Animal Health Law
- What do we need to know about it?

Søren Saxmose Nielsen
Animal Health Law (AHL)

- Rules of transmissible diseases of terrestrial and aquatic animals
  - Disease prevention, awareness, biosecurity, traceability, movements of animal (intra-EU and into EU), surveillance, disease control, eradication
  - Not animal welfare, except when disease impacts welfare
- Most relevant aspects will come into force in 2021
  - Replacing 33 Directives, 2 Regulations and 3 Decisions, e.g. Directive 64/432/EEC
  - All countries have to implement rules that are yet to be defined
Management of transmissible diseases in EU

• First common veterinary legislation adopted in 1964
  • On health requirements for intra-community trade in cattle and pigs (Council Directive 64/432 EEC)
• Animal Health Law adopted 2016 - implemented by 2021
• Denmark became part of European Communities (EEC) in 1973 along with Ireland and United Kingdom
  • “Better” disease status in the “new” compared to the existing EEC countries, e.g.
    • Denmark had no Classical Swine Fever since 1933, Ireland since 1958 and UK since 1971
    • Denmark had no Foot and Mouth Disease since 1970, Ireland since 1941 and UK since 1968
• Consequences (needed implementation in the legislation)
  • Ban on imports of cattle, sheep, goats, pigs, and fresh meat from these
  • Immediate elimination by stamping-out – directed by efficient veterinary services established e.g. in the UK following the great FMD epizootic in 1967-68
Objective: status quo / control / eradication?
- assessing the individual disease/microorganism

Character in population
- Exotic
- Sporadic
- Endemic

Purpose
- Impact reduction on production or society
  - Including economy, public health, animal health
  - Also possible impact for bioterrorism, bio-diversity and environment

Lead in decision making
- Farmer
- International organisations

Impact
- Small/localised
- Big/many affected

Objective/task
- Status quo
- Control
- Eradication

Activity
- Toolbox (examples)
  - Zoning. Regionalisation. Compartmentalisation
AHL: Assessment and management of listed diseases in the European Union

- Decisions on framework <- European Parliament (decision makers, politicians, lay-persons)
  - Assessment of specific diseases <- European Food Safety Authority (EFSA) (assessors, disease experts)
  - Decisions on specific diseases <- European Commission (technocrats, managers, politicians)
  - Implementation in individual countries <- National governments and competent veterinary authorities
Assessment on listing and categorisation of diseases in AHL framework

Disease assessment

Art. 7 criteria
Fact-sheet: Disease profile and impacts
Compiled by disease scientist; reviewed by EFSA AHAW

Art. 5: Listing
Disease assessment
Expert judgement (9-12 judges from EFSA AHAW)

Art. 9: Categorisation
Disease assessment
Expert judgement (9-12 judges from EFSA AHAW)

Art. 8: Species to be listed
(a) Susceptible species
(b) Vectors or reservoirs

Production impact
Public health impact
Animal welfare impact
Ecological impact
Crisis or Bioterror?
Prevention & Control?
Feasibility
Cost & Impact

EFSA AHAW Panel, 2017. EFSA J, 15(7): 4783
Judgement on listing according to Article 5

Art. 5: Listing
Disease assessment
Expert judgement (Art. 7 params)

A(i) The disease is transmissible: Y
A(ii) Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union: Y
A(iii) The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character: Y
A(iv) Diagnostic tools are available for the disease: Y
A(v) Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union: Y

B(i) The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character: na
B(ii) The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union: N
B(iii) The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union: N
B(iv) The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism: N
B(v) The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union: NC

All A-criteria should be "Y" for listing to be recommended
Over and above all A-criteria, at least one B-criterion should be "Y" for listing to be recommended

Conclusion: Eligible for listing: Y/N/NC
If listed: which intervention?
Judgement on categorisation - Article 9

<table>
<thead>
<tr>
<th>Category</th>
<th>Article 9 criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st set of criteria</td>
</tr>
<tr>
<td></td>
<td>All should be Y</td>
</tr>
<tr>
<td>A</td>
<td>Mostly absent</td>
</tr>
<tr>
<td>B</td>
<td>Endemic &amp; free zones</td>
</tr>
<tr>
<td>C</td>
<td>Endemic</td>
</tr>
<tr>
<td>D</td>
<td>Movement control on animals or products effective and proportionate for risk mitigation</td>
</tr>
<tr>
<td>E</td>
<td>Surveillance required for reasons relating to animal health, animal welfare, human health, economy, society or environment</td>
</tr>
</tbody>
</table>
## Enzootic bovine leukosis – listing (Article 5)

### Criteria to be met by the disease:
According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
<th>Final outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>A(i)</td>
<td>The disease is transmissible</td>
<td>Y</td>
</tr>
<tr>
<td>A(ii)</td>
<td>Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union</td>
<td>Y</td>
</tr>
<tr>
<td>A(iii)</td>
<td>The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character</td>
<td>Y</td>
</tr>
<tr>
<td>A(iv)</td>
<td>Diagnostic tools are available for the disease</td>
<td>Y</td>
</tr>
<tr>
<td>A(v)</td>
<td>Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union</td>
<td>Y</td>
</tr>
</tbody>
</table>

### At least one criterion to be met by the disease:
In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
<th>Final outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>B(i)</td>
<td>The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character</td>
<td>NC</td>
</tr>
<tr>
<td>B(ii)</td>
<td>The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union</td>
<td>na</td>
</tr>
<tr>
<td>B(iii)</td>
<td>The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union</td>
<td>NC</td>
</tr>
<tr>
<td>B(iv)</td>
<td>The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism</td>
<td>N</td>
</tr>
<tr>
<td>B(v)</td>
<td>The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union</td>
<td>N</td>
</tr>
</tbody>
</table>

All should be Y

At least 1 should be Y
Enzootic bovine leukosis – categorisation (Art. 9)

<table>
<thead>
<tr>
<th>Category</th>
<th>Geographical distribution</th>
<th>Transmissibility</th>
<th>Routes of transmission</th>
<th>Multiple species</th>
<th>Morbidity and mortality</th>
<th>Zoonotic potential</th>
<th>Impact on economy</th>
<th>Impact on society</th>
<th>Impact on animal welfare</th>
<th>Impact on environment</th>
<th>Impact on biodiversity</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>NC</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>NC</td>
<td>N</td>
</tr>
<tr>
<td>B</td>
<td>NC</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>NC</td>
<td>N</td>
</tr>
<tr>
<td>C</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>NC</td>
<td>N</td>
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<tr>
<td>D</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NC</td>
<td></td>
<td></td>
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<tr>
<td>E</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EBL – Non-consensus: Art. B(i)

<table>
<thead>
<tr>
<th>Question</th>
<th>Final outcome</th>
<th>Y (%)</th>
<th>N (%)</th>
<th>na (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B(i) The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character</td>
<td>Non-consensus</td>
<td>62</td>
<td>38</td>
<td>0</td>
</tr>
</tbody>
</table>

Reasoning supporting the judgment

Supporting Yes
• In endemic areas within the EU, seroprevalence ranges from 0.01% to 12% (2015), 0% to 1–2% of BLV-infected animals can develop lymphomas. Furthermore, there is evidence that BLV-infected herds register a reduction in milk yield

Supporting No
• The probability to develop lymphomas over the lifespan of the animals is low
<table>
<thead>
<tr>
<th>Disease</th>
<th>Listed in DK</th>
<th>EFSA assessment</th>
<th>Union intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brucellosis</td>
<td>L1</td>
<td>Yes</td>
<td>B, C, D, E</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>L1</td>
<td>Yes</td>
<td>(B), C, D, E</td>
</tr>
<tr>
<td>Paratuberculosis</td>
<td>No</td>
<td>Yes</td>
<td>C, D, E</td>
</tr>
<tr>
<td>Border disease</td>
<td>No</td>
<td>Yes</td>
<td>C, D, E</td>
</tr>
<tr>
<td>Borna disease</td>
<td>No</td>
<td>Yes</td>
<td>C, D, E</td>
</tr>
<tr>
<td>Trichomononosis</td>
<td>No</td>
<td>Yes</td>
<td>C, D, E</td>
</tr>
<tr>
<td>Bluetongue</td>
<td>L1</td>
<td>Yes (BTV1-24 (not BTV16))</td>
<td>B, (C), E</td>
</tr>
<tr>
<td>BVD</td>
<td>L2</td>
<td>Yes</td>
<td>(C), D, E</td>
</tr>
<tr>
<td>IBR</td>
<td>L1</td>
<td>Yes</td>
<td>(C), D, E</td>
</tr>
<tr>
<td>Campylobacter fetus subsp. fetus</td>
<td>No</td>
<td>Yes</td>
<td>(C), D, E</td>
</tr>
<tr>
<td>Contagious bovine pleuropneumonia</td>
<td>L1</td>
<td>No</td>
<td>D, E</td>
</tr>
<tr>
<td>Anthrax</td>
<td>L1</td>
<td>Yes</td>
<td>D, E</td>
</tr>
<tr>
<td>Enzootic bovine leukosis</td>
<td>L1</td>
<td>No consensus</td>
<td>(D), (E)</td>
</tr>
<tr>
<td>Equine encephalomyelitis (eastern and western)</td>
<td>L1 (not cattle)</td>
<td>Yes</td>
<td>(D), E</td>
</tr>
<tr>
<td>Venezuelan equine encephalitis</td>
<td>L1 (not cattle)</td>
<td>No consensus</td>
<td>(D), (E)</td>
</tr>
<tr>
<td>Trypanosoma evansi</td>
<td>No</td>
<td>No consensus</td>
<td>(D), (E)</td>
</tr>
<tr>
<td>Japanese encephalitis</td>
<td>L1</td>
<td>No</td>
<td>E</td>
</tr>
<tr>
<td>Aujeskey’s disease</td>
<td>L1 (multiple sp)</td>
<td>No (not cattle)</td>
<td>D, E</td>
</tr>
</tbody>
</table>

A = Eradication of exotic diseases  
B = Control with an aim of eradication  
C = Prevention of spread from infected to free MS  
D = Prevention of spread via movement control  
E = Surveillance
Disease listing and categorisation

- Eligibility for Listing (Art 5) dependent on disease profile (Set A) and disease impact (Set B)
  - Most challenging for new diseases with limited information, and
  - Old diseases that has been eradicated from most MS and where updated disease information is not available
- Categorisation – for intervention (tools)
  - To great extent based on occurrence, transmission and morbidity and mortality
    - A: Immediate measures must be taken to eradicate disease
    - B: Must be controlled in all MS with a goal to eradicate from EU
    - C: Spread from MS with endemic disease to free areas must be prevented
    - D: Movement control into and between MS to prevent spread
    - E: Need for surveillance
- Animal species
  - List can be very specific or very long

Assessments a reflection of the specific experts’ expertise and beliefs