Member States. Some progress has also been made on a wider international scale through the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). Research and good scientific data underpins the regulatory processes across the world and provides the technical solutions to respond to the regulatory hurdles. It is important to build a robust regulatory process to provide re-assurance to the European consumer and to ensure that effective risk-based regulations exist in Europe.

There have been a number of important issues which have arisen from this approach, creating perceived barriers to the development of new tools for the control of both major and minor diseases on a global basis. However it is recognised that minor diseases and minor species may have regional impacts that go beyond the agricultural impact in a regional area.

6.2 Specific issues identified

What follows are some examples of scientific issues that arose during the development of the SRA but others may arise as work progresses and may also need consideration.

Variations in strains and antigenic drift

The variety of strains in some pathogens and the allied issue of antigenic drift in others is an important factor in the development of effective immunological tools to prevent disease. The regulatory requirements linked to this issue are often considered to be a constraint on the rapid development of new vaccines specifically tailored to be effective against outbreaks of disease (e.g. FMD virus and Equine Flu virus). In the case of equine influenza, a network of laboratories works effectively together to identify suitable strains of virus for inclusion in vaccines. Unfortunately the process is currently too slow to permit the industry to develop a suitable vaccine dossier to allow a timely change to a new vaccine formulation when the epidemiological situation changes. The system works more efficiently in the case of human influenza partly because important quality aspects, such as testing for extraneous agents, is undertaken centrally before the tested strains are released to the industry. On the veterinary side, quality aspects are less advanced before the animal health industry obtains the new virus strains.

Overcoming the problems of testing seed strains is a major issue but not one which requires significant research as the methodology and quality standards for handling master seed stocks are defined in the European Pharmacopoeia. It is important that those in the laboratories and technical research areas understand the importance of testing for extraneous agents and in providing tested strains to the vaccine manufacturers at the earliest possible time. This is an expensive and time-consuming activity for which a funding mechanism will also need to be found.

The substitution or addition of one antigen to an authorisation currently requires a submission of an extensive dossier (line extension) even though the change is restricted to the seed strain with the manufacturing process of the new antigen remaining unchanged. This is not required in the case of human influenza vaccines and creates delay in the case of animal vaccines where there is the potential for considerable antigenic drift in the virus or due to the wide variety of strains that may be involved in an outbreak (e.g. Equine Influenza, FMD, Bluetongue, Avian influenza).

From a vaccine production perspective the ability to substitute one strain for another provided the seed strain is correctly evaluated would improve

the rate at which new vaccines could be authorised and reduce costs. Novel ways of addressing this problem for both conventional vaccines and those obtained by recombinant technology are needed such as developing an approved antigen bank of seed strains within the terms of the authorisation which is established during "peace time", any one of which could be used without the need for obtaining new authorisations.

The development of vaccine antigen master files (VAMFs) is an alternative or complementary approach to resolving some of the issues outlined above, but different views are held by member states on the benefits of VAMFs. It is important to differentiate technical concerns from administrative, political and general concerns. This is a potential barrier and a survey to identify the detail of the technical concerns could result in the requirement for research to resolve the technical problems.

Regulation of human and veterinary medicines

The same regulatory approach is applied to human and veterinary medicines. There is a need to differentiate the human and veterinary regulatory systems where there is justification for doing so and where the human medicine approach is not appropriate to veterinary disease control. A research programme to define the drivers for the regulation of veterinary medicine, a comparison with those for human medicines and an understanding of the mechanisms involved could lead to the development of a research agenda that would better support a more specific targeted regulatory framework which could have many advantages for the future development of veterinary medicines in Europe and the world. This research programme could identify if there are particular research or regulatory requirements that could be introduced in the context of veterinary medicines to promote product availability, particularly for minor use and minor species.

Efficacy Data

The quantity of data required for the efficacy evaluation by the regulatory authorities in Europe prior to authorisation of a product was considered to be an issue for further investigation. The question was raised whether efficacy assessments could be increasingly linked to pharmacovigilance thereby reducing the initial data required for authorisation. It was not always clear whether the quantity of pre-authorisation efficacy data based on limited field trials provided added value for the regulator in every case. It should therefore be considered if the current requirements for expensive clinical trials prior to marketing are of value. In addition the move towards a more effective risk: benefit evaluation suggests that sufficient efficacy data to ensure a suitable risk-benefit justification could be a minimum requirement. Field studies could then be carried out following the launch of a new product providing far more useful information in the ongoing risk evaluation of medicines. This could significantly reduce the cost of developing effective veterinary medicines without increasing the risk to the consumer, patient and environment and could be of use in the authorisation of medicines for minor use and minor species.

The example of the development and authorisation of the West Nile Fever vaccine in the USA demonstrated that the industry can, in the right circumstances, react very quickly. A benchmark review of the situation in the USA compared to Europe would be of use to identify the similarities and differences in the regulatory procedures linked especially to establishment of GMP principles and the requirements for efficacy data in order to authorise a product. This may also provide benefits for harmonisation between the two regions.

Animal Testing

Within Europe a major objective in animal welfare is to reduce the use of animals in testing programmes for pharmaceutical and immunological veterinary medicines. Animal experiments, and especially those causing discomfort, should be avoided wherever possible and considerable importance is attached to this objective. There is already quite an active body of work going on in Europe in this area with groups such as ECOPA (European Consensus Platform for Alternatives), ECVAM (European Centre for Validation of Alternative Methods) as well as the EU-based industrial forum, IVTIP (In Vitro Testing Industrial Platform) who collaborate with these other groups as

well as the EU Commission and the EU Parliament. It is opportune that this area of research is also of significance in this SRA.

A programme should be developed to actively produce a reduction in animal testing requirements through, for example, the replacement of animal challenge testing with in-vitro assays. The aim should be to produce new guidelines reducing the requirements for animal testing for safety and efficacy by identifying alternative technologies or new methods to provide assurances on safety, quality, potency and efficacy of veterinary medicines. Extensive research is needed in this area. As in-vitro testing would be more acceptable to the public, this would create an environment in Europe that is more receptive to research into animal and human medicines and restore some of Europe's competitiveness as a centre for research into tools and solutions for dealing with animal disease.

Development of in-vitro potency tests as markers for efficacy is one option to be considered. However regulatory authorities will need robust scientific reassurance that products will continue to comply with accepted standards for safety and efficacy. In parallel, the regulatory authorities should actively pursue and encourage replacement of animal tests with validated markers and in-vitro tests and should work actively with industry to ensure their adoption.

Industry here has an obligation to promote data sharing. Pooling of data currently considered commercially confidential would lead to a substantial reduction in the need for animal testing. A survey should be conducted to identify the areas where data sharing could reduce animal use and the impediments, particularly in terms of commercial confidentiality, that currently limit the extent of data sharing between companies.

Technical Guidelines and Monographs

The Committee for Medicinal Products for Veterinary Use (CVMP) produces a range of formal technical guidelines which provide guidance to the industry on the procedures and scientific requirements for justifying the safety, quality and efficacy of veterinary medicines. For practical purposes, the guidance often has almost the same status as legislation. Pharmacopoeial monographs are also produced which act as technical guidance and standards for the production of active ingredients and final products. It would be valuable to undertake a review of the guidelines not only of their content and their relevance but also of the impact and benefit which the guidelines deliver. In addition all guidelines and monographs should be actively reviewed to ensure they are consistent with leading edge technology if they are to remain useful and not become a barrier to progress. Much depends on the interpretation of the guidelines by those using them. No research has been undertaken into the value of guidelines or ways in which they could be improved if they are not meeting the needs of the regulators or the industry.

Other issues

Other areas of interest where regulation is expected to have an impact:

- The need to evaluate the benefits of the Minor Use Minor Species (MUMS) requirements that are currently under development in the European regulatory network
- Requirements for use of vaccines against emergency animal diseases
- Definition of minimum safety and efficacy requirements for emergency vaccines
- Development of predictable and consistent Risk Analysis and Risk Management Models
- Inconsistencies in animal health policies at EU level (i.e. authorisation requirements, vaccination policies, trade policies, sanitary policies in case of emergency situation)
- Differences between EU and US approaches to veterinary medicine regulation

The areas which would act as enablers for better regulation are defined as:

- Better implementation of harmonised regulatory requirements – e.g. Centralised procedure and the new decentralised procedure
- Defined fast-track approaches for EU-wide Marketing Authorisations for products for epidemic disease
- Defined and predictable Minor Use Minor Species (MUMS) procedures

- Rapid regulatory procedures to allow for changing the composition of vaccines in the face of actual epidemic strains (AI, FMD)
- Important for Regulatory authorities to be an integral part of the process from innovation to delivery to ensure new technologies requiring new thinking or advice can be anticipated
- Ensure academia and small/medium sized enterprises are aware of regulatory requirements to better design their research programmes to inform the final regulatory assessment

6.3. Research Agenda

At present much of the basic information on the pathogenesis of a disease and the pathogen itself is not fully understood. Fundamental research is still needed in many areas. Historically when approaching the authorisation of a product the regulators have been given little option other than to evaluate risk in isolation with little or no balance of the risks against an assessment of the benefits. The new legislation encourages a greater consideration of the risk-benefit ratio. However, research is needed to justify the development of the risk-benefit concept to ensure it can be more effectively incorporated into the regulatory process with confidence. There should be closer links and networks between the research workers and industry with the development of centres of excellence to facilitate this approach.

The recently revised EU pharmaceutical legislation includes a requirement for environmental risk assessment. Research should be conducted into how such testing might be harmonised in relation to the type of product examined thereby reducing cost and the requirement for animal testing.

Other more specific areas for consideration in the SRA include:

- Identify the technical issues related to the effective use of antigen vaccine banks
- Detailed understanding of antigenic variation and the impact on authorisations
- Diagnostic acceptance (proficiency testing and demonstration of relevance for control of diseases)
- What is reasonable to expect in the validation of potency tests ?
- Is there scope for research into reg-

ulatory monographs for environmental risk assessment for veterinary medicines ?

The main recommendations are:

6.3.1 Undertake an assessment and comparison of the different drivers for regulation of veterinary medicines as compared to human medicines in order to design specific research programmes to better support the specific requirements of the veterinary regulatory environment.

6.3.2 Conduct research into the value, use, impact and lessons learned from the practical experience of technical guidelines and monographs in order to ensure that guidelines and monographs remain appropriate to developing scientific knowledge.

6.3.3 Develop an effective risk-based methodology to define the risks and benefits in the use of veterinary medicines with the intent to use the model to make risk-benefit based decisions and determine the testing required for new products to underpin this approach.

6.3.4 Initiate coordinated action to identify the research needed to reduce animal testing by either using alternative methods or by reducing the testing required.

6.3.5 Evaluate the harmonisation and consistency of the regulatory approach between EU member states. Identify scientific issues acting as a barrier to implementation of such harmonisation and define research designed to resolve the issues.

6.3.6 Identify and evaluate the quality of data required by the regulatory process to approve a veterinary medicine. Define the most appropriate level to satisfy the needs of the system.

6.3.7 Evaluate the relevance and importance of the environmental assessment process and define the quality of data required for veterinary medicines of differing types. To what level of detail should environmental risk assessment be established to be effective and what further research would assist in improving the importance, relevance and value of environmental assessments for veterinary medicines?

6.4 Diagnostic Tests

In many countries there is an unregulated market in veterinary diagnostic tests. There is an active registration policy in some European countries with Germany, Spain and others requiring registration of all diagnostics for detecting animal diseases. Spain also requires the registration of the establishment where production takes place. France is currently working on a project to regulate veterinary diagnostics. Some diseases are regulated on a national or European level. For these diseases (for example Enzootic Leucosis Virus, Pseudo Rabies Virus) there is a batch-to-batch release control in some countries (France, Belgium). Diagnostic products for use in the human field are regulated through EU legislation.

One issue which will require clarification is whether any proposed registration or regulatory system should apply to in-house diagnostic testing by laboratories or only to the manufacture and supply of diagnostic test kits for animal disease by any public or private organisation.

The OIE has developed a diagnostic test registration procedure which sets standards but for which the OIE is not a regulator as registration is voluntary. The registration is based on a comprehensive validation using a template requiring a dossier of information from the company seeking registration. The OIE registration will be based on the concept of 'fit for purpose' relating to sensitivity and specificity of the test and whether it is to be used for screening or confirmation of disease. The OIE procedure is very recent but has received widespread acceptance and it is hoped that it could be used as a model for future regulation.

Veterinary diagnostic producers consider that the OIE registration is at this moment useful only as a "marketing tool". It can be exploited as a logo to

be added to the packaging declaring the 'fit for purpose' validation. The current fee for registration (9000 Euros plus a small percentage of the business generated by the product) could have an adverse effect on the availability of diagnostic tests for small markets or the market for MUMS (minor use or minor species) assays. Even for major diagnostic applications, the market size may be too small to bear the costs of a fully regulated registration system.

The OIE system is advanced and could provide the basis for an approval system although it is not currently based on the type of tightly defined regulatory procedures and requirements that are applied for the authorisation of veterinary medicines. As with the development of medicines it is important that those developing new diagnostic tests are aware of the need to collect appropriate data to validate the tests.

OIE validation is not currently recognised by any European country that has an active registration policy for veterinary diagnostics and in the longer term it is not clear whether the EU will accept the OIE process or demand additional testing to validate the tests for the European context. The US authorities recheck tests on the grounds that checking under the epidemiological and field conditions related to their situation is essential. Diagnostic tests must be validated but whether this should be by the OIE alone or whether the EU should develop an EU-wide system similar to the US needs more consideration.

Regulation varies from country to country with some working on a national registration procedure. Harmonisation or mutual recognition of national registration would be welcome for at least the most important diseases to avoid the individual registration of the same product in different countries. The possibility of harmonising the different regulations with the goal of improving the quality of diagnostics is important but must be introduced in such a way as to avoid acting as a brake on the development of new products or having an adverse effect on the availability of diagnostics for MUMS.

The main recommendations are:

6.4.1 Support projects for the establishment of international sample panels or standard sera, that can be used in test validations. They should be available for all diagnostics producers.

6.4.2 Encourage and finance joint projects between institutes and the industry.

6.4.3 Establish links and promote the information flow between institutes and vaccine and diagnostics producers especially for the marker vaccine development area.

6.4.4 Support projects shared with "Central and Reference laboratories" for the validation of diagnostic products in different geographical locations to facilitate the "Fit for purpose" recognition.

6.4.5 Develop and introduce quality standards regarding diagnostic producers, concerning the implementation of an industrial standard that sets the conditions of the production of quality veterinary diagnostics.

6.5 Societal Acceptance of Technology

Current position

In the EU there is concern over the use of genetically modified products, eating food from animals treated with antibiotics and the development of resistance to antibiotics and anthelmintics used in animal health which may impact on human health or the availability of efficacious medicines.

Whilst many aspects of safety of veterinary medicines are a scientific issue, public perception is equally important in the policy making process especially if the issue has a high political impact. The discussions around vaccination against FMD, CSF and AI show that there are potentially non-scientific concerns over vaccination. Historical failures are also seen with the GMO debate in the production of food crops. Many agree on the value of new veterinary medicines but the main obstacle to their success may turn out to be acceptance by the public. Lack of societal acceptance can be a barrier to the development and use of new technologies to control di-

sease. It is essential to build confidence in the new technologies and to promote their acceptance by the general public.

It is important to investigate the background of these concerns by developing an understanding of public perception and societal views on a range of issues such as risk, benefits, genetically based products and ethics. There is a seemingly large information gap between public perception and the scientific situation in reality. It is important to be aware of how society will view advances in technology and the use of new technologies as not addressing these issues will lead to misunderstanding and mistrust. We must also develop the proof where possible to allay public concerns. The actual rather than the perceived risk for new technologies or existing technologies to control animal diseases must be discussed with the wider public to ensure social acceptance

Societal studies are needed to assess the impact of new technologies and to evaluate the most effective ways to present new technology to the public. An assessment of the risks and benefits of new products along with an evaluation of the risk communication and science strategies available to present the new technologies to the public would be valuable. A number of studies into public engagement and understanding have been carried out but a specific analysis in relation to technology and veterinary medicines would provide the necessary background to develop appropriate communication strategies.

The main recommendations are:

6.5.1 Establish a research programme into consumer perception and expectations of new technologies and the consequent acceptance of new veterinary medicines.

6.5.2 Review existing research findings on social perceptions of new technologies and new veterinary medicines.

6.5.3 Study factors which influence consumer behaviour in relation to food safety.

6.5.4 Develop a risk communication strategy to educate the public on GM vaccines and pharmaceuticals and identify the most effective ways to communicate the information.

6.6 Community Animal Health Policy (CAHP)

In December 2004 the European Health and Consumer Protection Commissioner announced a new EU Animal Health Strategy to improve the prevention and control of animal disease in the EU. The existing Community Animal Health Policy (CAHP) has enabled the EU to implement the internal market in which animal health inspections are carried out at point of origin and not at internal borders. It has also contributed to the eradication of many serious diseases which represent obstacles to free movement of animals and their products, and as a consequence allows the single market to function normally. Full details are to be found at http://europa.eu.int/comm/food/animal/index_en.htm .

Nevertheless the crises experienced by the EU in the livestock sector, caused by the occurrence of widespread diseases or by events calling into question the safety of the food chain, highlight the need to consider the adequacy of a number of aspects of the CAHP. An external evaluation of the CAHP was proposed in 2004 and began in July 2005. The results of the evaluation will be a key element in developing the CAHP for the future. The evaluation will analyse the effectiveness of the existing CAHP and identify whether any changes are necessary. The Commission intends to develop a new and improved animal health strategy for the EU, to go beyond what has already been achieved with the existing animal health policy.

The Revised Inception Report prepared by the Food Chain Evaluation Consortium in December 2005 outlines the work carried out by the evaluation team since the launch of the project. Their report emphasises that due to its evolution the current CAHP appears to be a series of linked and interrelated policy actions rather than a single policy framework. The current CAHP framework covers a number of policy areas one of which is research on animal health issues in the context of Community multi-

annual Framework Programmes (FPs).

The evaluation team are considering research and have included as one of their key evaluation question the following: "To what extent has Community funding for research, scientific advice and laboratory networks on animal health contributed to achieving the CAHP objectives?" Through the interviews and survey of relevant stakeholders, the evaluation will address a range of issues.

At both the launch of the strategy by the Commissioner in 2004 and again in the interim report of the evaluation team the existence and role of the ETPGAH is acknowledged. The aim of the ETPGAH is consistent with the existing and developing CAHP, especially as effective tools for controlling animal diseases of major importance to Europe and the rest of the world will be required if the CAHP is to be successful.

The main recommendations are:

6.6.1 Maintain contact with the CAHP Evaluation Team in order to contribute to their review of the research requirements for the CAHP.

6.6.2 Ensure that the work of the Platform contributes and supports the CAHP through the Strategic Research Agenda.

7 Global Perspectives.

7.1 Introduction

There is a global public good from helping to address major animal diseases worldwide. Given the importance of livestock to developing countries, control¬ling and eradicating where practical animal diseases will have direct and major impacts on food security and poverty alleviation. Furthermore, the effective control of major animal diseases will have a positive impact in many areas of concern to society. All the predictive trends indicate that the growth of animal production systems will be located in the developing world. Due to intensification trends in animal production systems in the developing countries there will be more animal health problems and diseases of intensification that will be different from those found in Europe.

The ETPGAH will concentrate on animal diseases of priority for Europe, but must also take into account the perspectives of the globalised setting in which these diseases move. There can be no question that combating diseases at their source is the most efficient strategy. The global nature of these problems and the scale and complexity of new product development means that solutions will not be very effectively produced or very robust if developed exclusively for and/or in Europe. The scale and complexity of vaccine and diagnostics development is such that alliances with non-European countries and international organisations such as the OIE and FAO will be essential.

7.2 International partnership with developing countries

Research carried out in the countries of origin of these diseases will provide valuable lessons on the epidemiology and control measures for the problem. It also allows for the trialling of control approaches including vaccines and diagnostics. Many epizootic pathogens cannot legally be introduced into Europe even for research purposes. More importantly, research such as field trials with vaccines and /or diagnostic tests can be conducted in the developing world, when, for both technical and practical reasons, it cannot be carried out in Europe. Ethical issues must be taken into account in these circumstances when research is proposed in developing countries which would not be permitted in Europe.

A partnership is essential and will assist in improving the technology and scientific capabilities of the developing countries for controlling animal diseases. The ETPGAH will help to develop appropriate technologies and tools for application at the source of many disease problems where the practices, incentives and infrastructure may be less than optimal.

Such a partnership will provide unique opportunities to the benefit of all partners.

- There is an appreciable amount of local expertise on animal diseases in the developing countries. For many diseases this is needed to complement the work in Europe
- Research infrastructures exist in the developing countries including experimental facilities in the national and institutional laboratories. Industry support for the use of such facilities should be encouraged. There is a need to map the infrastructure, facilities and activities to better understand the resources available to the partnership. Linkage to similar information in the EU would allow the development of synergy
- Diseases which do not exist in Europe provide unique appropriate models for:
  - ✳ studying disease ecology and epidemiology
  - ✳ studying host, vector and pathogen biodiversity
  - ✳ understanding novel or emerging diseases (tropical diseases)

The focus of the SRA is not aimed exclusively at the European level, but considers the global dimension of the technologies concerned. Improved links to R&D worldwide are a priority. Participation by developing countries, for example through reference laboratories of the OIE and FAO, will be

highly beneficial especially in the field trials of some diagnostics and vaccines for exotic diseases such as FMD which is absent from the EU but endemic in other countries.

Full engagement of developing country partners will be critical to conduct research in an effective manner and to having researchers within these countries that understand the issues and support the implementation of subsequent control programmes. Thus active engagement of the developing countries and modern research partnerships are essential for the Platform to be effective. This implies the need for strategic joint programmes involving research and capacity building. A postgraduate programme for developing country nationals and EU nationals might be a cornerstone of the initiative, creating a powerful international network to handle global problems.

An aspect of technology transfer relates to the products which already exist in Europe but which are not used by developing countries either due to lack of knowledge or lack of funds to purchase and apply the product. This links to the global perspective of the platform especially in terms of EU cooperation and EU aid to developing countries. Capacity building in the developing world is also a major issue. European research funding into disease control measures would help capacity building in the developing countries and would improve access by the EU research workers to the diseases which may not be present in Europe at the present time. Financing of the joint projects by the Europe (Commission, National Governments, and Industry) would be an important way of capacity building in the developing countries. The role of the Global Alliance for Livestock Vaccines (GALV) is to obtain funds in order to facilitate the transfer of available products from the shelf to the market by funding products which are commercially non-viable at present.

Regarding the international collaborations that the EU Animal Health industry may have with institutions in the developing world, the most obvious category is technology transfer. It is feasible that the private sector in some developing countries could manufacture products under licence. A more important aspect in vaccine development will be in joint ventures with both the public and private sectors in developing countries. Developing country partners can bring local knowledge of the disease situation, the business context and the regulatory environment. The key inputs of the European partners would be in the research and development process. Partnership agreements and the resolution of intellectual property rights will be important factors for success.

7.3 International partnership with other countries

Europe has difficulty in assembling enough critical mass to apply comprehensive biology in the veterinary field in a similar way to how it is applied in the medical field, in particular the acquisition and use of very expensive cutting edge technology. The best way to address this might be ensure a truly global approach as advocated in this section. Similarly, it is certainly true that there is limited global capacity in Category 4 animal accommodation and it makes sense to try to use this strategically on a global basis rather that each region pursue its own research programme without consi-

deration of avoiding duplication or attempting to derive added value by working together. Close working arrangements with many other countries worldwide will also to be to the benefit of all.

Analysis of research activities worldwide, the cooperation with other research institutes and funders will all contribute to the development of new and improved tools for the control of animal diseases.

7.4 Research Agenda: Global Perspective

In the context of the priority diseases identified in this SRA and based on the gap analysis and the research needs for each of the priority diseases, input into the developing countries should be included in the proposals below. In general projects should be promoted in partnership with the developing countries.

The main recommendations are:

7.4.1 Introduce joint research programmes with institutes in non-EU countries, for important diseases that do not occur in the EU, in order to conduct risk analysis, undertake epidemiological research, investigate outbreak scenarios and evaluate intervention and control strategies.

7.4.2 Validate tools developed using modern biotechnology to control animal diseases representing a sanitary risk for Europe and other countries in cooperation with developing countries.

7.4.3 Provide sustainable support for research through international cooperation in order to improve knowledge and information for animal diseases and zoonoses.

7.4.4 Promote partnerships and provide finance for joint research and development projects with developing countries in order to assist with capacity building by improving training, infrastructure, technical and scientific capabilities for control of diseases.

7.4.5 Develop and fund collaborating centres linking EU and developing country institutes.

8 Implementing the Strategic Research Agenda

8.1 Current position

The SRA has strong support from all the stakeholders after an extensive consultation and discussion at a stakeholder forum. Now that the SRA has been agreed by the stakeholders, it needs to be supplemented by an action plan. The overall aim of the SRA is to provide a road map of the research requirements and the actions necessary to achieve the aim of the ETPGAH. It is important to recognise that some of the proposals in the SRA focus on specific research whilst there are other components which focus on specific actions to facilitate the translation of that research into usable products for the control of animal diseases.

The SRA proposes a range of work to meet the aims of the ETPGAH but in the available time the level of detail varies depending on discussions in the working group meetings. The level of detail on the research recommendations needs to be expanded in consultation with all the stakeholders.

The action plan is structured around the 6 main themes of the SRA within each of which there are a series of recommendations. For each of the recommendations a series of deliverables will need to be identified along with agreement amongst the stakeholders and authorities at all levels over where the responsibility and funding for implementation should lie. Collaboration between all the partners of the ETPGAH will be critical for the successful development and implementation of the plan.

The successful implementation of this SRA and establishment of the required level of collaboration between the different partners requires commitment, resources and efficient management of the SRA. This chapter presents the initial thoughts which will be followed up by further in-depth discussions between stakeholders. The development of a more detailed action plan over the next few months following additional analysis and consultation is essential.

Each of the themes and associated recommendations needs further analysis to assess the costs of the programmes and to determine the timescale for implementation. It will be feasible to break the work into three priority categories in relation to timescale but this can only be achieved once the gap analyses described in chapter 3 are completed for each of the priority diseases. However, a brief assessment is shown below.

- Priority 1: targets that are achievable in the short-mid term.
- Priority 2: targets that are potentially achievable in the mid-long term (brucellosis, tuberculosis, some antiparasitic vaccines, oral vaccination (for selected targets)
- Priority 3: "Ideal World Projects" (Long term) – parasite vaccines, mastitis vaccines, food safety vaccines.

8.2 Funding

Within Europe a substantial programme of research is funded by each Member State, private bodies, charities etc. A review is required to assess what the current research funding covers and to evaluate what the future research should be. A complete inventory of the bodies funding research is required. It would be appropriate for any gaps which appear between the remits of the various funders to be catalogued and evaluated.

In the context of the ETPGAH, it is foreseen that research performed by public organisations would be funded by the EU and National Organisations, while industry will contribute in kind. The importance of the Platform is that it brings together stakeholders involved with research in animal health but it is not a programme for research in itself. An overview of the potential funding sources is shown in table 5, below.

As yet the recommendations have not been costed and this remains an action in the development of the action plan. Furthermore the funding organisations in Europe or at national level have not been consulted regarding the future support for the programme.

Wider consultation is necessary

amongst the stakeholders in particular the national organisations and authorities in the member states to determine their current levels of funding and their priorities. It is important to take stock of the present funding arrangements with a view to identifying future contributions from the funding organisations and authorities.

Table 5 - Proposed funders

Funder	Contribution	Mechanism
European Union	Funding of the secretariat Funding of research	Specific support Action Coordination Collaboration
Member States	Funding of research Funding of infrastructure	Variable depending on the MS
IFAH-Europe	Funding of the secretariat	Funding via companies
Animal Health Industry	Research Data Infrastructure Expertise	Funding via companies
SME	Research Data Expertise	Funding via companies
Academia	Research Data Infrastructure Expertise	Funding via the EU and/or Member
Private funding organisations Charities e.g. Welcome	Funding of research Funding of infrastructure	
Financial institutes World Bank European Investment Bank	Funding of research Funding of infrastructure	

Proposed funding principles (source Innovative Medicines Platform)

8.3 Ownership and Organisation

The ETPGAH includes representation from all relevant stakeholders involved in animal health. The Platform is driven by the industry and is formally structured with a Steering Council, an Executive Board, a Stakeholder Forum and a Secretariat. The governance of the Platform with the roles and responsibilities are detailed in Annex 6. The management of the Platform is such that the structures are in place to continue to develop the SRA and action plan. The Platform will monitor progress and review the situation at regular intervals. Full details will be available to all stakeholders through the Platform web site provided by the industry.

To work effectively this initiative needs the active support of all the stakeholders as well as engagement with international and national funders. Without this top level stewardship the SRA will not be dynamic and achieve its objectives.

8.4 Action Plan

Coordination, standardisation and effective leadership is essential for the success of the SRA and will be dependent on the adequate funding of a coherent and sustainable nature. The timescales must be carefully defined, risks identified and strategies for managing them determined. There is a need for further work on priorities and contingency planning for the success of the SRA.
The action plan will be developed to ensure the SRA delivers the vision. Road maps will be produced with milestones that will need careful monitoring. The road map derived from the SRA will be for all parties involved and for the private and public sectors to realise together. A secretariat will be needed to support of the Steering Council to monitor progress and take action to terminate programmes if it becomes apparent they will not deliver.

The following steps are proposed:

8.4.1 Action plan to be produced following consultations with stakeholders and member states authorities. These will complement the vision document and the SRA.

8.4.2 Identify funding sources for the implementation of the SRA. This will involve meetings with international funders and with the funding authorities in the EU and the member states.

8.4.3 The recommendations in the SRA will need to be discussed with all stakeholders to identify who will have responsibility and ownership of the different components of the SRA.

8.4.4 Once the gap analyses have commenced the results will need to be reviewed by the platform in order to identify and make recommendations to develop specific diseases, technology and science programmes to fill the gaps.

8.4.5 When the action plan is completed and agreed with stakeholders, the Platform will be responsible for monitoring progress and undertaking an annual review of activities.

Annex 1 Membership of the Working Groups

Working Group 1:

Basic Research and Mapping

Chair:
- Prof P-P. Pastoret, BBSRC

Vice-Chair:
- Prof J.M. Sanchez-Viscaíno, Facultad de veterinaria, Madrid

Members:
- Prof O. Alpar, London School of Pharmacy
- Mr J-Ch. Audonnet, Merial
- Prof S. Belak (or Dr. F. Widen), Uppsala Diag. Lab.
- Dr J. Bires, CVO Slovakia
- Dr I. Capua, IZS-Venezie, Italy
- Dr K. De Clercq, CODA-CERVA
- Dr F. Koenen, CODA-CERVA
- Dr B. Kadra (or Dr E. Balla) , CEVA
- Prof R. Kroker, BVL
- Dr D. Lütticken (or Dr. Danny Goovaerts), Intervet
- Dr D. Martinez, CIRAD
- Prof Q. McKellar, Royal Veterinary College
- Prof Dr Th.C. Mettenleiter, Friedrich Loeffler Institut
- Prof I. Minkov (or Dr A Arnaudov), Univ of Plovdiv
- Prof V. Moennig, Tierärztliche Hochschule Hannover
- Prof I. Morrison, University of Edinburgh
- Dr F. Moutou, AFSSA
- Dr D. Paton (or Dr J. Bashiruddin), IAH-Pirbright UK
- Dr J. Plana Duran, Fort Dodge
- Prof P. Roy, London School of Hygiene and Tropical Medicine
- Dr Ch. Schelp, Bommeli
- Dr A. Schudel, OIE
- Prof J. Scudamore, Consultant for IFAH-EU
- Prof J. Van Oirschot, ESVV
- Dr M.J. Witty (or Dr Theo Kanellos), Pfizer AH

Observers:
- Mr H. Bourhy, Pasteur Institute Paris
- Mr N. Tordo, Pasteur Institute Paris
- Dr J. Vandeputte, Trivarop
- Prof J. Vercruysse, University of Ghent

EC Observers:
- Dr B. Arbelot
- Dr I. Minguez-Tudela

Working Group 2:

Technology Exchange and Transfer

Chair:
- Dr P. Van Aarle, Intervet

Vice-Chair:
- Prof I. Maudlin, GALV

Members:
- Dr Ch. Bruschke, OIE
- Dr M. Bublot, Merial
- Prof Dr M.J.T. Carrondo, University of Nova, Lisboa
- Dr T. Drew, VLA
- Dr E. Espuña-Maso, Hipra
- Dr Th. Gauthier, INRA
- Dr A. Läufer, Vakzine Projekt Management
- Dr M. Merza, SVANOVA
- Dr J. Salt, Pfizer AH
- Dr C. Schumacher, Merial
- Prof J. Scudamore, Consultant for IFAH-EU
- Dr J. Thevenon, CEVA
- Dr C. Vela, Ingenasa Madrid
- Dr Barrett (or Mr. K. Walshe), Tridelta
- Dr P. Willeberg, CVO Denmark

EC Observers:
- Ms B. Arbelot
- Dr I. Minguez-Tudela
- Dr Ph. Steinmetz

Working Group 3: Horizontal Issues

Chair:
- Dr S. Dean, HMA, UK

Vice-chair:
- Dr P. Jones, IFAH

Members:
- Dr R. Banks, Fort Dodge
- Dr Ch. Bruschke, OIE
- Dr P. Castle, European Pharmacopoeia
- Dr M. Chaton-Schaffner, CEVA
- Dr P. De Winter, COPA/COGECA
- Prof S. Edwards, VLA/OIE
- Prof T. Fernandes, Universidade Técnica de Lisboa
- Dr S. Graham (or Dr B. Perry), ILRI
- Dr M. Gravendijck, Intervet
- Dr J. Lechenet, Merial
- Dr D. McKay, Institute for Animal Health
- Prof A. Peters, Pfizer
- Dr A. Rodolakis (or Dr F. Lantier), INRA
- Prof J. Scudamore, Liverpool University
- Prof T. Soos, HMA, Hungary
- Dr J. Vaarten, FVE
- Dr M. Weijtens, Debut CVO

EC Observers:
- Dr B. Arbelot
- Dr A. Gautrais
- Dr I. Minguez-Tudela
- Dr Ph. Steinmetz
- Dr P. Vialatte

Annex 2 Bioterrorism and diseases

Source: Institute for International Cooperation in Animal Biologics
(An OIE Collaborating Centre)
http://www.cfsph.iastate.edu/Products/wallchartlivestock.htm

A range of animal pathogens can be used for bioterrorist purposes. These need to be prioritised to ensure that vaccines and diagnostic tests are available for the most important. The pathogens can be divided into those which have the potential to cause diseases as bioterrorist agents affecting humans and animals. The second category are those additional agents which have a high consequence for livestock but do not affect humans.

Category 1 Disease from potential bioterrorist agents

- Anthrax
- Botulism
- Plague
- Smallpox
- Tularemia
- Viral Haemorrhagic fevers
- Brucellosis
- Glanders
- Melioidosis
- Psittacosis
- Q Fever
- Typhus fever
- Viral encephalitis
- Toxins
- Nipah virus
- Hantavirus
- West Nile fever
- Hendra virus
- Rift Valley fever virus

Category 2 High consequence livestock pathogens

- African horse sickness virus
- African swine fever virus
- Akabane virus
- Avian Influenza (highly pathogenic)
- Bluetongue virus
- BovineSpongiform Encephalopathy agent
- Classical swine fever virus
- Coccidioidomycosis
- Contagious bovine pleuropneumonia
- Contagious caprine pleuropneumonia
- Foot and mouth disease virus
- Goat pox virus
- Sheep pox virus
- Heartwater
- Japanese encephalitis virus
- Lumpy skin disease virus
- Malignant catarrhal fever virus
- Menangle virus
- Newcastle disease virus
- Peste des petits ruminants virus
- Screwworm myiasis
- Swine vesicular disease virus
- Vesicular stomatitis virus

At some stage it would be appropriate to re-examine the diseases which could be used for terrorist purposes to ensure the main diseases or pathogens are included. These should then be placed in priority order with an indication of the risk to Europe, the availability of diagnostic tests and vaccines for control purposes. The availability of vaccines should be assessed and where necessary the timescale and cost of developing vaccines identified. This would then be linked to the priority diseases identified as the major economic problems for Europe in the SRA.

Animal Health Priority Score Card

Disease:

Diseases Incidence Likelihood/Probability
Clinical Disease Impact on Production
Disease Knowledge
Risk of Zoonosis
Risk of emergence
Monospecies affliction
Feral/Wildlife Animal Reservoir
Food Safety Impact
Impact on Domestic/EU Community Trade
Impact on International Trade
Economic Impact
Public Perception
Ecological Consequences
Likelihood of Collateral Damage (i.e. Trade, Tourism)
Status in other Countries (prevalence/spread)
Technology (Vaccine/Treatment) / Tool Availability
Diagnostic Tools Availability
Existing Proven Controls/Treatments
Host Range List (Combined GVP per industry)
Experience in Other Countries List
Poverty Alleviation/Benefit for developing world

Annex 3 Disease Prioritisation

European Animal Health Disease Prioritisation:

Proposed Score Card

Matrix compiled for discussion by Working Groups

1	2	3	4	5	Result
rare	unlikely	possible	likely	certain	
no	low-grade	sub-acute	acute	severe	
very high	high	moderate	low	limited	
no	-	-		yes	
no	-	-		yes	
mono	two minor	>than two	>two major	multi	
negligable	minor	moderate	significant	serious	
no	minor	moderate	significant	serious	
negligible	minor	moderate	significant	serious	
negligible	minor	moderate	significant	serious	
negligible	minor	moderate	significant	serious	
no	minor	moderate	significant	serious	
no	minor	moderate	significant	serious	
no	minor	moderate	significant	serious	
limited	stable	some spread	considerable	sudden/rapid	
very high reliability	high reliability	moderate reliability	low reliability	extremely limited	
very high reliability	high reliability	moderate reliability	low reliability	extremely limited	
very high reliability	high reliability	moderate reliability	low reliability	extremely limited	
minor industry	moderate industry	significant industry	major industry	key	
no success/experience	low	moderate	high	consistently high	
extremely limited	low value	moderate	high	very high	

Annex 4 Evaluation of research requirements for priority diseases

1. Methodology

The working group on fundamental research considered the areas of importance in relation to specified diseases. To define the priorities in terms of fundamental research in animal health, the main animal diseases, both for the member states and for the third countries with a special emphasis to developing countries were listed. The diseases were ranked in relation to their importance for coming years based on today's knowledge. The research needs for each of the ranked diseases were evaluated in relation to a set of criteria linked to gaps in current knowledge.

The following criteria were associated with research needs:

- Gaps in pathogenicity knowledge
- Gaps in immunology knowledge
- Gaps in epidemiology
- Gaps in control (Prevention, Diagnostic and Treatment)
- Gaps in infrastructures for conducting in vitro and in vivo experiments

2. Host - pathogen interaction

The development of novel control strategies is critically dependent on an understanding of host and pathogen biology as well as host-pathogen interactions at a molecular level. This includes the immune response of the host organism against the infectious agent. Different levels of host-pathogen interaction can be distinguished: host and pathogen populations including vectors and reservoirs, single animals, tissues, cells and sub cellular compartments.

3. Immunology

In defining the needs for immunological research on the major diseases the following questions were taken into consideration:

- Is there a requirement for vaccine development?
- If so, is the vaccine likely to be in the form of a subunit vaccine, which would require more detailed knowledge of the protective immune responses?
- Is there a need for improved diagnostics and will information on the immunology of the disease help in the development of diagnostic tests?
- Can knowledge of the immunology of the disease contribute to understanding the host/pathogen/vector interaction (particularly with respect to strategies adopted by pathogens for modulating host immune responses)?

4. Epidemiology

The following criteria were used to assess the research requirements:

- Knowledge of the whole epidemiological cycle of the disease, means of transmission for instance, direct or indirect though an arthropod vector.
- Existence of a wildlife reservoir or not.
- Knowledge of the eco-ethology of the wild species involved when present.
- Existence of surveillance and control tools (diagnostic methods, serology tests, vaccines).
- Needs in bio-informatics, bio-statistics and modelling.
- Overall control of human behaviour linked to the related risks (illegal movements of animals and of products) although this is more linked to social sciences and to the acceptability of control measures than to fundamental research.

5. Control

Under this heading the following were included: Prevention, Diagnostic and Treatment. The criteria used to determine the research requirements were:

- Knowledge of the disease
- Availability of a challenge model
- Economical impact of disease in affected areas
- Potential market for the animal health industry
- Need to eradicate or control the disease through DIVA and vaccine prevention
- Need to control the disease through drug treatment
- Need to improve or change vaccine manufacturing technology(ies)

6. Research requirements

Based on the evaluation in the above disciplines the research requirements for each of the diseases can be identified. Each of the priority diseases must be considered in detail using the above criteria and under the headings: host-pathogen interactions, immunology, epidemiology and control.

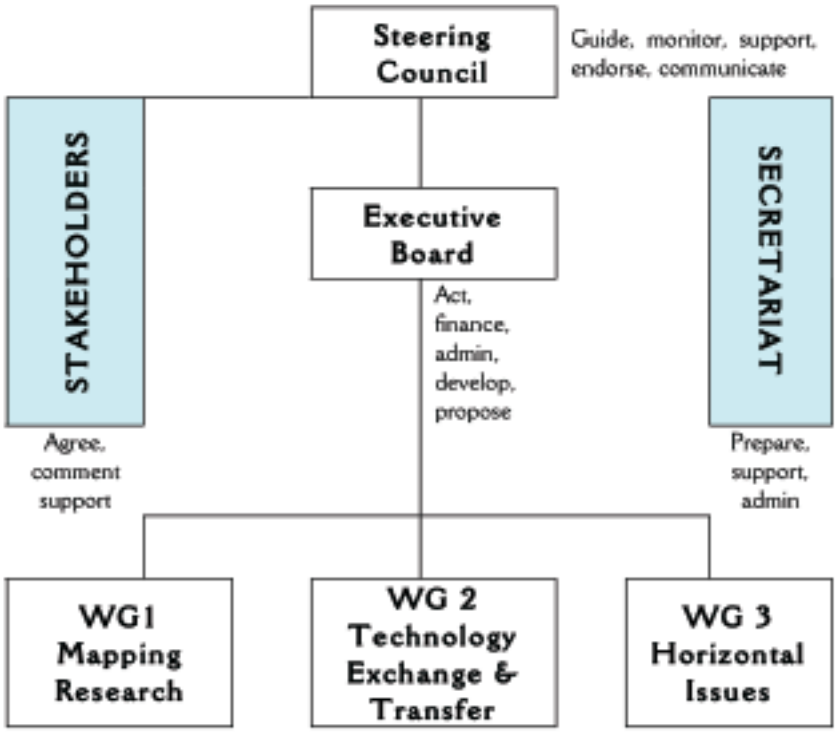
Annex 5 Proposals for the Criteria in a Gap Analysis

			Avian influenza	FMD
1a	Mapping	Map Research, Technologies, Patents etc	yes	yes
1b		Identify existing producers worldwide identify gaps	yes	yes
2a	Disease Prioritisation	Develop a risk-based disease prioritisation model for Europe	yes	yes
3a	Sourcing strategy development	Develop a risk-based sourcing strategy for required product from within and outside the EU	yes	yes
4a	Response capacity	Develop contingency plans	yes	yes
5a	New product needs		Cell culture vaccines with mass application and diagnostics	Vaccines against new strains
6a	Evaluation of existing products	Evaluation of products (EU and worldwide) to match minimum requirement for purity, safety, efficacy (individual/herd level)	Efficacy against different strains, from different origins, ability to prevent spread	DIVA compatibility of existing vaccines, prevention of shedding, cross protection between strains, early onset of immunity
6b		Test against new requirement in field (DIVA on herd level, new species, new application)	Avian species other than chicken	
7a	Knowledge of the Diseases	Surveillance and epidemiology	In wild fowl	Carrier animals
7b		Pathologies		
7c		Immunology on individual level ()		
7d		Identification of relevant antigens for diagnostics	Differential diagnostic tests	
8a	Research into control methods	Efficacy of sanitary control	yes	
8b		Efficacy of products in disease control at herd level (prevent disease, transmission, shedding, infection)	yes	
8c		Analysis of disease and control economics (pharmaco-economics)	yes	
8d		Capacity building of Veterinary services / improving access to control/tools/field competencies in endemic and non-endemic countries	yes	

9a	Technology Transfer (TTJ	Foster passage from research to application by protection of intellectual property (IP) through patenting		
9b		Move research to Proof of Concept as enabler to TT (purity, reproducibility, scalability, safety, efficacy)		
9c		Foster understanding of what is required to move to application (training/communication/collaboration)		
9d		Foster TT from industry in EU to industry in developing countries (i e for exotic diseases! (CNCO-DG Research + DG AID/Development)		
9e		Review mechanisms (incl Timing) for transformation of research findings into disease control policies and legislation		

Annex 6 Organisation of the European Technology Platform for Global Animal Health

Organisation of the platform.



The Steering Council (SC)

is at the core of the ETPGAH. It is a network connecting the Platform to the major stakeholders and the pool of ideas. The membership of the SC shall not exceed 30 members. The Commission attends as an observer. The Steering Council oversees the Technol¬ogy Platform and acts to move the ETPGAH forward. The SC is the main point of contact for all other stakeholders.

The Executive Board (EB)

comprises 7 members selected from industry, users, and public bodies. The chair is held by IFAH-Europe. There are observers from the Commission as necessary. The EB is responsible for ensuring that the process is directed in an efficient and transparent way.

A Stakeholder Forum

is essential as the active and commit-ted involvement of all the stakeholders is vital to the success and credibility of any Technology Platform. The forum is multi-disciplinary including industry,

public and private research institutions, universities, public authorities, livestock producers, civil society, consumers, funding bodies, third countries, international organisations (e.g. OIE, FAO), and International Research Institutes (e.g. ILRI).

The daily work of the ETPGAH shall be co-ordinated via a secretariat, which is lead by IFAH-Europe, located in Brussels. The secretariat works in close collaboration with the Executive Board.

The Member States

are involved through representation at the Steering Council by 4 Chief Veterinary Officers, responsible for the Animal Health Policy in each Member State. A representative of the Heads of Medicines Agencies of the EU, responsible for the licensing of veterinary medicinal products also represents the Member States by membership of the SC and the EB. The Member State representatives are responsible for the dissemination of information through their relevant channels across the Member States authorities. There is a pressing need for an improved mechanism to involve the National Authorities of the Member States who both fund and conduct research. The national consultations will be organised by members of the Executive Board, the Steering Council and other stakeholders in cooperation with national organisations, stakeholders and national authorities.

Annex 7 List of Abbreviations

CAHP	Community Animal Health Policy
CVMP	Committee for Medicinal Products for Veterinary Use
ECOPA	European Consensus Platform for Alternatives
ECVAM	European Centre for Validation of Alternative Methods
EDEN	Emerging Diseases in a Changing Environment
EMEA	European Medicines Agency
ETPGAH	European Technology Platform for Global Animal Health
EU	European Union
FAO	Food and Agriculture Organisation
FP	Framework Programme
GALV	Global Alliance for Livestock Vaccines
GLP	Good Laboratory Practice
GMO	Genetically Modified Organism
IFAH	International Federation for Animal Health
IPR	Intellectual Property Rights
IVTIP	In Vitro Testing Industrial Platform
Med-Vet-Net	Network for Prevention and Control of Zoonoses
MUMS	Minor Use Minor Species
OIE	World Organisation for Animal Health
PCR	Polymerase Chain Reaction
POC	Proof of Concept
SRA	Strategic Research Agenda
VAMF	Vaccine Antigen Master File
VICH	The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
WHO	World Health Organisation

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http://www.europa.eu.int/comm/research/biosociety/index_en.htm
http://www.cordis.lu/technology-platforms

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