European Technology Platform for Global Animal Health

Action Plan

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Executive Summary

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The Vision document for the European Technology Platform for Global Animal Health (ETPGAH) was published in August 2005. The Vision 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."

The Strategic Research Agenda (SRA) was published in May 2006 and sets out the agreed views of stakeholders on the short, medium and long-term research, development and delivery needs for global animal health over a period of 10 years. A strategic direction for research is defined in order to ensure the development and delivery of new tools for the control of the major infectious animal diseases and zoonoses. The SRA defines, in a very broad sense, the research necessary to deliver the Vision.

The Action Plan represents the actions needed to deliver the two main objectives of the SRA. Firstly to deliver new and improved tools for the control of major diseases and secondly to deliver the recommendations in the SRA which in turn will facilitate and accelerate the development and delivery of new tools. The Action Plan is the culmination of work by stakeholders to identify the practical steps, which are needed to ensure the two overarching objectives are met and that the Vision of the platform becomes reality. The Action Plan is also intended as a communication tool to explain in more detail the specific steps which are needed to deliver the Vision.

The plan is divided into three chapters and a number of annexes. The first chapter sets the scene by providing an overview of the structure, funding arrangements and management of the plan. It is clear that the ETPGAH will not fund research programmes directly but that it has an important role in guiding and facilitating funding from a wide range of sources both public and private. The plan is a flexible working document and will be subject to regular review and updating by the Steering Council of the ETPGAH to ensure that the SRA is on target and that the recommendations are being delivered. The success of the plan will also be evaluated against the primary aims linked to the Lisbon Agenda of improving the competitiveness of Europe.

A number of National Mirror groups have been established in Member States of the EU. They will provide an important link for two way communication between the ETPGAH and each country. This will be of particular importance for ensuring the coordinated funding of projects where there is Member State involvement.

Chapter 2 provides the detail of the actions required to implement the 61 recommendations contained in the six themes of the SRA. To achieve this, a number of sub themes have been developed into which one or more of the specific recommendations from the SRA have been allocated where appropriate. For consistency, each of the sub themes is presented in the same way using a standard layout. The key components include a description of the objectives followed by a list of the expected outcomes or deliverables. This is complemented by details of the tasks necessary to achieve the outcomes, their priority either high or medium, and the timescale for the work whether immediate, medium term or long term. Finally potential funding sources are identified in broad terms.

Although there are six themes in the SRA, it is recognised that the first priority is to identify and prioritise diseases of importance as described in Theme 1. The second stage in Theme 2 is to assess the gaps in the knowledge and understanding of these diseases to identify where research needs to be targeted. At the same time the gaps in the availability of products should be evaluated. With the implementation of the recommendations from these two themes it will be possible to select priority diseases and identify the research needed to fill the gaps in knowledge along with the actions needed to develop new and improved tools for the control of those diseases.

Fundamental science, which is of importance if the EU is to develop the innovations necessary for progress in meeting the Vision of the platform, is covered in Theme 3. The importance of strengthening fundamental science and maintaining capacity to deal with new and emerging problems is reflected in the three sub themes. A series of sub themes which range from quality assurance, intellectual property rights, overcoming barriers to technology transfer, networks of excellence, education and training and having the correct infrastructure are included in Theme 4.

In Theme 5 the importance of regulatory issues is emphasised by the five sub themes each of which identifies a series of deliverables which recognise that research and good scientific data underpins the regulatory processes. It is important to build a robust regulatory process, but also

to ensure this is proportionate and balanced against the needs of animal health. To achieve this, assessments of benefit against risk are required to provide re-assurance to the European consumer and to ensure that effective risk-based regulations exist in Europe. Societal issues are also very relevant and studies are needed to assess the background to concerns and to evaluate the impact of new technologies. It is also important to identify the most effective ways to present and communicate the advantages and benefits of new technology to the public to avoid misunderstanding and mistrust.

The final theme is Global Partnerships as the ETPGAH must take into account the globalised setting in which these diseases move. The focus of the SRA and hence the Action Plan is not exclusively European and considers the global dimension of the technologies concerned. The best way to address this will be to ensure a truly global approach and this is reflected in the deliverables and tasks contained in this theme.

Chapter 3 covers specific diseases dealing with prioritisation and gap analysis. A considerable amount of work was carried out by ETPGAH working groups during the development of the SRA and the Action Plan. Work has continued on the prioritisation process by categorising of diseases into three categories which are slightly different to those in the SRA. The criteria on which to base a prioritisation model have been refined but further work is needed to develop this process. Validated high quality information is required on each disease for use in the models.

In the case of gap analysis a basic analysis was undertaken to identify the gaps in the current knowledge of host-pathogen interaction, epidemiology, immunology, and control methods for the diseases. Additional information has been collected for a series of diseases using a standard format. The next stage is to validate the information collected to date. This information can be used in the prioritisation process and gap analysis. It is anticipated that a manual of research requirements by disease will be produced, endorsed by stakeholders and will act as a basis for advice on research funding to the EC, to the Member States and to private funders.

An example of gap analysis and prioritisation information is provided for bluetongue in both Chapter 3 and in the annexes. This demonstrates not only the progress made but also the problems which can be encountered. A similar process is required for each of the diseases to provide an overview of the research requirements to develop new controls. In order to provide continuous feedback concerning the priority diseases and the priority gaps, it is necessary to continuously review the status of each disease. This is achieved by continuously updating our information on diseases, analysing gaps and scoring diseases via the prioritisation model. This provides an ongoing and updated list of priority diseases and the research requirements for each of the diseases.

Chapter 1:

The Action Plan

The Action Plan

1. Introduction

1. The development of the European Technology Platform for Global Animal Health (ETPGAH) is in three interlinked stages. Stakeholders led by industry agreed on a common Vision which was published in August 2005. The ETPGAH has a challenging and long-term Vision for the control of global animal health which 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."

2. The Strategic Research Agenda (SRA) complements the Vision. It sets out the views of stakeholders on the necessary short, medium and long-term research, development and delivery needs for global animal health over a period of 10 years. The SRA, which establishes a framework for guiding research over this period, was published in May 2006.

3. The SRA and its recommendations provide the strategic direction for the development of new tools for the control of major diseases and zoonoses. The success of the SRA depends on the stakeholders recognising their role and exploring new and collaborative approaches to global animal health. The third stage of development is this action plan to implement the SRA with mobilisation of appropriate human and financial resources.

4. The SRA contains 61 specific recommendations which fall into six thematic categories that now comprise the objectives of this Action Plan, namely:

   - Theme 1: Prioritisation of disease
   - Theme 2: Gap analysis
   - Theme 3: Fundamental science
   - Theme 4: Enabling factors
   - Theme 5: Regulatory and societal issues
   - Theme 6: Global partnerships

5. The Action Plan is intended to explain the research and information-gathering exercises that need to be completed to deliver the recommendations in the SRA. It will also act as a communications tool explaining the specific steps that need to be taken to deliver on the Vision and the SRA.

2. The Action Alan

2.1. Structure of the plan

6. The first stage is to identify and prioritise the diseases of importance as recommended in Theme 1 of the SRA. The second stage contained in Theme 2 of the SRA is to assess the gaps in the knowledge and understanding of these diseases and to identify where research needs to be targeted. At the same time the gaps in the availability of products must be evaluated.

7. With the implementation of the recommendations from these two themes it will be possible to select priority diseases and identify the research needed to fill the gaps in knowledge. Once the diseases are successfully prioritised the actions necessary to develop and deliver new tools for control will be identified and implemented. It is important to progress the prioritisation and gap analysis as soon as possible as Themes 1 and 2 are the initial components without which the aims of the platform cannot be met.

8. In all cases the successful delivery of the research agenda has a number of components. These include,

   - identifying the desired outcomes and deliverables
   - the actions to achieve them
   - agreeing timing and setting milestones
   - assigning lead responsibility and supporting activities
   - an indication of the priority
   - funding sources
   - priority as high or medium and timescale as immediate, medium term or long term.

2.2 Funding

9. It is unlikely that the ETPGAH will fund programmes directly. It has an important role to facilitate funding

from a range of sources. It is also hoped that the output from the ETPGAH and the SRA will act as a template for other funding agencies to base their priorities for funding research.

10. The SRA serves to provide an input for:

    - Future EU Framework Programmes which will involve close cooperation with European Commission, Member States and European Parliament representatives
    - Future national research programmes where it will provide better opportunities to align and coordinate national programmes
    - Public/private research partnerships exploring ways to develop an integrated approach to developing new tools to control animal diseases
    - Industry which has an important role working in partnership to develop new products, which can be delivered in the field.

11. It is important to exploit the available EU instruments under FP7 and within other areas of the EU. The promotion of networking and coordination of national programmes through an ERA-Net will be of particular importance in relation to animal health and welfare.

2.3 Management

12. The plan is intended to be a flexible working document, subject to regular review and updating by the Steering Council of the ETPGAH to ensure that the SRA is on target and that the recommendations are being delivered. The Steering Council will evaluate the success of the platform in meeting its primary aims linked to the Lisbon agenda of improving the competitiveness of Europe. The success of the platform in delivering new and improved tools for the control of major diseases will also be measured.

13. The Steering Council will consider the option of establishing an Advisory Group on funding to include the main funding organisations. This group would provide advice on possible sources of funding and assist in obtaining resources to deliver the Action Plan.

14 It will be important to develop and maintain links with the other technology platforms in the field of Knowledge Based Bio-Economy to share experiences and to develop common initiatives where appropriate. Contact must also be maintained with global organisations. Strong interaction and cooperation is also needed between the human and animal health domains both in research and policy considering the zoonotic nature of a number of the disease threats. There will be benefits from these interactions in the realm of development of new vaccines, pharmaceuticals and diagnostic tests.

15. Small expert groups would be established to develop specific proposals for each disease once the priority diseases are listed and agreed. These ETPGAH groups will also include industry and other stakeholders and not be limited to experts from academia or government laboratories as often occurs at present.

16. Mirror groups from the Member States of the EU will provide an important link for two way communication between the ETPGAH and each country. This will be of particular importance for ensuring the coordinated funding of projects where there is Member State involvement.

Chapter 2

SRA Recommendations

SRA Recommendations

Theme 1

Prioritisation of Animal Diseases and Infections

1.1. Prioritisation of Diseases

SRA Recommendations 1, 2

Objective: A method of prioritising animal diseases and zoonoses would enable funders to focus research in a manner which would allow the objectives of the ETPGAH to be met. To achieve this, a methodology is required which could provide a consistent and acceptable means of prioritising animal diseases and infections of major importance for the EU and worldwide. Further development of the prototype is needed to take account of the overall level of risk 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. The process should be developed to a stage where the model is peer reviewed and used by decision makers as a decision support tool.

Deliverables: The main deliverables will be:

- A working model for prioritisation which is peer reviewed and accepted by funders
- Publication of the prioritisation model
- Production of a peer reviewed prioritised list of diseases of importance
- Publication of the list
- Ultimately an IT solution with an interactive model
- Regular use of the model to determine funding priorities.

Tasks:

- Finalise and peer review the criteria identified for assessment and the scores to be allocated to each of the criteria for use in the model
- Provide an evidence base for each disease by the collection of information in a standard format which can be converted into scores
- Score each disease against the criteria to identify the importance of the disease to Europe
- Further development of the paper based prioritisation model
- Develop an IT based decision support tool
- Produce an interactive tool to help with prioritisation of research funding.

Priority: High and immediate

Funding: National Funders, EU Framework 7 Cooperation

Activity: Specific project, applied research, decision support tool

1.2. Emerging threats to Europe

SRA Recommendations 3, 4, 6

Objective: A methodology using agreed criteria is needed to identify new and emerging diseases and predict when they may become a threat to Europe especially in the context of global warming and climate change. A risk analysis methodology is essential to assess the probability of diseases entering the EU under different sets of circumstances. Risk analysis for potential bioterrorist threats is important, as is the development of an understanding of the epidemiology of these potential threats. There is a need to anticipate and adopt a proactive approach in order to respond rapidly to changing events and to develop contingency plans for their prevention or control. Surveillance for these diseases/infections must be introduced as quickly as possible after their initial detection. Research capacity in Europe must be sustained above a critical level to ensure an ability to respond rapidly to deal with the unexpected diseases or infections.

Deliverables:

- Identification of the risk factors that might lead to the future emergence of new disease conditions or changing disease threats to human and animal health in Europe which predispose to emergence of new diseases
- A validated and functional predictive model to identify threats
- Risk analysis methodology to identify threats to Europe from any source whether natural or due to bio-terrorism
- Targeted surveillance systems to monitor occurrence and distribution of new diseases
- Established networks with common knowledge on the diseases, sharing and exchanging data, expertise, experiences and scientific information via regular meetings
- Effective dissemination and training of personnel.

Tasks:

- Identify the risk factors to provide an evidence base for setting policy for the detection and control of emerging infections
- Develop a predictive model linked to the prioritisation model
- Peer review the model
- Use the model to identify threats and conduct risk analysis of emerging diseases
- Establish networks aimed at creating focus on disease detection and control tools
- Involve third countries, in particular those where disease represents a major threat to the EU, as well as those more active in research, and also international organisations
- Create an international network of laboratories and scientists with expertise in these diseases and which are ready to act should the diseases occur, thus improving the EU's response to outbreaks of disease and contributing to the community animal health policy
- Hold workshops and develop other methods of communication.

Priority: High and immediate

Funding: EU Framework 7 Cooperation, National Funders, international organisations

Activity: Fundamental research, applied research, decision support tool, review

1.3. Wildlife Diseases

SRA Recommendation 7

Objective: Recent experience has shown that wildlife are 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. Research funding should be directed into wildlife diseases especially in relation to zoonoses, which may have an impact on human and animal health.

Deliverables: A better understanding of wildlife diseases to enable:

- Rapid identification of new or emerging pathogens with the ability to predict their occurrence
- Rapid response to new threats
- Understanding of the underlying mechanisms for emergence of wildlife pathogens and diseases.

Tasks:

- Use novel screening assays, such as micro arrays, to mass screen wildlife populations for the presence and distribution of infectious agents that cannot be isolated in culture and/or which are only distantly related to known infectious agents
- Use new technologies coupled with more classic techniques to discover new and emerging pathogens
- Develop generic approaches to wildlife surveillance by providing baseline data for disease control and intervention
- Develop insights into evolutionary trends using phylogenetic studies comparing old and new strains of already know species
- Anticipate and adopt a proactive approach in order to respond rapidly to new and emerging animal diseases, including zoonoses
- Develop appropriate epidemiological tools and the rapid establishment of surveillance for this category of disease or infection.

Priority: High and intermediate

Funding: EU Framework 7 Cooperation, National Funders, international organisations

Activity: Collaborative Research: applied research, surveillance, risk analysis

1.4. Supporting Activity

SRA Recommendations 5, 8

Objective: Prioritisation of diseases is an important component of the SRA. Without a specific priority setting process there will be a lack of clarity over priorities for research funding and the successful outcomes from the funding. Research funding should be targeted 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. Research programmes for the priority diseases should be initiated in cooperation with developing countries in order to develop sustainable strategies for control.

Deliverables:

- Better focused research into those areas where new tools and methods for control have a priority
- Improved public and private sector funding

Tasks:

- Provide advice and guidance to funders regarding the targeting of research
- Increase coordination between National programmes
- Develop global partnerships.

Priority: Medium and medium-term

Funding: All funders

Activity: Support and advice to funders.

Theme 2 Gap Analysis

2.1. Gap Analysis for Priority Diseases

SRA Recommendations 9, 10, 11

Objective: A comprehensive analytical methodology is required to identify gaps which currently exist in the knowledge and understanding of the priority diseases. This needs to be linked to the research and development requirements necessary to overcome the existing shortcomings in the availability of effective tools for the control of priority diseases. Preliminary analysis in the SRA attempted to identify the overall gaps. A more detailed assessment of host-pathogen interaction, epidemiology, immunology and control tools for each priority disease is required. Further work to develop and implement the methodology to identify gaps in key areas is an essential prerequisite to the effective targeting of research funding to ensure the availability of new and improved tools for the control of these diseases.

Deliverables:

- A comprehensive standardised analysis for each of the priority diseases
- A comprehensive database for each of the priority diseases
- A catalogue of the gaps in knowledge of the diseases and the available control tools
- Research requirements for the development of new or improved targeted tools for each of the priority diseases
- An acceptable refined methodology to determine the research priorities with more accuracy
- Answers to the following 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?

Tasks:

- Collect information for each of the priority diseases in a standard format
- The results of the gap analysis will need to be subjected to peer review in order to have agreement on the priorities for targeting research funding. Peer review the information gathered
- Identify the gaps in knowledge for each of the diseases
- Produce a catalogue of the priority diseases listing the gaps and identifying research required to develop new and improved methods of control
- Produce a disease summary identifying the main areas of need in relation to specific control measures such as surveillance, treatment, vaccines and diagnostic tests.

Priority: High and immediate

Funding: EU Framework 7 Cooperation, National Funders

Activity: Applied research, data collection, analysis

2.2. Gap Analysis of New Technologies

SRA Recommendation 12

Objective: There is a rapid advance in new technologies and techniques which could be used to develop more effective tools for the control of priority diseases. These newly developed technologies should be reviewed regularly to assess their potential and to ensure that they are being used to maximum benefit. By evaluating the relative value of the individual technologies and their potential capacity for the development of vaccines,

pharmaceuticals and diagnostics it will be possible to focus research in those areas which will provide the greatest benefits. There is also a need to evaluate the existing technologies versus new technologies, as a classical approach based on proven experience especially at the manufacturing level may be more appropriate. It is important to develop through public and private partnerships an overview of the technologies and their potential applications.

Deliverables:

- Rapid identification and assessment of new technology and techniques as they are identified or published
- Use of new technologies where appropriate to assist the development of diagnostics, pharmaceuticals and vaccines
- Proof of concept is demonstrated by researchers for new technologies
- New technologies for the production of veterinary medicines are accepted by civil society.

Tasks:

- Review new technologies through literature searches, workshops and conferences and the establishment of networks
- Evaluate the potential of new technological developments
- Monitor the availability of proof of concept new technologies
- Identify innovative technology and assess how it can be utilised
- Direct research funding to the new technology with the most potential
- Develop effective communication strategies for new technologies to ensure acceptance by the public.

Priority: Medium and long-term

Funding: EU Framework 7 cooperation, National Funders, industry funding

Activity: Applied research, review and analysis

2.3. Gap analysis of Current Research

SRA Recommendations 13

Objective: A clear picture or overview of the totality of current research into priority diseases throughout the EU and the world is urgently required. Information on research funding by public authorities at a national or regional level, by pharmaceutical and biotech companies would ensure that duplication and gaps in the research programmes are avoided. Information on planned or proposed research is needed. 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 has a lower priority 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.

Deliverables:

- Provision of an overview of research into the priority diseases
- An integrated and coordinated R & D programme across Europe
- Duplication of effort avoided
- Use of resources and limited funds effectively
- Major gaps in research identified and filled
- EU, national governments and other public/private organisations use the analysis to target and direct funding to achieve the maximum output for the investment
- Funding directed primarily to research which will deliver products
- Centres of excellence for research are identified and catalogued.

Tasks:

- Establish an ERA-Net, (European Research Area – Network)
- Map global research and development for each priority disease
- Catalogue the current research programmes against the research organisations both within the EU and globally
- Develop and maintain a database of research and centres of excellence throughout the EU
- Publish such a database
- Make the database available on the web.

Priority: High and immediate

Funding: EU Framework 7 Cooperation, National Funders, international organisations and industry

Activity: Review, analysis, database

2.4. Gap Analysis of Available Products

SRA Recommendations 14, 15, 16

Objective: 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 exists to some degree for Biologicals and is published by the Institute for International Cooperation in Animal Biologicals. There are a number of sourcing strategies for veterinary medicines, in particular vaccines, in the European Union Research. The development of a comprehensive, risk-based sourcing strategy for vaccines, pharmaceuticals and diagnostic tests to meet EU animal health priorities linked to the important diseases is a priority. In the case of products for MUMS conditions, 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 could ameliorate the situation.

Deliverables:

- Identification of suitable products already available in the European Union
- Procedures established to manage the risk from unauthorised vaccine/product to allow import and assure supervised use under special authority
- Procedures considered allowing the import of master seed, antigen or other starting material from other countries, test against European standards and protocols and producing finished vaccine/product in the EU
- Research sponsored 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
- Public Private Partnerships created to develop and bring to market veterinary medicines currently not available or needed in the future in the EU.

Tasks:

- Catalogue and create a database of the available products worldwide for the control of major disease
- Evaluate their potential for use in the EU
- Mapping the animal health companies producing veterinary medicines and diagnostic tests worldwide.

Priority: Medium and medium term

Funding: EU Framework 7 Cooperation, National Funders, international organisations, industry

Activity: Review

Theme 3 Fundamental Science

3.1. Support and Strengthen Fundamental Sciences in the EU

SRA Recommendations 17, 18, 20

Objective: Over the next 10 years it is vital to foster a creative environment for fundamental research and to stimulate investment in research areas such as Host/Pathogen interactions, Fundamental Immunology, Epidemiology, Genomics and Integrated Biology. A sound and stable base for fundamental science is vital if innovation and the development of new tools are to be successful. The fundamental sciences 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. Research scientists must be encouraged to develop expertise in those areas where gaps currently exist. Programmes need to be established which inherently support fundamental research either directly or indirectly linked to the priority diseases. 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. This area has a high priority in view of the long period before returns on investment will be seen.

Deliverables:

- 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
- Delivery of an EU-wide strategy to enhance the capacity and expertise in the fundamental sciences

- Identification of specific science and education programmes needed to develop and maintain expertise in each speciality area
- An assessment of capacity and expertise to deliver the science necessary to support research and new technologies needed to develop new tools to control diseases
- Fully funded fundamental sciences with appropriate specific programmes for each speciality.

Tasks:

- Conduct a review into the state of science in the EU
- Implement action where necessary to support the fundamental sciences
- Strengthen collaboration between the research organisations working on the fundamental sciences and those responsible for the disclosure of scientific results
- Target research funding to those areas of fundamental science critical to the development of prioritised vaccines, pharmaceuticals and diagnostic tests.

Priority: High and immediate

Funding: EU Framework 7 Cooperation, National Funders,

Activity: Review, applied research, targeting funding.

3.2. Establish a European Centre for Epidemiology and Infectious Animal Diseases

SRA Recommendation. 21

Objective: In Europe, epidemiological research is carried out in national institutions and is mainly organised and funded by the EU Member States. A central institution with coordinating responsibilities for fundamental and applied research in the field of infectious diseases and epidemiology is required. 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.

Deliverables:

- A scoping study of the options available for improving applied research into epidemiology and infectious diseases and the development of an appropriate infrastructure with responsibility for training epidemiologists to create a critical mass for the future
- A report into the pros and cons of a virtual versus a physical centre
- The implementation of the most appropriate option either the establishment of a specific or a virtual European Central Institution for Epidemiology and Animal Infectious Diseases. Alternatively a fully funded community reference laboratory could be established. The centre would act as a repository for a range of databases on disease information
- Availability of a budget for the centre whether virtual or physical.

Tasks:

- The Collaborative Working Group of the Standing Committee on Agricultural Research to consider with the ETPGAH the development of this work
- Establish a network of excellence and develop a virtual centre which would involve centres of excellence around Europe in the initial stages
- Identify all the functions which ideally would be included in the terms of reference for a European Centre. The suggested task areas for a European Centre, be it virtual or actual, are defined in annex 1
- Develop a business plan and investigate potential funding for a European Central Institution for Epidemiology and Infectious Animal Diseases either as a separate centre or as a community reference laboratory
- Develop ultra-fast information links and methods for data exchange whether a virtual or actual centre is established.

Priority: High and immediate

Funding: EU Framework 7 Cooperation and Capacity, National Funders, international organisations, industry

Activity: Network

3.3 Specific Requirements for Fundamental Research

SRA Recommendation 19

Objective: 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. Capacity must be maintained in the fundamental sciences to deal with any new or developing problems. It would be appropriate to consider specific programmes for each speciality as indicated below.

Deliverables:	Task:
Host Pathogen interaction • Increased understanding of host and pathogen biology • Increased knowledge of host-pathogen interactions at a molecular level • Novel control strategies for the priority diseases based on the increased understanding are developed.	• Increased understanding of host and pathogen biology • Increased knowledge of host-pathogen interactions at a molecular level • Develop Novel control strategies for the priority diseases based on the increased understanding • Understand the molecular basis for host range and adaptation to new host species • Identify the genetics of hosts influencing susceptibility to disease • Determine the genetics of pathogens and pathogen populations relating to virulence and antigenic variability • Investigate the mechanisms of persistence (host and population levels) • Target therapeutics in relation to pathogenesis, pharmacokinetics.
Fundamental immunology • A better understanding of the immune system of the relevant target animal species • The provision of tools to perform fundamental immunological studies to provide a solid basis for the new approaches to the development of veterinary medicines and diagnostic tests.	• 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.
Epidemiology • An understanding of the important infectious diseases based on increased funding of epidemiological research • New methods to monitor wildlife and domestic animals for existing and newly emerging infectious diseases • Development of new sampling and survey methodology.	• 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 & vector (if appropriate) surveillance of diseases inside and outside the EU (including exotic) • Investigate the role of vaccination in limiting transmission and spread.

Genomics • Understanding the expression systems from viral and bacterial vectors • Identification of the relevant gene(s) from large bacterial and parasite genomes and new methodologies to screen for these genes • Better understanding of the molecular basis for disease, host pathogen interactions, etc. • Maximum exploitation of genomics technologies.	• 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.
Bio-informatics • Ability to handle, analyse, and interpret the wealth of information generated from research into genomics, proteomics and metabolomics in the context of disease problems • Information held in appropriate databases that are accessible in a user-friendly manner by the research community • New bioinformatics facilities developed and maintained to allow access through the EU research community to all the sequences and analytical software required for the analysis and exploitation of the information.	• Establishment of bio-informatics capability • Standardisation and linking of structural, genomic, proteomic etc… data • Establishment of parallel databases for biological data to allow interpretive analyses.

In order to assist in all these areas the establishment of tissue banks and banks of reference material could be envisaged.

Priority: High and immediate

Funding: EU Framework 7 Cooperation, ideas, people and capacity, National Funders, international organisations, industry

Activity: Fundamental research

Theme 4 Enabling Factors

4.1. Quality Assurance

SRA Recommendations 22, 23, 24

Objective: Academic institutes in Europe are not accustomed to working to independently audited quality standards. This result is a severe gap in the knowledge and understanding by European scientists of the importance of compliance with regulations and standards. Even in fundamental research where basic concepts are developed, the work should be undertaken to an appropriate quality standard. There is a need for a coordinated effort aiming at raising awareness among the research institutions and academia on the importance of issues such as, Good Laboratory Practice (GLP), the development of ideas to the proof-of-concept stage and Intellectual Property Rights (IPR).

Deliverables:

- ❖ All research should be quality assured
- ❖ All laboratories and organisations that conduct research that might ultimately lead to the authorisation of a veterinary medicine operate to appropriate quality standards that are independently audited

- A clear description of standards (quality, scientific, legal) to be followed is available to all research partners.

Tasks:

- Incorporate a requirement for quality management into research funding contracts
- Research funders request that the partners specify the standards that they will work to
- Partners ensure that the relevant researchers have the necessary scientific and quality training appropriate for the project
- Industry and the public sector must take account of the additional costs required by GLP when funding research projects as this can be very expensive
- Develop a harmonised database of standards including legal requirements and guidelines
- Carry out dissemination activities, education, training and advice to researchers and research establishments
- Implement educational material brochures/video/etc.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation and people, National Funders, international organisations, industry

Activity: Education and training, funding protocols, quality standards

4.2. Intellectual Property rights

SRA Recommendations 25, 26, 27, 28

Objective: Major problems relating to intellectual property rights (IPR) have been identified in Europe but the solution for many of these is outside the remit of this technology platform. Europe has many of the best scientists but this is not reflected in the number of successful patent applications. It is important to ensure that 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. 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. IPR should not be seen as a hurdle but rather as an essential prerequisite to the development and use of innovative ideas.

Deliverables:

- Researchers and research establishment throughout Europe aware of the importance of IP and patenting new discoveries
- Funders aware of the importance of including funding in the grants to cover IP and patenting costs
- More awareness of IP issues generally throughout the science community dealing with the development of new and improved tools for the control of priority diseases
- Education and training programmes available
- Industry involved in the development of IP training.

Tasks:

- Survey of best practice in the EU for handling IP issues
- Encourage and educate the research scientists to understand the importance of IPR and to assess the potential future use of their discoveries
- Develop training programmes on IP issues with industry and researchers both national and EU wide to include finance for workshops for senior scientists
- Include training of IP in post graduate studies
- Industry to become more proactive regarding needs and expectations
- Provide advice on the actions necessary for the correct filing of a patent application
- Stimulate awareness re potential use of products for the market
- EU and National organisations to include in their funding IP application and implementation costs
- Fund IP applications even after the main project is finished
- Provide incentives to reward the inventor both nationally and within the EU and also the research institute
- Resolve the problems of confidentiality.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation and people, National Funders, international organisations, industry

Activity: Education and training, funding protocols

4.3. Overcoming Barriers to Technology Transfer

SRA Recommendations 29, 30, 31

Objective: The fundamental problem for Europe 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. A gap exists between the scientist and the development process. 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 can be delivered. There is a need to develop a Europe wide system to identify innovation and enhance transfer to commercial companies for development.

Deliverables:

- A Europe wide system in place for the identification of innovation and enhancement of the transfer to commercial companies for further development and commercial exploitation. Establish clearly identified criteria for the selection of innovative ideas and further development
- Better understanding, planning and partnership with industry
- Advice available from the industry on feasibility of acceptance and the practicality of manufacture
- More linkages between research, industry, users
- Improved delivery of proof of concept.

Tasks:

- Establish a system for Europe to identify innovation and take it forward through:
  - ⇛ Better identification and evaluation of research findings
  - ⇛ Review of publications
- Need for expert consultants to advise on implications
- Give more focus and clear priorities in research funding to bring products to the market and to shorten the development time frame
- Develop awareness programmes regarding the definition of proof of concept and provide appropriate funding.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation and people, National Funders, international organisations, industry

Activity: Education and training,

4.4. Networks and Centres of Excellence

SRA Recommendations 32, 33

Objective: The 6th EU Framework Programme sought 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. None of the existing networks has the full participation or integration of the animal health or biotechnology industries to assist in coordination and collaboration. 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.

Deliverables:

- Completion of a comprehensive review of the usefulness of existing networks of excellence and integrated projects on the delivery of vaccines, pharmaceuticals and diagnostics
- Relevant stakeholders participate in existing and future networks
- The future of the existing networks which are effective and relevant are secured financially.

Tasks:

- Carry out an independent audit/review of existing networks of excellence in order to answer questions such as:
  - ⇛ Have they improved the efficiency of research?
  - ⇛ Have they delivered what they were set up to do?
  - ⇛ Were the objectives of the network systems appropriate?
  - ⇛ Are the networks sustainable?

- Provide additional funding to allow networks to expand and include a wider range of stakeholders
- Ensure membership criteria are clear and inclusive of relevant stakeholders
- Assess together with the CWG of SCAR whether the proposed ERA-Net could offer specific opportunities to review and fund the most effective networks.

Priority: Medium and long term

Funding: National Funders, EU Framework 7 Cooperation, international organisations, industry

Activity: Review, ERA-Net

4.5. Education and training

SRA Recommendations 34, 35

Objective: In the EU the critical mass of expertise and the availability of qualified and skilled researchers are 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. 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. Education and training is an important component of many sections of this action plan.

Deliverables:

- A completed evaluation of the current position regarding the expertise available in the EU
- A completed assessment of the career prospects for young scientists in the EU working on animal health and related fundamental sciences
- Provision of a sustainable atmosphere for creative fundamental research in particular for the young scientists of today
- Improved interchange opportunities for PhD students and at the post doctorate level to industry. Better interaction between academia and industry.

Tasks:

- Develop a model to improve interchange at undergraduate, PhD and post doctorate levels in order to gain experience and/or work in industry and academia
- Identify financial mechanisms to enable interchange by graduates for variable periods of 3 months to two years
- Encourage and improve industry experience for academics
- Develop and catalogue expertise in Europe in the specialised subjects relevant to the SRA and the Vision of the platform
- Implement Continuous Professional Development and training programmes in the problem area(s)
- Ensure that specific expertise is maintained in Europe or that access is available
- Review what expertise is needed for each disease
- Develop a centre of expertise in Europe which is able to handle the specific disease problem if it occurs in Europe.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation, people and ideas, National Funders, international organisations, industry

Activity: Review, education and training

4.6. Infrastructure

SRA Recommendations 36, 37, 38

Objective: There is concern that the capacity for research in Europe and indeed worldwide is inadequate for the more serious diseases and infections. Currently the lack of suitable premises with appropriate containment facilities available for use by industry and other users is a major constraint to development of new tools for the control of the priority diseases. Clarity is required about the conditions for use of these specialised premises as the regulatory authorities have not clearly defined which micro-organisms should be handled under which type of containment. 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.

Deliverables:

- A comprehensive inventory of the available Containment Category 3 and 4 animal accommo-

dation throughout the EU for animal challenge experiments and disease investigation

- Provision of funding for additional facilities if there are gaps identified in the number and distribution of containment facilities
- Clear guidelines available in relation to the categorisation of containment levels
- Arrangements in place to ensure the most effective use is made of existing high containment laboratory facilities for exotic disease research
- Adequate access available to these facilities by industry at a cost they can afford
- A clear set of harmonised guidelines for the handling of various pathogens in containment facilities provided by the regulatory authorities
- An independent assessment of the containment facilities for category BSL 4 and a system of certification or accreditation.

Tasks:

- Support the ongoing work of CWG of SCAR (survey of facilities) and encourage all Member States to participate
- Explore relevant facilities outside of the European Union
- Establish clear and harmonised guidelines on the handling of pathogens in the various containment levels
- Identify funding to resolve gaps identified in the review of available containment facilities
- Develop a system for accreditation of high security containment facilities.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation, national funders, industry

Activity: Review, development

Theme 5
Regulatory and Societal issues

5.1. Regulatory issues

SRA Recommendations 39 to 45

Objective: Research and good scientific data underpins the regulatory processes across the world and provides the technical solutions to satisfy the regulatory process. It is important to build a robust regulatory process balanced against the needs of animal health using assessments of benefit against risk 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 significance that goes beyond the agricultural impact in a regional area.

5.1.1 Drivers for Regulation

Deliverables:

- Veterinary medicines legislation which, when needed, is specifically different from the parallel human legislation so that it is relevant to animal health but is of comparable quality and standard as the equivalent legislation for human medicines
- Introduce a system to allow for the rapid introduction of new variants of vaccine strains into veterinary vaccines without onerous and lengthy regulatory procedures
- Make associated guidelines also available
- A reduction in the use of animal testing requirements with the acceptance of alternative methods of assuring effectiveness and safety of veterinary medicines.

Tasks:

- Review the drivers for medicines legislation and identify the similarities and differences between the drivers for human and veterinary medicines. Consider how these have impacted on the legislation for veterinary medicines and identify any resulting issues
- Review the current arrangements to permit the introduction of strain variations into vaccines without the need for the full regulatory requirements for authorisation for each variant
- Carry out risk analysis of adopting a more tailored approach for dealing with veterinary medicines taking into account the differences in production, distribution and patient use in comparison to human medicine requirements

- Develop new regulatory concepts for the approval and authorisation of veterinary medicines and implement these concepts in practice to optimise regulatory quality
- Develop the concept of standardised pan European packaging and distribution for specific products of minor use and implement in practice
- Conduct research to identify the critical factors which need to be considered when developing legislation and guidelines for the control of veterinary medicines
- Conduct research into the impact that regulations and new guidelines are having on the critical success factors which determine the ability of companies to bring new products to the market place
- Undertake research to find alternatives to animal testing and develop and validate models so that animal testing is minimised
- Monitor and evaluate the progress achieved under the impact of the recently implemented EU Directive and identify where further changes would be advantageous.

5.1.2 Developing an effective Risk/Benefit assessment methodology

Deliverables:

- Evaluation of the applicability of the risk/benefit concept to veterinary medicines
- A model on which a risk/benefit evaluation should be based.

Tasks:

- Identify the circumstances under which the risk/benefit concept should be applied
- Create and publish details of an assessment tool
- Peer review the assessment tool and ensure that it is widely available and used by the regulatory authorities at EU and national level
- Develop a quality assurance programme for regulation and in particular for risk/benefit assessment.

5.1.3 Modernising Guidelines and Monographs

Deliverables:

- Review current guidelines and monographs and assess them in the context of their value for determining risk/benefit seeking to reduce the requirements for animal experimentation and providing risk proportionate veterinary medicine regulation
- Options for the future development, use and format of guidelines and monographs
- Clarity on the legal status of guidelines and the process by which they can be modified or adapted.

Tasks:

- Review and analyse the value of guidelines to the regulators, animal health industry and public
- Analyse the impact of new guidelines on safety of medicines over a determined period of time versus impact on introduction of new medicines within same time frame
- Research the impact of guidelines on product development in its broadest sense
- Determine impact of findings on future guideline development
- Develop a model to enable evaluation of the need for any new guideline for veterinary medicines
- Review the extent to which the interpretation and application of guidelines within the EU are truly harmonised or if national trends prevail.

5.1.4 Relevance and importance of Environmental Risk Assessment (ERA).

Deliverables:

- Research how the latest requirements in guidelines for ERA for veterinary medicines (and especially vaccines) came into being and assess the intent and its justification
- Better understand the environmental risks associated with the use of veterinary medicines and in particular for live vaccines associated with GMO technology and zoonotic disease

- Better understand how veterinary medicines can be developed to reduce potential adverse effects on the environment
- Analyse the benefits or otherwise of the existing environmental risk assessment on the development of veterinary medicines benchmarked against the regulatory requirements of other developed third countries
- Provide clarity on the scientific rationale for the current environmental risk assessment guidelines for veterinary medicines to ensure that the data requirements are proportionate to the need to control risk.

Tasks:

- Undertake an assessment of the data requirements for environmental risks associated with veterinary medicines to ensure that regional issues such as local strains of organisms, epidemiology, animal husbandry, differences in soils, temperatures, etc are taken into account
- Research the exposure of the aquatic environment and its relationship to the assessment of environmental exposure
- Develop or adapt tools and models to improve the environmental risk analysis for veterinary medicines. Focus particularly on how models relate to actual environmental exposure
- Review the scientific basis for the current guidelines on environmental risk assessment for veterinary medicines
- Conduct an assessment of the environmental risks and the relevant risk/benefit balance with economic, social and environmental impact of the current measures
- Develop new evaluation methods for assessing the environmental exposure effects of veterinary medicines
- For vaccines, produce guidance on how best to take account of viral resortment and reversion to virulence in considering environmental risk.

5.1.5 Barriers to harmonisation

Deliverable:

- Solutions exist for harmonisation of veterinary medicines throughout the EU.

Tasks:

- Explore the impact of the perception of risk in different Member States
- Facilitate access of countries to all necessary scientific disciplines
- Survey current human capacities and capabilities in relation to the authorisation of veterinary medicines
- Organise workshops at national level with assessors and associations to ensure a common understanding and approach to the authorisation of veterinary medicines
- Encourage education and training of assessors to achieve a harmonised approach
- Agree how to define serious risks and have this accepted and made workable in practice
- Evaluate pro/cons for establishing an EU Approval Authority.

Priority: Medium and long term

Funding: European Commission, national and industry funders

Activity: Survey, applied research, demonstration, education and training.

5.2. Diagnostic Tests

SRA Recommendations 46 to 50

Objective: In many countries there is an unregulated market in veterinary diagnostic tests. There is an active registration policy in some European countries. Diagnostic products for use in the human field are regulated through EU legislation. Whether diagnostic tests must be validated under an EU-wide system similar to the US needs more consideration. 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. This is a small industry and the Cost-Benefits of any regulation must be considered very carefully.

Deliverables:

- Core collection of reference panels established for animal protein and serological assays for the priority diseases in order to evaluate and compare the performance of diagnostic tests
- Quality Control for Molecular Diagnostics (QCMD plc) established and in use
- Global validation of pre import/export health screening tests is available
- Achieve clarity and harmonisation about the level of regulation for diagnostic tests in animal health which is required in the EU and worldwide.

Tasks:

- Catalogue, collate and exploit existing collections of reference material and assess their value
- Establish core collections of reference material for the priority diseases which are accessible to researchers worldwide for the development and validation of diagnostic tests
- In the case of Quality Control for Molecular Diagnostics (QCMD) adapt the human infectious disease model and validate for use with animal diseases
- Identify and validate specific tests for use in live animals within the EU and outside (China, Africa, South America)
- Conduct a survey of the public, veterinarians, producers, kit manufacturers, diagnostic laboratories, importers/exporters to support the current discussions which are going on between the EU regulators and the AEFRV on how a regulation for diagnostic materials should be developed for the EU
- Cost-Benefit analysis of the value of current arrangements (e.g. OIE) and potential new regulations.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation, National funding agencies

Activity: Review, survey, archives

5.3. Societal issues

SRA Recommendations 51 to 54

Objective: In the EU there is concern over the use of genetically modified products, eating food from animals treated with veterinary medicines 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. 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. Societal studies are needed to assess the impact of new technologies and to evaluate the most effective ways to present and communicate the advantages and benefits of new technology to the public to avoid misunderstanding and mistrust. 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 strategies for communicating with the public.

Deliverables:

- A better understanding of consumer perception and expectations of new technologies and the consequent acceptance of new veterinary medicines
- A published review of existing research findings on social perceptions of new technologies and new veterinary medicines
- Identification of factors which affect consumer behaviour in relation to food safety
- A communication strategy in place to show the public that new vaccines and pharmaceuticals are safe and that the EU regulatory systems are effective in protecting them
- Increase involvement and interaction between veterinary sciences and the social sciences.

Tasks:

- Review existing and published studies of societal and consumer perceptions, understanding and acceptance/rejection phenomena, of innovations such as GM crops and food, GM health products
- Analyse the structure and impact of anti-innovation propaganda programmes over the past 20 years, in order to understand the likely responses of interest groups and NGOs to new technologies in veterinary medicine
- Research how society reacts to new technologies and determine how to better communicate the science to the public at large
- Establish fora where animal health researchers can interact with academics covering cultural, religious and social sciences

- Develop a research programme into consumer perceptions and understanding of new technologies used in veterinary medicines using Questionnaire, Focus groups, interviews
- Review published surveys to identify and analyse factors affecting consumer behaviour in relation to food
- Develop a communication strategy based on the reviews, research and surveys
- Identify which bodies have the most influence on the public (NGOs, media, journalists, maybe teachers) and how to approach the public through these
- Identify the sectors of the public (schoolchildren, college students, product purchasers) which need to be approached
- Develop and establish fora where veterinary medicine, social science and the public can engage in an open transparent dialogue about the new tools to control the priority animal diseases.

Priority: Medium and long term

Funding: EU Framework 7 Cooperation, National funders

Activity: Applied research

5.4. Community Animal Health Policy (CAHP)

SRA Recommendations 55 and 56

Objective: 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 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.

Deliverable:

- Ensure that the Action Plan contributes and supports the CAHP.

Task:

- Maintain contact with CAHP.

Priority: Medium and long term

Funding: Not applicable

Activity: Liaison and communication

Lead Organisation: ETPGAH

Theme 6: Global Partnerships.

SRA Recommendations 57 to 61

Objective: The ETPGAH concentrates on animal diseases of priority for Europe, but must also take into account the perspectives of the globalised setting in which these diseases move. The focus of the SRA is not aimed exclusively at the European level, but considers the global dimension of the technologies concerned. 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. A partnership is essential and will assist in improving the technology and scientific capabilities of the developing countries for controlling animal diseases. Improved links to R&D worldwide are a priority. 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 to ensure a truly global approach.

Deliverables:

- 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, partnerships need to be developed in different ways but in general projects should be promoted in partnership with the developing countries.

6.1 Introduce Joint Research Programmes

SRA Recommendations 57 and 58

Deliverables:

- Key research groups identified in the EU and outside EU for priority diseases
- Research needs for developing countries in relation to the priority diseases identified
- Prioritised list of key diseases in non EU countries where the EU has the capacity to support and deliver
- Identify international collaboration projects for the priority diseases
- Expert International Working group established to link non EU organisations

- Technology transfer opportunities from the EU to developing countries identified.

Tasks:

- List of names, addresses, existing capabilities, track record, current research programmes, existing involvement with developing countries (OIE, FAO)
- Facilitate (a) meeting(s) of scientists to develop firm proposals for research (ETPGAH Executive)
- Collect information and publicise the list of key diseases as soon as possible
- Establish an international forum of research funders
- Establish a global mirror group.

6.2 Promote Research Partnerships

SRA Recommendation 60

Deliverables:

- Opportunities to involve non-EU institutions in existing networks are identified
- Twinning projects between labs in industrialised and developing countries are developed and established
- Role and research interests of industry in both EU and developing countries are clear
- A database of interests which can be searched and referenced is created and maintained
- An ongoing focus in research calls on particular diseases emerging or endemic or occurring in LDC and that may be of risk to other parts of the globe is in place
- Laboratories in developing countries are upgraded to international standards
- EU reference laboratories are supported and encouraged to support laboratories in developing countries
- Participation by developing countries, for example through reference laboratories of the OIE and FAO.

Tasks:

- Involvement of non-EU partners in research proposals (EC)
- Formally established twinning agreements (OIE)
- Better understanding of role of industry (IFAH)
- Match against prioritised disease list
- Support conferences in major disease categories - focus on Priority List 1 diseases
- Needs assessment (people and facilities) (OIE or FAO Reference Lab)
- Obtain development funding and implement (Development funders)
- Collaborate with laboratories in Developing Countries (DC) and investigate the possibility of supporting networks of laboratories in DC.
- Establish centres of excellence for specified topics (TP Executive)
- EU Innovation research initiative (CORDIS).

6.3 Supporting Activity

SRA Recommendations 59, 61

Deliverables:

- Developing country involvement in research calls from the EU
- National mirror groups influence national funders to apply SRA including developing country involvement
- Member States aware of the agenda to support the developing countries
- Funders to support projects that include capacity building.

Tasks:

- Incorporate the requirement for third country involvement in research calls (EC)
- Permit access to national research funds by developing countries as partners with national groups (TP Executive)
- Encourage and facilitate joint applications by developed and developing country institutions
- Support consortia including EU and Developing Country private enterprises e.g. help to upgrade to GLP, etc
- Link into FAO initiatives which support networks and platforms, and which promote research leading to capacity building including product development.

Priority: High and immediate

Funding: All funders

Activity: Survey, review, fundamental and applied research, education and training

Chapter 3:

Research Requirements for Priority Diseases

Research Requirements for Priority Diseases

1 Introduction

In order to provide continuous feedback concerning the priority diseases and the priority gaps, it is necessary to continuously review the status of each disease. This is achieved by continuously updating our information on diseases (Annex 4), continuously analysing gaps (Annex 5) and scoring diseases via the prioritisation model (Annex 3). This provides us with an ongoing and updated list of priority diseases (Annex 2).

2 Prioritisation of diseases

2.1 Initial stages

The first stage in developing the SRA was to define priority diseases using a simple methodology. Allocation of diseases into a simple classification was difficult as there were a large number of variables contributing to the prioritisation process. An interim list of 30 priority diseases or infections was published in the SRA along with a preliminary gap analysis identifying areas where further work was required. This list was subdivided into 3 groups: major diseases, diseases for surveillance and neglected zoonoses. Each group included emerging or re-emerging diseases as appropriate (Annex 2).

2.2 Categories for diseases

The following disease categories are presented in Annex 2:

- Category 1: Epizootic diseases and diseases for surveillance
- Category 2: Zoonoses and food-borne diseases
- Category 3: Major food-producing animal disease complexes

2.3 Prioritisation model

Details of the revised prioritisation model are shown in Annex 3.

The issues which remain to be resolved include:

- The weighting for each criterion could be different according to the category of disease, the individual perception or the current occurrence of the disease under consideration (existing diseases in the EU; diseases at the boarder of the EU and presenting a risk for the EU; emerging diseases not in the EU)
- The methodology may be improved by grouping the criteria according to the thematic feature and risk: impact of the disease, tools, epidemiology (virus, reservoir). Therefore, sub-totals of scoring may better reflect the diversity of nature in priorities and avoid an excessive and unexpected homogenisation
- Scoring is a mathematical system with the risk of being too rigid and with too little flexibility when disease occurrence, disease impact or knowledge on disease change. It must have the ability to evolve
- The model has to be validated.

This work can only be taken to a certain stage by the ETPGAH. Further work is needed to deal with the above issues and to develop and complete an IT based model.

2.4 Future action on prioritisation

There is also a need to rework the detail in Annex 2 by categorisation of criteria and to adopt a subscoring approach by group of criteria. This work needs to be closely linked to the recently launched EU specific call (Concerted action, FP VII., KBBE-2007-1-3-03) where an "integrated, rational and methodological approach…to development of effective tools for controlling infectious animal diseases...(in which the first stage is) the prioritisation of diseases…" This work should be conducted in close relation with the upcoming FP VII project.

3. Research Requirements for the Priority Diseases.

3.1 Initial stages.

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 SRA categories.

3.2. Development of the gap analysis

The next stage is to validate the information collected to date. This will be achieved by establishing small groups who will consider the gaps and the research needed to deliver the new tools. It is anticipated that a manual of research requirements for diseases will be produced, endorsed by stakeholders and act as a basis for advice on research funding to the EC, Member States and to private funders.

3.3 Bluetongue as an example

Annex 4 and 5 give details of bluetongue and provide an initial gap analysis. The analysis indicates that the specific requirements of those who are responsible for controlling disease are:

- Vaccines effective against all likely serotypes suitable for use in all ruminant species need to be developed and tested
- Vaccines to be placed in a European strategic bluetongue vaccine reserve (vaccine bank), ready for use when required
- New efficacious and safe vaccines with marker properties either based on DNA recombinant techniques or inactivated preparations to be developed

Similarly the requirements for diagnostic test development are listed as:

- Better knowledge of antigenicity of viral proteins
- Kinetics of antibody response
- Kinetics of virus replication at the genome and protein level

In order to meet the requirements of the users of the tools, the suggested research required for vaccine development is as follows:

- Better knowledge on the virus diversity and variability in different animal species and vectors
- Better knowledge on the function of viral genes and proteins
- Better knowledge on the virus biology and its capacity to persist in susceptible animals and in reservoirs
- Better knowledge on the immune mechanisms (cellular and humoral) involved in protection.

Further research is recommended in order to establish efficacy and safety of candidate vaccines in cattle, sheep and goats. With a high efficacy and safety, vaccination could be extended to all ruminant species in order to stop transmission of the virus. This policy would eventually lead to the eradication of BTV from affected areas.

In the case of diagnostics, it is recommended to develop diagnostic reagents based on viral genes and proteins to specifically distinguish viral infection from vaccination.

The work of the ETPGAH cannot be divorced from other workshops set up to identify research requirements. The most recent was the EU funded Workshop for research in bluetongue which was held in Brussels on 10 -11 March 2005. The conclusions from this workshop identified a number of areas for research which included that needed for the development of bluetongue vaccination.

(http://ec.europa.eu/research/agriculture/pdf/bt_summary_en.pdf)

The recommendations from the workshop covered pathogenesis and persistence in the host, vector issues, epidemiology and modelling, surveillance and diagnostics, vector control and vaccination. These recommendations were listed but not placed in any priority order nor was there any indication of where funding should be targeted. The workshop was extremely valuable as it brought together all the experts in the field and produced a comprehensive list of requirements. However, there was no indication of where funding was to be obtained nor any indication that a coordinated Europe wide plan for research into bluetongue would be developed.

The specific recommendations from the workshop in relation to vaccines were:

- Investigate responses of common European sheep breeds, cattle and goats to live BTV vaccination and to vaccination with the new inactivated or sub unit vaccines
- Confirm efficacy and duration of protection of new inactivated vaccines
- Devise, test and apply novel delivery systems designed to enhance vaccine performance

- Develop second generation inactivated vaccines based upon "virus like particles", proteins or other viral components
- Develop group-specific BTV vaccines, possibly based upon "core like particles" or serogroup proteins
- Determine the level of immune response required for protection
- Develop a framework to speed up authorisation of vaccines that incorporate new strains of virus as the need arises.

It is important to match the recommendations from the research workshops against the requirements of the vaccine producers and users. By doing this it should be possible to direct research funding into those areas which are of high priority to the whole of society rather than conduct research for its own sake. This should not detract from strategic or innovative research but would enable better direction and coordination of research effort to achieve effective outcomes. It is also important to balance the specific recommendations on vaccination with the other recommendations made at the bluetongue (BT) workshop as many of these are not associated with the development of veterinary medicines but may be equally important in developing better methods of control.

3.4 Future action on requirements

The example provided for bluetongue demonstrates the current difficulties in prioritising and targeting research. Information from all expert sources is required. In addition a clear strategy is required from those who will use the vaccines and diagnostics. This will enable an assessment to be made and agreed by all the stakeholders. The resulting research requirement document for each of the priority diseases would act as guidance to funders as to the priorities for development... This would not just be a list of topics proposed by the researchers but a prioritised list for the production of new veterinary medicines and diagnostic tests. A similar process is required for each of the diseases to provide an overview of the research requirements to develop new controls. This process would require extensive work and would need to be properly coordinated and controlled to obtain maximum benefit from the work.

Annexes

Annex 1

Tasks for an European Centre for Epidemiology and Infectious Animal Disease

The following task areas could be defined for an European Centre be it virtual or actual:

- Development of knowledge along the entire animal health chain, e.g.:
  - ⇛ Research in the area of interaction between epidemiology and infection biology focussed on the development of integrated control strategies
  - ⇛ Integration of innovation by research groups with development of vaccines and diagnostics by the pharmaceutical industry
  - ⇛ Policy support of governmental bodies in the fields of prevention and control.
- Development of risk assessment models
- Development and implementation of data mining techniques
- Reference Centre for education and training, particularly in the field of epidemiology
- Integration of research with research centres for human infectious diseases
- Management of a common European database for surveillance and early warning
- Initiation of joint research programmes and exchange of expertise with centres in developing countries, in particular the source countries for (re)emerging infectious diseases (i.e. twinning).

Annex 2 Categories of disease

Group 1 : Epizootic diseases and diseases for surveillance

African Horse Sickness

African Swine Fever

Avian Influenza

Bluetongue

Contagious Bovine Pleuro Pneumonia

Classical Swine Fever

Foot & Mouth Disease

Peste des Petits Ruminants

Rift Valley Fever

Ruminant Pox Virus infection

Swine Vesicular Disease

West-Nile Virus infection

Group 2 : Zoonoses and food-borne diseases

Rabies

Nipah virus infection

Anthrax

Brucellosis

Bovine Tuberculosis

Q Fever

Trypanosomiasis

Leishmaniosis

Leptospirosis

Chlamydiosis

Cysticercosis

Echinococcosis

Food-borne bacterial:

- Salmonella
- E. Coli
- Campylobacter

Cryptosporidiosis

Food-borne viral (Hepatitis E Virus)

Transmissible Spongiform Encephalopathies

Group 3: Major food-producing animal disease complexes

Parasitic gastro-intestinal diseases

- Liver Fluke
- Coccidiosis
- Nematodes

Paratuberculosis (Johne's)

Mastitis :

- Staphylococcus aureus mastitis
- Environmental/Streptococcal mastitis
- Small ruminant mastitis

Swine enteric

Swine Respiratory

- PRRS – CG3 + HN
- PCV II
- SIV
- A. pleuropneumonia
- Mycoplasma

Bovine Respiratory

- BVDV
- BRSV
- BHV-I (IBR)
- Mycoplasma

Annex 3
Criteria for prioritisation model.

Score	1	2	3	4	5
EPIDEMIOLOGY AND RISK					
Speed of spread	ND	ND	Slow	Medium	High
Number of species involved	ND	ND	Few (1-2)	Mean (>2 =4)	High (>4)
Persistence of infectious agent	No	ND	Rare	Constant	ND
Spreading potential to susceptible populations	No	ND	Low	Medium	High
Wildlife diseases risk potential threat to animal health and public health	Negligible	Minor	Moderate	Significant	Serious
Disease knowledge	Very high	High	Moderate	Low	Limited
Wildlife diseases that are at threat	Negligible	Minor	Moderate	Significant	Serious
Dynamic (temporal, spatial, species variability)	Negligible	Low	Moderate	High	Very High
IMPACT ON WIDER SOCIETY					
Disease impact on production	No	ND	Low	Medium	Severe
Economic direct impact (including cumulative cost eg enzootic vs epizootic)	No	ND	Low	Medium	High
Economic indirect impact (social, trade)	No	ND	Low	Medium	High
Impact on specific production and supply channels	No	ND	Low	Medium	High
Security of food supply/Benefit for developing world	Extremely limited	Low value	Moderate	High	Very high
IMPACT ON PUBLIC HEALTH					
Impact on Public Health and Food Safety	No	ND	Minor	Moderate	Severe
Risk of occurrence	No	Extremely rare	Occasionally	Regularly	Frequent
Impact of occurrence	No	ND	Low	Medium	High
IMPACT ON INTERNATIONAL TRADE					
Impact on International Trade and EU trade due to existing regulations	Negligible	Minor	Moderate	Significant	Serious
CONTROL MEASURES					
Effective prevention and control practices	None	Surveillance	Movement control	Culling	Vaccination
Tools for surveillance	Very high efficiency	High efficiency	Moderate efficiency	Low efficiency	None
Tools for prevention crisis	Very high efficiency	High efficiency	Moderate efficiency	Low efficiency	None
Tools for control and implementation	Very high efficiency	High efficiency	Moderate efficiency	Low efficiency	None
Success of prevention and control in other countries	No success/experience	Low	Moderate	High	Consistently high
Technology (Vaccine/Treatment) / Tool Availability	Very high reliability	High reliability	Moderate reliability	Low reliability	None
Commercial diagnostic tools availability	Very high reliability	High reliability	Moderate reliability	Low reliability	None
Points achieved					
Total achievable					

Annex 4
Bluetongue: Disease Information

1. Disease Analysis	Comments
Description and characteristics of the pathogen	The Bluetongue virus (BTV) belongs to the Reoviridae family, genus Orbivirus. The viral particle consists of a viral capsid formed by a protein bilayer, which enclose ten segments of double-stranded RNA. The viral genome codes for 7 structural proteins (VP1-VP7) and 3 non-structural proteins (NS1-NS3). All Bluetongue isolates share a common antigenic determinant called antigen protein VP7, which is used for BTV identification. Protein VP2 is variable and is used to determine the specific serotype of a virus. A total of 24 serotypes have been identified worldwide.
Species involved infected/carrier	Primarily a disease of sheep but other species such as goats, cattle, buffaloes, camels, antelopes and deer can be infected. Humans are not susceptible.
Description of infection & disease in natural host	Bluetongue is a non-contagious, arthropod-borne viral disease of both domestic and wild ruminants Acute form (sheep and some species of deer) Transient fever (up to 42°C), depression Inflammation, ulceration, erosion and necrosis of the mucosa of the mouth Swollen and sometimes cyanotic tongue Lameness due to coronitis or pododermatitis Abortion Complications of pneumonia Emaciation Either death within 8-10 days or long recovery with alopecia, sterility and growth delay Early embryonic loss and decreased reproductive efficiency is a more frequently seen manifestation of the disease in cattle and can be devastating to their calf/milk production. Clinical signs in cattle also include hyperaemia, necrosis of the muzzle ("burnt muzzle") and patchy dermatitis Unapparent infection is frequent in cattle and other species.
Zoonotic potential (disease and impact in humans)	None
Geographical distribution	The virus is present in a broad band of countries extending approximately between 53°N and 35°S. The bluetongue virus has been shown by serology to be present in regions where the Culicoides vector is present (e.g. Africa, the Mediterranean region, the Americas, Australia and some countries of southern Asia and Oceania). However, clinical disease with confirmation by virus isolation has been observed in a few countries only. In Europe, Bluetongue was confirmed in sheep flocks at the Baleares, Sardinia, Sicily, the south of Italy, Corsica. Recently outbreaks in cattle and sheep were confirmed in Netherlands, Germany, Belgium, Luxemburg and the north of France.

Route of Transmission	Bluetongue virus (BTV) is transmitted between mammalian hosts via bites from adults of certain species of Culicoides midges.
Immune response to infection	Complex: Humoral with neutralizing and non-neutralizing antibodies. Cell-mediated immunity Inflammation Immunity (naturally acquired after infection or induced by vaccination) against one serotype is often ineffective in case of infection due to a different serotype BTV can persistently infect ovine γδ T-cells in vitro, a process that may also occur during infection in mammalian hosts, thus providing a mechanism for virus persistence Cleavage of virus surface proteins by host protease enzymes associated with inflammation generates infectious subvirus particles that have enhanced infectivity (100 times) for the insect vector.
Main means of prevention and control	Sanitary measures: quarantine and serological survey; vector control Diagnostics: Competitive ELISA ; Agar gel immunodiffusion ; Virus neutralisation ; Complement fixation Vaccines: Inactivated and modified live virus vaccines are available for several serotypes. Attenuated vaccines cover more types but are considered less safe. Because of very limited cross protection between strains, vaccine strains must be of the same type as those causing infection in the field Therapeutics: No efficient treatment.
Disease outbreaks reported to OIE in last 18 months	YES: Netherlands, Germany, Belgium, France, Portugal and Spain.
Economic impact	High: Direct economic loss through diseased animals and high indirect economic impacts through trade barriers. The duration of BTV viraemia in domestic ruminants has been a critical issue in international trade and placement of trade barriers. The OIE currently recognizes a 60 days infective period.
Main perceived obstacles for effective prevention and control	Diversity and variability of virus strains Diversity of vector (>20 competent culicoides species)
Main perceived facilitator for effective prevention and control	Virus is relatively well known. Effective attenuated and inactivated vaccines are avai lable. Several experimental candidate recombinant vaccines are currently being analysed.

Annex 5
Bluetongue Gap Analysis

2. Product/Gap Analysis	
Commercial Diagnostics available worldwide	Yes
Commercial Diagnostics available in Europe	Yes
Diagnostics in reference Labs:	Host : agar-gel-immunodiffusion and competitive ELISA ; virus neutralization test; RT-PCR Pathogen: virus isolation in embryonated chicken eggs and cell culture
Diagnostics registered with OIE	Agar-gel-immunodiffusion ;competitive ELISA ; virus neutralization test; virus isolation in embryonated chicken eggs and cell culture
Commercial potential for diagnostics in Europe	?
Commercial vaccine availability (globally)	Attenuated virus vaccines are cheap, easy to produce and are administered in a single dose. Potent, purified inactivated bluetongue vaccines achieve similar efficacy while non-purified inactivated vaccines usually require two or more injections to achieve similar results. Modern inactivated vaccines are better controlled for extraneous agents and safer, but not available for all serotypes. Both vaccine types, if used according to label instructions, are very effective in controlling clinical outbreaks of bluetongue in areas of endemic disease and in the face of outbreaks.
Commercial vaccine authorised in Europe	Conditional: Inactivated and attenuated vaccines under conditional/temporary license
Marker vaccines available worldwide	None
Marker vaccine authorised in Europe	None
Effectiveness of vaccines	Live attenuated and purified inactivated vaccines are effective and provide long lasting immunity with a single dose (in sheep) Non-purified inactivated or recombinant vaccines need two injections to afford protection.
Commercial potential for vaccines in Europe	Inactivated vaccines offer significant advantages over attenuated vaccines because absence of replicating virus eliminates concerns about viraemia, vector transmission and reversion to virulence Recent recombinant DNA technology has provided novel approaches to developing safe vaccines. This technology offers advantages both in terms of safety and the potential of developing a marker vaccine. The latter could be used as a prophylaxis in areas at risk, without endangering the "free" status of the region. An accompanying serological test would allow the distinction between vaccinated and infected animals. DNA recombinant technology involves the synthesis of immunogenic proteins and particles that elicit highly protective immune responses. Naked DNA vaccines may have a similar potential.
DIVA tests required and / or available	Antibodies to non structural proteins could differentiate infection from vaccination
Current Therapy	None
Future therapy	None

3. New Developments for vaccines	
Requirements for Vaccine development	• Vaccines effective against all likely serotypes suitable for use in all ruminant species need to be developed and tested • And placed in a European strategic bluetongue vaccine reserve (vaccine bank), ready for use when required • New efficacious and safe vaccines with marker properties either based on DNA recombinant techniques or inactivated preparations should be developed.
Time to develop new or improved vaccines	5-7 years per serotype with full market authorization
Cost of developing new or improved vaccines	8 -10m$
4. New Developments for diagnostic tests	
Requirements for diagnostic tests development	• Better knowledge of antigenicity of viral proteins • Kinetics of antibody response • Kinetics of virus replication at the genome and protein level
Time to develop new or improved diagnostics	?
Cost of developing new or improved diagnostics	?
5. Research Requirements for vaccines	• Better knowledge on the virus diversity and variability in different animal species and vectors • Better knowledge on the function of viral genes and proteins • Better knowledge on the virus biology and its capacity to persist in susceptible animals and in reservoirs • Better knowledge on the immune mechanisms (cellular and humoral) involved in protection • Further research is recommended in order to establish efficacy and safety of candidate vaccines in cattle, sheep and goats. With a high efficacy and safety, vaccination could be extended to all ruminant species in order to stop transmi sion of the virus. This policy would eventually lead to the eradication of BTV from affected areas.
6. Research Requirements for diagnostics	Develop diagnostic reagents based on viral genes and proteins to specifically distinguish viral infection from vaccination.
7. Risks	In infected areas, monovalent live virus vaccines or less efficient subunit vaccines may force selection of new variant strains of BTV through genetic drift or shift.
8. Conclusion:	From 1998 to 2006, BT occurred in 20 countries in Europe; 14 of these countries reported BT to the OIE for the first time. The outbreaks were primarily caused by serotypes BTV-2, BTV-4, BTV-9 and BTV-8. BTV-2 spread from northern Africa to France and then into Italy. BTV-9 was first reported from the south-eastern Mediterranean basin, and moved north and east to Italy. BTV-8 was reported recently in the Netherlands, Germany, Belgium, Luxemburg and the north of France, as well as in Bulgaria. Mechanisms for spread of BTV are thought to include illegal movement of viraemic animals and wind translocation of infected vector Culicoides spp. During the outbreaks, several countries implemented emergency use of mass vaccination with commercial attenuated or inactivated vaccines. Preliminary evidence indicates that mass vaccination may be a useful tool in controlling the outbreak, although additional research is needed regarding use of vaccine during outbreaks. The safety of certain attenuated vaccine subtypes has been insufficient. Traditional control measures for BT include animal movement restrictions, vector control, slaughter of viraemic animals, and management to reduce animal vector exposure.

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