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

USAHA/AAVLD Committee on International Standards
21 October, 2013

Francisco Javier Reviriego Gordejo
EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL
G2 - Animal Health
Head of Sector Disease Control and identification
The European Union:

- 500 million citizens
- 28 countries
- 24 official languages
Citizens, interest groups, experts: discuss, consult

Commission: makes formal proposal

Parliament and Council of Ministers: decide jointly

National or local authorities: implement

Commission and Court of Justice and Court of auditors: monitor implementation
Contents

• Animal Health Law: what it is all about?
• Main new elements & specific changes
• Why this is of any interest overseas?
• Expected timetable
ANIMAL HEALTH LAW: Why a new law and what is it all about?
Animal Health Strategy (2007-2013)
"Prevention is better than cure"

Underlying principles: Partnership and Communication

<table>
<thead>
<tr>
<th>Pillar 1</th>
<th>Pillar 2</th>
<th>Pillar 3</th>
<th>Pillar 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defining Priorities</td>
<td>Modern Legal Framework</td>
<td>Prevention and Controls</td>
<td>Science, Innovation &amp; Research</td>
</tr>
</tbody>
</table>

The EU Animal Health Law

- The **main instrument to implement** the objectives of the Animal Health Strategy (2007-2013)
- **Aims at a** more risk based, proactive, preventive behaviour
- **Provides for a** single and robust legal framework
- **Achieves** simplification of existing rules:
  - **Numerically** (from legislation of ca. 40 major pieces of legislation - Directives and Regulations)
  - **In substance** (real simplification)

No revolution, but evolution
What is **in** the Animal Health Proposal?

- **Transmissible animal diseases** **in:**
  - Kept and wild animals (not only production animals) and their products
  - Terrestrial, aquatic and other categories of animals

- **Animal health rules for:**
  - Disease prevention (disease awareness, biosecurity surveillance, traceability,)
  - 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
What is **out** of the Animal Health Proposal?

**Not in scope:**
- Welfare of animals
- Pathologies of individual animals
- Veterinary checks, controls
- EU veterinary expenditure
- Feed, medicated feed
- Veterinary medicines
- Veterinary education

**In scope but specific rules remain in place:**
- ABPs (!!!)
- TSE rules
- Certain zoonoses (e.g., Salmonella)
Animal Health Law:
NEW ELEMENTS AND SPECIFIC CHANGES
New elements in the proposal (1)

- **An explicit scope:**
  - Transmissible diseases
  - Kept and wild animals (not only production animals) and their products
  - Terrestrial, aquatic and other animals

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

- **Clear responsibilities** of keepers, operators, veterinarians, competent authorities, etc.

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

- **Improved response to emerging diseases**
New elements in the proposal (2)

- **More prevention:**
  - Biosecurity at farms, in transport, assembly points, at borders
  - Enhanced surveillance (animal health visit), disease notification and reporting
  - Clearer policy framework for the use of vaccines

- **Easier but safe trade:**
  - Enhanced convergence with international standards on animal health (OIE)
  - Basis for compartmentalisation
  - Requirements for export
New elements in the proposal (3)

- **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.)
Union intervention for transmissible animal diseases

- **Disease listing and categorization:**
  - listing of diseases requiring EU intervention (Study with OIE on a the disease categorisation and prioritisation tool)
  - which measures to be applied for which diseases

- **Clusters of rules [boxes] for listed diseases** (categories of diseases, not exhaustive!)
  - Diseases for immediate eradication, surveillance (FMD)
  - Diseases eradication & disease freedom with measures in "trade" and movements (Bru)
  - Diseases with voluntary control eradication and additional guarantees for trade (Auj)
  - Disease with general monitoring control measures (BVD)

- **Response to emerging diseases**
Union intervention: Antimicrobial resistant pathogens

- AMR pathogens are considered as "disease agents"
- Following the outcome of disease categorisation / prioritisation
  - Different disease preventive and control measures may be applied (notification, surveillance, eradication, disease control measures, movement control, etc.)
Union intervention for different species kept animals and for wild animals (scope)

• **Kept animals:**
  • Animal health requirements mainly apply to certain animal species (bovines, sheep & goats, pigs, horses..)
  • Other species and other animals: basic requirements apply & possibility to lay down rules (bees, amphibians, etc.)
  • Special rules for certain categories (pet animals, zoos, circuses, "confined" establishments, etc.)

• **Wild animals:**
  • Possibility to lay down rules (surveillance, eradication, disease control, movements)
Movements within the Union

- General animal health requirements apply for all movements of kept animals (excl. pet animals)
  - Traceability, disease prevention in transport, animals from establishments without restrictions, etc.
  - Some trade facilitation mechanisms foreseen

- Disease specific requirements apply for movements between MSs
  - Animal species presenting risk for spreading diseases
  - Operations presenting risk (assembly of animals)

- Certain differences between terrestrial and aquatic
Entry into the Union: the approach

- **Animal health requirements:**
  - As stringent as those within the Union, or
  - Recognised as equivalent

- **For:**
  - Live animals
  - Germinal products
  - Products of animal origin

- **Other material presenting animal health risk**
  - e.g. Disease agents, feed and fodder accompanying animals, etc.

- **For Animal by-products:**
  - **Remain** in existing **ABP regulation** (Not in AHL)
Animal health requirements for entry into the Union: basic requirements

- **Animals and products ONLY IF:**
  - **From listed countries & territories**
    - Zones and compartments
  - **From listed establishments (where relevant)**
  - **Comply with specific animal health conditions in relation to:**
    - Species and categories of animals or products
    - Related disease(s)
  - **Accompanied by animal health certificate and/or another document**
  - **Presented to the Union's border control**
The vision

REGULATION on ANIMAL HEALTH

GENERAL RULES:
Responsibilities, biosecurity, disease categorization and prioritization, notification, surveillance, disease freedom

• Disease control
  • Entry into EU
  • Emergency measures

TERRESTR. ANIMALS
• EU movements

AQUATIC ANIMALS
• EU movements

OTHER ANIMALS
• EU movements

Secondary rules: Delegated/ implementing

DISEASE CONTROL

MOVEMENTS:
Animals & Products

ENTRY into EU:
Animals & Products
Animal Health Regulation: WHEN?

- **AHL proposal adopted** by the Commission on 6th May, 2013
- **Discussions in the Council and the EP ongoing**
- **Envisaged period for adoption of delegated and implementing acts**: 36 months from the date of entry into force
- **To learn more about the Animal Health proposal:** [http://ec.europa.eu/food/animal/animal-health-proposal-2013_en.htm](http://ec.europa.eu/food/animal/animal-health-proposal-2013_en.htm)
In conclusion

- Animal health Regulation builds upon the good experiences of the existing legal framework

- Provides:
  - Solid ground for healthier animals and humans
  - Clearer and better understood framework for operators, citizens and non-EU countries
  - Flexibility

- Provides new elements for more:
  - Competitive and sustainable livestock and aquaculture sectors
  - Confident consumers
Thanks