FUTURE CHALLENGES FOR VETERINARY DIAGNOSTICS

VETERINARY SERVICES PERSPECTIVE

The new EU Regulation on Animal Health (Animal Health Law)

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Evolution of veterinary services

*From* traditional approach aiming at protecting domestic agriculture production
- national control of pests and diseases

*To* a broader mandate requiring stronger alliances with
- other competent authorities (e.g. public health)
- private sector
- non-agriculture stakeholders
- trading partners
Evolution of veterinary services

New challenges for veterinary services

- Globalisation of trade
- Climate change and ecology of vectors
- Emerging diseases
Evolution of veterinary services

Modern VS have to operate in the context of the WTO SPS Agreement (OIE and Codex standards)

- rights and obligations
- transparency (disease notification)
- scientifically based risk analysis
- not more trade restrictive than necessary
- provisional measures
- equivalence
- proportionality
- non-discrimination
Veterinary services and emerging diseases

Addressing emerging diseases requires an interdisciplinary approach with trained staff being able to take advantage of the latest diagnostic techniques and sound communication strategy.

This is necessary to ensure the credibility of VS:

- national stakeholders
- trading partners
Network of EU Reference Laboratories

38 EU Reference Laboratories:

- 21 in the sector of feed and food
- 17 in the field of animal health and live animals (e.g. AI, CSF, BT)

Around 4 Million € for financing AH and live animals EURL in 2011 from the EU budget alone

3 main tools for coordination:

- Common basic EU legal framework
- Common financing provisions and management
- Evaluation of performance

Additional tool:

- Scientific forum for EURL
Network of EU Reference Laboratories

Common basic EU legal framework

- **Horizontal rules** (Regulation (EC) No 882/2004)
- **Vertical by disease**
  - obligation to establish a National RL in each EU Member State
  - designates the EU Ref Lab for a particular disease
  - obligation to submit isolates to the EU Ref Lab
  - minimum safety requirements to be met by the labs

  e.g. COUNCIL DIRECTIVE 2001/89/EC on Community measures for the control of classical swine fever and COMMISSION DECISION 2002/106/EC approving a Diagnostic Manual
EU ANIMAL HEALTH LAW: Why a new law and what is it all about?
The EU Animal Health Law

- The main instrument to implement the objectives of the Animal Health Strategy (2007-2013)
- More risk based, proactive, preventive behaviour
- Horizontal principles and rules for transmissible diseases
- Simplify existing rules:
  - Numerically
  - In substance
- Align with Lisbon Treaty
- Fit for decades to come
- No revolution, but evolution
The Animal Health Law (AHL)

- **From** a fragmented legislation of ca. 40 Directives and Regulations
- **To** a single and robust legal framework for animal health
- Laying down the overarching principles for:
  - Disease prevention (disease awareness, registration, traceability, biosecurity)
  - Disease control and eradication
  - Intra-EU movements and entry into the EU of animals and animal products
  - Emergency measures
  - *Supplementing rules needed to ensure complete implementation*
    - Detailed provisions of the current Directives and Regulations included in delegated and implementing acts
Animal Health Law:
NEW ELEMENTS AND SPECIFIC CHANGES
AHL – New elements

• The main instrument to implement the objectives of Animal Health Strategy (2007-2013) "Prevention is better than cure"

• The scope:
  • Transmissible diseases
  • Kept and wild animals (not only production animals) and their products
  • Terrestrial, aquatic and other animals

• Responsibilities of keepers, operators, veterinarians, competent authorities, etc.

• Risk based approach: Categorization/prioritisation of diseases for EU intervention

• Improved response to emerging diseases
AHL – New elements

• **More prevention:**
  - Biosecurity at farms, in transport, assembly, at borders
  - Enhanced surveillance, disease notification and reporting
  - Clearer policy for the use of vaccines and in relation to disease control & diagnosis **also some other veterinary medicines**

• **Easier and safer trade:**
  - Enhanced convergence with international standards on animal health (OIE)
  - Compartmentalisation
  - Requirements for export
  - Added flexibility
AHL – Added flexibility

More flexibility to adjust to:

- Climate changes and emerging risks
- International standards and scientific developments
- Different sizes and types of establishments, types of animal production
- Local circumstances (registration, approval, etc.)
- Systems providing equal guarantees (for animal movements, traceability, etc.)

Objectives:

- Better response to new threats and adjustment to local circumstances
- Reduce administrative burdens/costs, where involved risks permit so
Surveillance

*The competent authority shall:*

- **conduct surveillance for the listed diseases and for emerging diseases**
  Surveillance plan shall ensure timely detection, collating and analysing relevant information relating to the disease situation

- **ensure that the surveillance information is collected and used in an effective and efficient manner**
Union intervention for transmissible animal diseases

- **Disease listing and categorisation:**
  - listing of diseases requiring EU intervention
  - which measures to be applied for which diseases

- **Clusters of rules for listed diseases** (categories of diseases)
  - Disease notification, surveillance
  - Measures in "trade" – movements within and between Member States and entry into the Union
  - Eradication (compulsory or voluntary) & disease freedom
  - Disease control measures

- **Response to emerging diseases**
Categorisation and prioritisation

- *Study with OIE and the disease categorisation and prioritisation tool*
  - Available on SANCO web
- *Dynamic and transparent:*
  - Criteria for categorisation and prioritisation in AHL
  - Lists and tables in Commission acts
Risk communication

- The **competent authority** shall take appropriate steps to **inform** the general public of the nature of the risk and the measures which are taken to prevent or control that risk.
Laboratories

- *take appropriate biosecurity, biosafety and bio-containment measures to prevent the escape of the disease agents*
- *movement of disease agents/vaccines between laboratories do not give rise to a risk of the spread of listed and emerging diseases*

- Delegated acts envisaged
Surveillance

- *The competent authority shall:*  
  - **conduct surveillance for the listed diseases and for emerging diseases**  
    Surveillance plan shall ensure timely detection, collating and analysing relevant information relating to the disease situation  
  - **ensure that the surveillance information is collected and used in an effective and efficient manner**
Disease control measures

- *Investigation by the competent authority in the event of disease suspicion*
  - official veterinarians to carry out laboratory examination to confirm the presence of the particular listed disease
Disease confirmation and lifting of preliminary control measures

- The competent authority shall base an official confirmation on:
  - results of the clinical and laboratory examinations
  - epidemiological enquiry
  - other available epidemiological data

- Delegated acts
AHL: When?

- **AHL proposal adopted by the Commission**
- **Discussions in the Council and the EP will start**
- **Envisaged period for adoption of delegated and implementing acts: 36 months**
In conclusion

- **AHL builds upon the good experiences of the existing legal framework**
- **provides solid role played by the veterinary services in using veterinary laboratories to obtain swift and reliable diagnostic support when investigating suspected outbreaks or when communicating and acting on a confirmation of an outbreak of a relevant disease**
In conclusion

- newly available diagnostic techniques will likely lead to the detection of previously unknown viruses and disease agents all over the world
- this will be a crucial test for the international community
- any country that follows international standards and acts within the spirit of the SPS Agreement must not be unduly penalised
In conclusion

- scientific community should continue to perform its research activities, with its traditional transparent approach, without having to consider the implications that each new finding might have on international trade