

# Disease and Product analysis

**Disease:** \_\_\_\_\_

Revised 30 November 2010

## PART 1: CONTROL TOOLS

Product Analysis	Current knowledge	Gap(s) in availability of products/knowledge
<b>Part 1 Control Tools</b>		
<b>1 Diagnostics availability</b>		
<b>1.1 Commercial Diagnostic kits available worldwide</b>		
<i>Host/Pathogen</i>		
<b>1.2. Commercial Diagnostic kits available in Europe</b>		
<i>Host/Pathogen</i>		
<b>1.3. Diagnostic kits validated by International Standards(OIE) or European Standards (EU) or National Standards</b>		
<b>1.4 Diagnostic method(s) described by International standards (OIE) or European Standards (EU) or National Standards</b>		
<b>1.5. Commercial potential for diagnostic kits in Europe</b>		
<b>1.6. DIVA tests required and / or available</b>		
<i>Intended for eradication of disease or economic control of disease/ need and nature of the desired DIVA test</i>		

<b>1.7 Opportunities for new developments</b>		
<b>2. Vaccines availability</b>		
<b>2.1 Commercial Vaccines availability (globally)</b>		
<i>Live or dead, Rdna, sub-unit, application, production, administration, geographic availability</i>		
<b>2.2 Commercial Vaccines authorised in Europe</b>		
<i>Live or dead, sub-unit, application, licensing (type, countries)</i>		
<b>2.3. Marker Vaccines available worldwide</b>		
<i>Live or dead, sub-unit application, production, administration, geographic availability</i>		
<b>2.4 Marker vaccine authorised in Europe</b>		
<i>Live or dead, sub-unit application, licensing (type, countries)</i>		
<b>2.5. Effectiveness of vaccines/main shortcomings of current vaccines</b>		
<i>Type(s), effectiveness (level, immunity)</i>		
<b>2.6. Commercial potential for vaccines in Europe</b>		
<i>Type(s), Potential (advantages, weaknesses, particularities)</i>		
<b>2.7 Regulatory &amp;/or policy challenges to approval</b>		
<b>2.8 Commercial feasibility (e.g manufacturing)</b>		
<b>2.9. Opportunity for barrier protection</b>		
<b>2.10 Opportunities for new developments</b>		

<b>3. Pharmaceutical availability</b>		
<b>3.1 Current Therapy (curative and preventive)</b>		
<i>Treatments, prevention tools (ie repellents)</i>		
<b>3.2 Future therapy</b>		
<i>Exploring ways to develop better treatments</i>		
<b>3.3 Commercial potential for pharmaceuticals in Europe</b>		
<b>3.4 Regulatory &amp;/or policy challenges to approval</b>		
<b>3.5 Commercial feasibility (e.g manufacturing)</b>		
<b>3.6 Opportunities for new developments</b>		
<b>4. New developments for diagnostic tests</b>		
<b>4.1. Requirements for diagnostics development</b>		
<i>Related to the pathogen/antigen characteristics and host characteristics</i>		
<b>4.2. Time to develop new or improved diagnostics</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>4.3. Cost of developing new or improved diagnostics and their validation</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>4.4. Research requirements for new or improved diagnostics</b>		
<b>4.5. Technology to determine virus freedom in animals</b>		
<b>5. New developments for vaccines</b>		

<b>5.1. Requirements for vaccines development/ main characteristics for improved vaccines</b>		
<i>Related to the pathogen/antigen and host characteristics</i>		
<b>5.2. Time to develop new or improved vaccines</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>5.3. Cost of developing new or improved vaccines and their validation</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>5.4. Research Requirements for new or improved vaccines</b>		
<b>6 New developments for pharmaceuticals</b>		
<b>6.1. Requirements for pharmaceuticals development</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>6.2. Time to develop new or improved pharmaceuticals</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>6.3. Cost of developing new or improved pharmaceuticals and their validation</b>		
<i>Related to the pathogen/antigen characteristics</i>		
<b>6.4. Research Requirements for new or improved pharmaceuticals</b>		
<b>7. Conclusion</b>		
<i>Other information/comments/gaps</i>		

## PART 2: DISEASE DETAILS

Name of the disease		
	Current knowledge	Gap(s) in scientific knowledge
<b>Part 2 Disease Details</b>		
<b>8 Description and characteristics</b>		
8.1 Pathogen		
8.2 Variability of the disease (agent types and mutations, host and vector range, temporal, spatial and species variability)		
8.3 Stability of the agent/pathogen in the environment		
<b>9. Species involved</b>		
9.1 Animal infected/carrier/disease		
9.2 Human infected/disease		
9.3 Vectors cyclical/non-cyclical		
9.4 Reservoir (animal, environmental)		
<b>10 Description of infection &amp; disease in natural hosts</b>		
10.1 Transmissibility		
10.2 Pathogenic life cycle stages		
10.3 Signs (for the different possible clinical forms of the disease)/ morbidity		
10.4 Incubation period		
10.5 Mortality		
10.6 Shedding kinetic patterns		
10.7 Mechanism of pathogenicity		
<b>11. Zoonotic potential</b>		
11.1 Reported incidence in humans		
11.2 Estimated level of under-reporting in humans.		
11.3 Risk of occurrence in humans, populations at risk, specific risk factors.		
11.4 Symptoms described in humans		

11.5 Likelihood of spread in humans		
<b>12. Impact on animal welfare and biodiversity</b>		
12.1 Both disease and prevention/control measures related		
12.2 Endangered wild species affected or not (Estimation for Europe / worldwide)		
12.3 Slaughter necessity according to EU rules / or other regions		
<b>13 Geographical distribution and spread</b>		
13.1 Current occurrence/distribution		
13.2 Epizootic/endemic- if epidemic frequency of outbreaks		
13.3 Seasonal cycle (seasonality)		
13.4 Speed of spatial spread during an outbreak		
13.5 Transboundary potential of the disease		
13.6 Seasonal cycle linked to climate		
13.7 Distribution of disease or vector linked to climate		
13.8 Outbreaks linked to extreme weather		
13.9 Sensitivity of disease or vectors to the effects of climate change / environmental changes/land use)		
<b>14. Route of Transmission</b>		
14.1 Usual mode of transmission (introduction, means of spread)		
14.2 Occasional mode of transmission		
14.3 Conditions that favour spread		
<b>15. Detection and Immune response to infection</b>		
15.1 Mechanism of host response (neutralization,		
15.2 Immunological basis of diagnosis		

<b>16. Main means of prevention, detection and control</b>		
16.1 Sanitary measures (effectiveness)		
16.2 Mechanical and biological control		
16.3 Diagnostic tools		
16.4 Vaccines (inactivated, attenuated, sub-unit, GMO)		
16.5 Therapeutics		
16.6 Biosecurity measures effective as a preventive measure		
16.7 Border/trade/movement control (management) sufficient for control		
16.8 Prevention tools		
16.9 Surveillance		
16.10 Past experiences on success (and failures) of prevention, control, eradication in regions outside Europe		
16.11 Costs of above measures		
<b>17. Disease information from the OIE</b>		
17.1 Disease notifiable to the OIE		
17.2 OIE disease card available	Direct links to the OIE	Not applicable
17.3. OIE Terrestrial Animal Health Code (reference)	Direct links to the OIE.	Not applicable
17.4. OIE Terrestrial Manual (reference)	Direct links to the OIE.	Not applicable
<b>18. Socio-Economic impact</b>		
18.1 Zoonosis: Impact on affected individuals and/or aggregated DALY figures		
18.2 Zoonosis: Cost of treatment and control of the disease in humans		
18.3 Direct impact on (a) on production (farm losses due to mortality and morbidity)		
18.4 Direct impact (b) cost of private and public control measures)		

18.5 Indirect impact (probable market / fall in price, tourism, disruption of production, security of food supply, constraints on livestock production systems/breeds used)		
<b>19. Trade implications</b>		
19.1 Impact on international trade/exports from the due to existing regulations		
19.2 Impact on EU intra-community trade due to existing EU regulations		
19.3 Impact on national trade due to existing regulations		
<b>20. Main perceived obstacles for effective prevention and control</b>		
<i>Obstacles in applying prevention and control measures due to poor diagnostic tests, pharmaceuticals or vaccines</i>		
<b>21. Main perceived facilitators for effective prevention and control</b>		
<i>Facilitators to apply prevention and control measures <b>related to</b> diagnostic tests, pharmaceuticals or vaccines</i>		
<b>22. Risk</b>		
<i>Potential or effective direct and indirect risk associated to the disease</i>		
<b>23. Conclusion</b>		
<i>Other information/comments/gaps</i>		
<b>24 Sources of Information</b>		
24.1 Name of expert group leader		
24.2 Name of reviewers		

24.3 Date of preliminary approval		
24.4 Date of final approval		