Report of the meeting of the
Task Force on Animal Disease Surveillance
Brussels, 17 and 18 May 2010

Participants:

1. Executive summary

1.1. Swine Vesicular Disease (SVD): Currently there is mainly a passive surveillance system which has limitations for demonstrating freedom from disease/infection, but it is acknowledged that alternative systems would involve significant costs and result complications for trade. The importance of SVD surveillance should be in the context of an SVD disease control policy, and both surveillance and control measures should remain proportionate to the economic and other impacts of the disease. Several factors should be considered in order to optimise SVD surveillance.

1.2. Surveillance under the Animal Health Law (AHL): A combination of compulsory minimum requirements and voluntary guidelines may be the best option. The appropriateness of options such as "guidelines" or "minimum requirements" depends on the disease. The term risk-based surveillance (RBS) should be used with caution. A challenge for RBS is to be as effective as "standard" surveillance approaches and to be recognised as such by all stakeholders and trading partners. Good prior epidemiological knowledge that allows meaningful risk stratification is a pre-requisite for RBS. There is a need for a comprehensive and practical glossary on surveillance in the AHL.

1.3. Bluetongue: Monthly testing may provide a better approach for earlier detection of cases if sufficient, representative susceptible animals are tested. It also has a cumulative effect by providing more confidence in the disease status data. However, the design prevalence for BT surveillance and the required frequency for monthly or annual testing should be reconsidered.
2. **Discussion**

2.1. **Swine Vesicular Disease**

2.1.1. Background

The aim of the discussion is to outline the minimum requirements for SVD surveillance programmes and the surveillance procedures required for Member States (MS) to be able to obtain free from SVD infection status. The main questions proposed for discussion were:

a) *Which are the main criteria to be considered for SVD surveillance in order to lay down minimum requirements (or guidelines) for possible surveillance activities to be considered free from SVD according to OIE Terrestrial Animal Health Code?*

b) *Which should be the adequate minimum measures to regain free status (according to OIE) for a M) with an ongoing surveillance programme?*

c) *Is zoning in itself a reasonable measure to prevent spread of SVD?*

d) *How could additional guarantees be granted to MS where SVD is absent?*

2.1.2. **Outcome of the discussion**

The purpose of surveillance for SVD at EU level is unclear to the group.

For the purpose of demonstrating freedom from SVD infection, current passive surveillance has limitations due to the low morbidity of SVD circulating strains but alternative systems are likely to incur significant costs and may result trade complications. Therefore, given the poor effectiveness of passive surveillance for SVD, active surveillance for SVD would provide more useful information, but the implementation of such a strategy may not be proportional and sustainable.

A major issue identified is that current EU control measures for SVD are disproportionate and therefore are a major impediment to implementing any active surveillance.

Passive surveillance may be useful due to FMD being a differential diagnosis, but it needs to be recognised that it is not for demonstrating freedom from SVD infection. Therefore, the reporting requirement for suspect clinical SVD cases should remain in place as part of early detection of FMD.

Possible alternatives to passive surveillance that might be explored are:

- A one-off (snapshot) EU wide serological survey could be used to demonstrate freedom from SVD infection as an active surveillance programme. But, a well designed and scientifically meaningful survey will be time and resource consuming.

- Current active surveillance in Italy (Decision 2005/779/EC) should be reviewed and its epidemiological and therefore economic effectiveness potentially be improved.

Some disease features to be considered are that:

- Almost the whole EU is SVD free and in the infected Italian regions SVD is not a major constraint for the sustainability of the pig industry
- SVD is not easily transmitted (no aerosol transmission, main route of transmission is contact with contaminated faeces…) and close contact between animals is needed. In fact, between-herd transmission rarely occurs under extensive rearing conditions.
- No carrier status exists, viremia has a very short duration (two days) and flow quantities of virus are shed
- SVD virus is very stable and persists in the environment for a long time.
- Biosecurity plays an important role in the transmission of SVD
- The impact of SVD consists only of trade restrictions.
- Risk factors are not well understood.
- Dealer's premises are a hotspot for SVD transmission in Italy.
- Currently available, diagnostic tests are suitable for differential diagnosis and surveillance purposes.
- As regards surveillance system design:
  o The design prevalence will vary from country to country.
  o The intra-herd seroprevalence varies depending on farming system type.
  o There is uncertainty with respect to the expected prevalence.
  o Proving absence of SVD infection is difficult for a disease with low prevalence.
  o Passive surveillance is in general less effective now than in the past due to issues related to disease reporting.
  o Possible options that could be explored are:
    ▪ surveillance based on serum banks.
    ▪ testing fallen stock in rendering plants taking into account that the expected mortality is around 3%.

2.2. Surveillance in the context of the new AHL

2.2.1. Background

In the context of the new EU AHL, the Commission (DG SANCO/D1) is extensively reflecting on surveillance as one of the key elements of this law. Previous TFADS meeting already discussed this issue1.

The conclusions from a stakeholder consultation2 on this issue indicate that there is a substantial support towards the Commission's approach to strengthening surveillance. However, the views on the need to introduce surveillance networks were more diverging. It seems that this latter approach would largely be welcomed, but that it should aim for a robust and flexible disease surveillance system that would be able to adjust to different production types and different diseases. Flexibility to allow additional provisions and specific solutions at the level of MSs should be maintained, using where possible a soft regulatory approach.

In the framework of the informal meeting of the EU Chief Veterinary Officers (CVOs) in Seville (14-16 April 2010), the Spanish presidency organised a seminar dedicated to the Animal Disease Surveillance Systems in the EU. The CVOs discussed the key objectives of surveillance, its importance for animal health policy, best uses, cost-effectiveness, the approaches to be introduced to make it more efficient and adjust it to changing circumstances, new environments and emerging and re-emerging diseases. The conclusions3 of the EU CVOs underline in particular the importance of clear objectives, cost-effectiveness and use of risk based surveillance.

2.2.2. Outcome of the discussion

There is a need for a comprehensive but practical glossary on surveillance in the AHL. The discussion focused on the following 7 main points:

2.2.2.1. Surveillance for AMR

Conceptually, it should be monitoring for AMR instead of surveillance.

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1 http://ec.europa.eu/food/animal/diseases/surveillance/docs/meeting_1617122009_en.pdf
The comparison and analysis of outcomes should take the source of samples into account: samples usually come from healthy animals and human clinical cases.

2.2.2.2. Surveillance and One Health (OH) concept

It is appropriate to look for synergies but it is also necessary to focus on the individual needs of both AH and OH approaches because they may have different aims (prevention vs treatment) that may jeopardise a synergistic approach. In fact, synergy does not necessarily mean merging of both (human and veterinary) surveillance systems.

It is not recommended to incorporate poorly defined "in-fashion" concepts in the AHL. Furthermore the OH concept does not look appropriate for a regulatory approach but more for a soft-regulatory or for cooperative approach in relation to surveillance.

2.2.2.3. Surveillance and compartments and zones

There are significant differences between compartments (compartments as establishments with a common biosecurity management system for a specific disease) and zones (parts of territories with a certain status for a specific disease). As regards zones, general surveillance principles may be laid down according to the character of the each disease/zone (e.g. infected/protection, surveillance, etc).

The focus of surveillance in compartments should be the "biosecurity" and "monitoring of biosecurity" that are essential components of compartments.

Monitoring the disease status of compartments may pose a challenge for surveillance. Compartments in general represent a lower level of animal health risk as compared with the surrounding animal subpopulations in the zone or country. But if the compartment includes several, spatially non-contiguous entities/holdings, they can result in increased exposure risks from the multiple ‘surrounding’ populations, unless sufficient biosecurity standards are assured for all the entities/holdings of the compartment. For that reason, authorities from areas/countries involved in or responsible for the compartment should be engaged in the monitoring of the biosecurity with clearly defined procedures for ensuring the integrity and functioning of the compartments.

2.2.2.4. Surveillance systems

The TFADS discussed key issues for ensuring proper design of surveillance systems:

2.2.2.4.1. Stakeholders

Stakeholder involvement, especially for reporting, depends on the balance between incentives (e.g. compensation, but also other means) and disincentives (e.g. confidentiality issues) for the providers of the information. Mutual trust between government authorities and other stakeholders remains an issue.

Stakeholder involvement is dependent on the category of disease (four levels from pure private interest to full public interest can be identified). In principle, the engagement of stakeholders (especially farmers) is higher for everyday problems (endemic diseases) than for unexpected problems (exotic) that are the main concern of public authorities.

Surveillance programmes, in particular those publicly funded, are usually limited to diseases of public interest but the system should be flexible enough to allow key stakeholders to develop their own initiatives.

The veterinary services have a key role in the design and implementation of the surveillance systems and should pay special attention to the involvement of other stakeholders, including stakeholders other than farmers.
2.2.2.4.2. **Scope of surveillance and categorization/prioritisation of specific surveillance programme**

The categorization/prioritisation of surveillance activities should be subjected to periodic re-assessment on the basis of their impact (risk perception, disease situation…) based on *a priori* agreed criteria.

There is an increasing demand for the inclusion of monitoring animal health conditions as indicators of welfare problems (e.g. lameness). Therefore the prioritization exercise should also include a welfare criterion.

2.2.2.4.3. **Risk-based surveillance (RBS)**

Effective and comprehensive surveillance should be the ultimate objective. The term RBS should be used with caution, since it can be easily misinterpreted and it could be argued that any surveillance system is informed by risk. It may therefore be preferable to refer to "surveillance informed by risk assessment". Adequate understanding of the disease’s epidemiology and therefore of important risk factors allowing reliable risk stratification is a necessary pre-requisite for RBS (prior knowledge about the risk factors).

The challenge for RBS is to be as epidemiologically effective as "standard" surveillance approaches and to be recognised as such by all stakeholders, including trading partners. It requires good understanding of the epidemiology of the disease under surveillance.

The comparability of the RBS systems and their credibility rely on the quality and methodology (criteria) of the risk assessment. The latter needs to be conducted prior to the design of RBS, and will have to be reviewed on a regular basis to ascertain that risks have not changed.

The estimation of the statistical confidence levels of the disease prevalence data generated through RBS represents an additional challenge, since RBS does not involve sampling of the whole population at risk, and it is therefore more difficult to generate valid numeric estimates of the sensitivity of the surveillance system.

RBS requires transparency with respect to the assessment of the risks that were conducted to inform the RBS. For that reason, the AHL should define the main requirements for the design and implementation of RBS, including the minimum components of the risk assessment (RA) that has to be conducted prior to the design and needs to be reviewed at regular intervals. "Check lists" (minimum requirements) for the documentation of RA may be drafted. Some key elements of such RA documentation are baseline information on the disease, the most important risk pathways and the resulting recommended stratification of the population according to the risk which will also take population structure and animal movements into consideration.

2.2.2.4.4. **Backyard holdings, hobby farms, wildlife and surveillance**

No general recipe can be recommended for conducting surveillance in these animal population types.

The challenge is to know which is the population at risk, how many they are, where they are and also to what extent they interface with the whole population of that species, depending on the disease.

In general, backyard/hobby holdings have to be considered in the design of a surveillance system.

Surveillance in ‘peace’ time in these holdings presents difficulties as regards sustainability but:
- for passive surveillance they should not be excluded
- for early detection of disease/infection and even for disease/infection freedom demonstration these holdings should be included
- fallen stock surveillance in these populations could be considered
- backyard holdings may even be the target of some surveillance activity depending on the outcome of the risk assessment (e.g. trichinella).

2.2.2.4.5. Surveillance networks

The veterinary services should play an active role in implementation of surveillance systems in case of notifiable diseases, especially with respect to the overall management of reporting, sampling, testing and evaluation. However, for other diseases the veterinary services do not need to be involved to quite the same extent in the implementation of surveillance but they should still have a key role in the surveillance system, potentially through connecting all surveillance components.

With respect to the relationship between diagnostic laboratories and the surveillance systems/networks, the laboratory diagnostic investigation is one component of a surveillance system/programme (a service to surveillance) and data from diagnostic laboratories has to be integrated into the surveillance system but the diagnostic laboratories cannot be the core of the surveillance system.

Laboratory testing is an important diagnostic tool and it has to provide test results according to stated quality standards. Data flows between the laboratories and the other surveillance components of a surveillance system/programme should be clearly defined.

Passive surveillance based on samples collected for other purposes (e.g. syndromic surveillance) can also provide useful information and be integrated into surveillance systems.

2.2.2.4.6. Integration of surveillance principles into the legal texts of the AHL

It is necessary to maintain flexibility: In principle, concise and precise minimum requirements avoid divergent interpretations while guidelines allow better design and implementation of the systems. A combination of (compulsory) minimum requirements and (voluntary) guidelines may be the best option. The appropriateness of both options "guidelines" vs "minimum requirements" depends on the disease, impact on trade, impact of the disease. However, in general, just setting criteria for surveillance is not recommended.

3. Bluetongue

3.1.1. Background

MS suggested that the Commission explores the possible use of "lower risk areas" (LRA) as introduced in Regulations (EC) No 123/2009 and 789/2009 in different epidemiological contexts and for different purposes:

- In a restricted territory (not free from the disease because it has experienced virus circulation in the last two years) whether vaccination has been implemented or not.
- In a territory where recent information obtained through passive and active surveillance indicates that there has not been virus circulation in the last year (vector season).
- For the purpose of avoiding the "uncontrolled" introduction of animals from the same restricted zone where the same serotype(s) had circulated in the last year (season) that may pose a risk of re-introduction of the virus to the territory that is in a favourable position of becoming free in the near future.
For this "half-way" to freedom the demarcation of a LRA will help to protecting against re-introduction while remaining restricted so movements towards free areas need further health requisites (in practice vaccination).

The Commission services considered that the current rules pose no obstacle for the use of the LRA for the purpose suggested by MS provided that the other components and specifically appropriate surveillance are in place.

The text in the Regulation "for the purpose of demarcating a part of a protection zone as a "lower risk area" in accordance to Article 7(2a) the survey must have a sample size calculated to detect a monthly prevalence of 2 % with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area" does not explicitly establish a monthly demonstration nor a monthly sampling but the detection of a monthly prevalence. However, the Commission services interprets that the sentence in the historical context with special reference to the recitals of both Regulations 123/2009 and 789/2009 indicating that surveillance in the LRA should be an ongoing activity all over the year and not a snapshot survey.

The question posed is to ascertain if, from an epidemiological point of view, it is sensible to maintain continuous surveillance in the LRA through sentinels or repeated surveys to demonstrate absence of virus circulation after one year of virus circulation not detected in a survey. In other words: is it excessive and unnecessary to make the effort of maintaining expensive "continuous surveillance" instead of a single survey at the end of the presumable first season without virus circulation with negative results?

3.1.2. Outcome of the discussion

The Portuguese experience on use of LRA (only MS using LRA currently) comes from the risk assessment as importing country and due to the risk of introduction from Africa. PT does not use sentinels but monthly surveys to achieve:

- Monitoring BTV1.
- Proving freedom from BTV8.
- Proving freedom from BTV4.

UK colleagues consider 3 possible disease statuses: endemic, epidemic, free (epidemic - describes countries which have had one or more sporadic incursions but have no evidence of continuing circulation; this may be a transitional phase).

It would be important to better understand the benefits, and the confidence gained by the continuous (or relatively frequent) surveillance using the monthly testing as compared to annual testing based on a defined sample size.

The appropriate value for design prevalence used for sample size calculation remains controversial particularly in an area where vaccination is used. It should be necessary to clearly identify which is the susceptible population in this case. If the sample size is too small or not sufficiently representative of the susceptible population then active surveillance might not be providing any additional information.

In order to better reply to the question it would be good to know the effectiveness of monthly compared with annual testing for early detection of virus circulation:

- Monthly testing may provide a better approach for earlier detection of cases if a sufficient sample of representative susceptible animals is tested, although the extent to which it can achieve this may be affected by the exposure risk and/or likelihood of limited propagation or low level circulation of virus. This situation is further complicated by the effect of herd
immunity in vaccinated populations. In addition, further information and a review of the data are needed. Monthly testing might even provide false reassurance due to the complex epidemiology of the disease in a vaccinated population.

- Monthly testing to some degree also has a cumulative effect giving more confidence since it is not necessary to test the same animals, and it could therefore be argued that the effective annual sample size is then the total number of samples taking during a year. The effective total sample size per year is therefore quite large, and may provide higher statistical confidence than a survey based on a single sample of a given size. But it needs to be acknowledged that the infection risk will be heterogeneous throughout the year, and the increase in total cumulative effective sample size is not as much as if the risk were homogenous. As in many such situations, an adequate sample size carefully selected at a particular point in time may well be as meaningful as several samples collected from less well-defined populations.

- In addition, PCR tests can revert to negative after infection; thus monthly testing or additional serological testing can reduce this type of false negative finding provided representative susceptible animals are tested.

- The frequency with which monthly testing has detected early incursion of disease has not been assessed. The TF suggested that pre-movement testing may well be more successful in some cases for early detection in MSs, and it is therefore recommended to conduct a detailed analysis of the effectiveness of current measures in place aiming at detecting infection.

In is recommended that:

- the design prevalence for BT surveillance is reconsidered since the 2% design prevalence value currently used is based on limited data from Italy.

- the required frequency of BT survey/surveillance at either monthly or annually should be reviewed, and this should include an analysis of existing data with a view to determining the effectiveness of the currently used approaches for detecting infection.

- scientific evidence on exposure risk (likelihood) should be considered for the design of surveillance systems. This relates both to disease intrinsic factors such as distance from an endemic area or time elapsed since last outbreak, as well as any applied control measures (e.g. vaccination, post-import controls).

- further evidence needs to be gathered with respect to the usefulness of wildlife monitoring for could demonstrating freedom and the risks posed by wildlife for spill-over infection to domestic animals.