OIE endorsement of FMD control programs and recognition of disease-free status

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President: OIE Scientific Commission for Animal Diseases
The OIE disease status recognition process

- **Two categories of disease status recognition:**
  - **Official** – endorsed by Resolution at OIE Annual General Assembly – published on OIE website
  - **Self-declaration** – no official status – published in *Bulletin* of OIE

- **Official disease status recognition:**
  - FMD – 1995
  - CBPP – 2003
  - BSE – 2004
  - AHS – 2012
  - CSF – due for adoption

- **Self-declaration not applicable to non-listed diseases or diseases listed for official recognition**
TERRESTRIAL ANIMAL HEALTH CODE and MANUAL

- To allow trade in animals and products while avoiding unjustified trade barriers
- To support countries in the control, prevention and diagnosis of animal diseases
- To allow recognition of disease status for OIE listed diseases
- To recognise and endorse official control programs for FMD
Principle of Terrestrial Code chapter on FMD

- Define disease for trade purposes
- Define infectivity
- Categories of disease freedom
- Endorsement of official control programs for FMD
- Risk mitigations for trade in animals and animal products
- Surveillance guidelines to prove absence of disease/absence of infection
- Requirements for recovery of status
Provisions of the OIE Terrrestrial Animal Health Code for freedom from foot and mouth disease

- Generic to all FMD status classifications and recognition of control programs
  - Disease is notifiable
  - Surveillance
  - Regular reporting
  - Proof of absence from infection/virus circulation
  - Separation of animals from different health status
  - Application of health measures to prevent introduction of FMDV
Provisions of the OIE Terrrestrial Animal Health Code for freedom from foot and mouth disease

• Historical freedom
• Free country without vaccination
• Free country with vaccination
• Free zone without vaccination
• Free zone with vaccination
• Containment zone
• Free compartment with vaccination
• Trade in safe commodities
Mandate of the Scientific Commission for Animal Diseases (SCAD) – Resolution 25

- Reinstatement of loss of disease free status following an outbreak of disease
- Approval of establishment of a containment zone
- Recommendation to International Committee of OIE for new zones/free countries/extension of existing zones
- Recommendation for the endorsement of official control programs for FMD
- Subject to country comments 60 days prior to General Session
Criteria/mandate to SCAD for assessing applications by Member Countries

- Mandate to SCAD through democratic election by the OIE World Assembly of Delegates
- Specific requirements of Chapter 8.5 of the *Terrestrial Animal Health Code*
- Requirements contained in horizontal chapters of the *Code* (Quality of Veterinary Services, Disease Surveillance, etc.)
- Requirements for FMD vaccines and diagnostic tests prescribed in the OIE *Manual*
- Resolution 25 as amended and adopted at the 80th OIE General Session (procedures for status recognition/suspension of status)
- Resolution 26 as amended and adopted at the 80th OIE General Session (cost recovery for status recognition)
Recognition of disease status: New application or re-instatement after an outbreak

• **Time frames** and requirements specified in the *Terrestrial Code*

• Documented evidence required

• Analysis by the Scientific Commission alone or in combination with an *Ad hoc* Group – Fast track procedure

• Endorsement by World Assembly of Delegates
Progression with disease status recognition for the purpose of trade

- Infected/unknown status
- Containment zone
- Trade in safe commodities
- Zonal freedom
- Containment zone
- Country freedom
- Compartments
- Endorsed official control program
Protection zone

‘means a zone established to protect the health status of animals in a free country or free zone, from those in a country or zone of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or free zone. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance’
Zone/Region

‘means a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade’
Compartment

‘means an animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade’
Protection zone

• Replace previous definition of buffer zone
• Emphasis on separating animals of different health status through application of measures to mitigate introduction of disease
• Incorporates definition of surveillance zone
• Could be within or outside a free zone
• If inside – outbreak in protection zone will affect status of free zone – if a containment zone is not created
• If outside free zone – outbreak in protection zone will not affect status of free zone
Management of disease status between zones of different status – progressive zoning
Management of disease status between zones of different status - progressive zoning (Resolution 25 of 80th GS)
ADJOINING COUNTRY REALITIES – CROSS-BORDER RELATIONS

Country A
FMD free

Country B
FMD infected
Official allocated disease free status by OIE (FMD) (2012)

- 65 Countries free without vaccination
- 1 Country free with vaccination
- 10 zonal freedom with vaccination
- 4 zonal freedom without vaccination
- 3 Countries with endorsed official programs

But...
>100 countries still endemically or sporadically infected
FMD – current status of reporting to OIE (2012)
OIE Member Countries' official FMD status map
As recognised during the 80th General Session in May 2012

Official FMD status of Member Countries - Whole country or zone(s)
- Green: Country/zone free without vaccination
- Light green: Country/zone free with vaccination
- Dark red: Suspension of the status free without vaccination
- Red: Suspension of the status free with vaccination
- White: Containment zone
- Gray: No recognised status
To further progress towards global FMD control.....
Endorsement of official control programs for FMD

• Article 8.5.48 endorsed for addition to Chapter 8.5 during 79th General Session
• Is not a status recognition but an endorsement of the national plan of a Member Country to progressively move towards freedom from FMD (with or without vaccination) in accordance with the requirements of the Code
• Country need not to be already free from FMD but must provide evidence that it already has a national plan in operation to move towards freedom
• Useful tools to help Member Countries to assess compliance with requirements of Article 8.5.48 and the information required in the Questionnaire in Chapter 1.6.7 of the Code are the OIE PVS Pathway and the FMD-PCP
• Endorsement can be suspended if non-compliance with Code requirements
Endorsement of an official national control program for FMD

- Is a voluntary decision by a Member Country
- Evidence of capacity of VS (PVS assessment)
- Plan applicable to entire country
- Evidence of disease reporting
- Information on epidemiology of disease in country
- Control measures to prevent FMDV introduction
- Surveillance in accordance with the Code
- Detailed plan on future timeline and intended milestones/performance indicators
- Diagnostic access/capabilities
- Vaccination program
FMD - General application/strategies/perceptions for vaccination

- In countries/zones officially free with vaccination – applied annually/bi-annually
- Seldom/selectively applied in countries endemically infected
- Emergency vaccination in the event of disease threat/disease introduction
- Cattle species of choice – sheep and pigs selectively vaccinated and mostly to counteract threat or perceived risk
- High potency vaccines for emergency vaccination
- High purity vaccines when moving towards disease free status and for demonstration of DIVA
- Mostly bi-valent or poli-valent vaccines
FMD - Vaccination of cattle
FMD – Vaccination of pigs

- Vaccination pigs
- Members free without vaccination

© OIE 2009
FMD - Vaccination of small ruminants

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<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Intention of OIE Member to apply for official dis. stat. recog.</td>
</tr>
<tr>
<td>2.</td>
<td>Detailed documentation from OIE Member to OIE hq</td>
</tr>
<tr>
<td>3.</td>
<td>Examination of data and supporting documents by OIE HQ Bureau and experts of an <em>ad hoc</em> Group</td>
</tr>
<tr>
<td>4.</td>
<td>If necessary, expert mission to the country</td>
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<tr>
<td>5.</td>
<td>Endorsement of recommendation by the Scientific Commission</td>
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<tr>
<td>6.</td>
<td>Decision of OIE International Committee by consensus – formal resolution</td>
</tr>
<tr>
<td>7.</td>
<td>Outcomes published on OIE Web site</td>
</tr>
</tbody>
</table>
Member country questionnaires (Chapter 1.6)

- To assist countries in submitting data in logical format
- Different questionnaires for different disease status application – free country with or without vaccination; free zone with or without vaccination
- Compliance with specific requirements in the FMD chapter for specific disease status
- Compliance with minimum requirements for veterinary service delivery
- Data on outcome of surveillance to demonstrate absence of disease/absence of virus circulation
Basic requirements for Member applications

- Veterinary services, general requirements
  - Compliance with Chapter 1.3.3. of the *Terrestrial Code* on the quality and evaluation of the Veterinary Services;
  - Transparency in the planning and execution of surveillance activities in accordance with Chapter 1.1.2. of the *Terrestrial Code*.
  - Compliance with the requirements of Chapter 8.5

- Continuous compliance with reporting obligations (e.g. WAHIS)
  - 6-monthly animal health reports
  - Annual animal health reports
  - Reporting of unusual animal disease events

- Payment of annual OIE Member contributions
Submission of dossiers

The OIE Member:

– Submits the complete documentation (dossier) based on a questionnaire – 45 days before meeting of AHG

– The Member has to document that it complies with the disease specific provisions of the Terrestrial Code
  • Eradication and surveillance
  • Legislation and its implementation
  • Import and border control
  • Animal movement control
  • ….

– Together with a cover letter signed by the OIE Delegate
– Pays the requested evaluation fees
At the Central Bureau of OIE:

- **Preliminary analysis** of the dossier for e.g. missing data
- Advice from an *Ad hoc Group* which analyzes the documentation for compliance with the *Terrestrial Code*
- Ask the Member for **additional information** if required
- Receives a delegation from the applicant Member for clarification of open questions if required
- Submission of AHG assessment submitted to SCAD for final evaluation/recommendation to General Assembly
Principles of *Ad hoc* Groups:

- OIE convenes a group of experts to examine specific scientific and technical issues, including official disease status evaluations.
- Internationally recognized expertise concerning the disease or the technical aspect under question.
- Geographically balanced.
- Technically balanced (diagnostics, field, epidemiology, ...).
- Reports serve as guidance for the Specialist Commissions and the International Committee in forming recommendations and taking decisions.
The Scientific Commission of the OIE:

- Analyzes the comments from the AHG
- Concludes with a final recommendation on the status of the applicant OIE Member
- Asks the Country for additional information if required
- Proposes the updated list (Resolution) for adoption by the General Assembly
- Receives a delegation from the applicant Member country for clarification if necessary
- Provide a detailed report to the applicant country in the case of a negative assessment
Once the application is endorsed by Scientific Commission:

– All the Delegates of OIE Members are informed about successful applicants’ claims

– Members have **60 days for written objections** (scientific or technical)

- consultation of experts and ad hoc Groups
- detailed analysis of submitted data/objections
The OIE World Assembly of Delegates

- Adopts amendments on the procedure once a year
- Adopts the new resolutions on disease specific categorisation status of Members
- Establishes an official list of countries, zones reflecting the relevant status
Publication of official disease status
Publication of official disease status

The Committee

RESOLVES THAT

1. The Director General publish the following list of Member Countries recognised as FMD free countries where vaccination is not practised, according to the provisions of Chapter 2.2.10. of the Terrestrial Code:

<table>
<thead>
<tr>
<th>Albania</th>
<th>Germany</th>
<th>New Caledonia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Greece</td>
<td>New Zealand</td>
</tr>
<tr>
<td>Austria</td>
<td>Guatemala</td>
<td>Nicaragua</td>
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<tr>
<td>Belarus</td>
<td>Guyana</td>
<td>Norway</td>
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<tr>
<td>Belgium</td>
<td>Honduras</td>
<td>Panama</td>
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<tr>
<td>Bosnia and Herzegovina</td>
<td>Iceland</td>
<td>Poland</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Indonesia</td>
<td>Portugal</td>
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<tr>
<td>Canada</td>
<td>Ireland</td>
<td>Romania</td>
</tr>
<tr>
<td>Chile</td>
<td>Ireland</td>
<td>Serbia and Montenegro (1)</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>Italy</td>
<td>Singapore</td>
</tr>
<tr>
<td>Croatia</td>
<td>Japan</td>
<td>Slovakia</td>
</tr>
<tr>
<td>Cuba</td>
<td>Korea (Rep. of)</td>
<td>Slovenia</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Latvia</td>
<td>Spain</td>
</tr>
<tr>
<td>Czech Rep.</td>
<td>Lithuania</td>
<td>Sweden</td>
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<tr>
<td>Denmark</td>
<td>Luxembourg</td>
<td>Switzerland</td>
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<tr>
<td>El Salvador</td>
<td>Madagascar</td>
<td>Ukraine</td>
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<td>Estonia</td>
<td>Malta</td>
<td>United Kingdom</td>
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<tr>
<td>Finland</td>
<td>Mauritius</td>
<td>United States of America</td>
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<tr>
<td>Former Yug. Rep. of Macedonia</td>
<td>Mexico</td>
<td>Vanuatu</td>
</tr>
<tr>
<td>France</td>
<td>Netherlands</td>
<td></td>
</tr>
</tbody>
</table>

(1) Including the territory of Kosovo administered by the United Nations

2. The Director General publish the following list of Member Countries recognised as FMD free countries where vaccination is practised, according to the provisions of Chapter 2.2.10. of the Terrestrial Code:

Taiwan, China and Uruguay
### Fees payable for official status recognition/official program

<table>
<thead>
<tr>
<th>Zone(s) under consideration</th>
<th>OIE Member Countries (except least developed countries)</th>
<th>Least developed countries (Members) based on the current official UN list</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BSE</td>
<td>FMD</td>
</tr>
<tr>
<td><strong>Entire territory</strong></td>
<td>9,000</td>
<td>7,000</td>
</tr>
<tr>
<td><strong>Only one zone</strong></td>
<td>9,000</td>
<td>7,000</td>
</tr>
<tr>
<td><strong>More than one zone at the same time</strong></td>
<td>9,000</td>
<td>7,000</td>
</tr>
<tr>
<td><strong>Reinstatement of the status within the same territory of the Members for the same zone/s</strong></td>
<td>free of charge</td>
<td>free of charge</td>
</tr>
<tr>
<td><strong>Endorsed official control programme for FMD</strong></td>
<td>2,000</td>
<td>free of charge</td>
</tr>
</tbody>
</table>
Reinstatement of status after an outbreak

- **Time frames** and requirements specified in the *Terrestrial Code*
- Documented evidence required
- Evaluation by the Scientific Commission on recommendation of *Ad hoc* Group – immediate reinstatement
- Visit to Member Country to verify situation if deemed necessary by SCAD – Resolution 25
Review of Chapter 8.5 (FMD)

- Special meeting of *ad hoc* Group – next meeting due in July 2012
- Simplify text
- Make concepts such as containment zone more user-friendly and more easy to apply
- Status with and without vaccination post outbreak
- Reassessment of time periods to recover status
- Amended text for endorsement of FMD official control programs
- Provided additional text in questionnaire to enable information on future plans and timelines for FMD control
- Resolution 25 to update procedures for official disease status recognition
- Resolution 26 to update the costs to be covered by Member countries applying for official disease status recognition or endorsement of official control programs
Thank you for your attention