



Project: Technical assistance to improve implementation of food safety standards and disease crisis preparedness

Training course: Emerging animal diseases OIE vs Animal Health Law - Regulation (EU) 2016/429

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- OIE perspective
- What is emerging disease?
- What is notifiable disease?
- Early detection
- Listing of diseases
- Categorization of disease

What is listed, emerging and notifiable disease?



- **Emerging disease** - means a **new occurrence** in an animal of a disease, infection or infestation, **causing a significant impact** on animal or public health **resulting from**:
 - a **change of a known pathogenic** agent or its spread to a new geographic area or species; or
 - a **previously unrecognized pathogenic** agent or disease diagnosed for the first time.
- **Notifiable disease** - means a disease **listed by** the Veterinary Authority, and that, as **soon as detected or suspected, should be brought** to the attention of this Authority, in accordance with national regulations.
- **listed disease** - means a disease, infection or infestation listed in Chapter 1.3. after adoption by the World Assembly of OIE Delegates.

Notification and eradication



- **Notification** means the procedure by which:
 - the Veterinary 'Authority' informs the Headquarters,
 - the Headquarters inform the Veterinary 'Authority',
- of the occurrence of disease, infection or infestation in accordance with Chapter 1.1.
- **Eradication** means the elimination of a pathogenic agent from a country or zone.



Notification of diseases



- Exchange of information between OIE MS
- OIE notification requirement
- Event of occurrence of **listed or emerging** disease subject to notification
 - Agent
 - Species
 - Number of affected animals
 - Geographical distribution
- OIE disease reporting format
- The detection of the **pathogenic agent** of a listed disease **in an animal** should be **reported**, even in the **absence of clinical signs**
- Animal health measures in place

Notification of listed disease



- Through the WAHIS, fax or e-mail
- First occurrence of a listed disease
- Reoccurrence of a listed disease
- First occurrence of a new strain of a pathogenic agent of a listed disease in a country
- Recurrence of an eradicated strain of a pathogenic agent of a listed disease in a country
- a sudden and **unexpected change** in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the pathogenic agent of a listed disease present a country, a zone or a compartment
- occurrence of a listed disease in an unusual host species

Notification of listed disease



- **weekly reports** subsequent to a notification
 - These reports should continue until the listed disease has been eradicated or the situation has become sufficiently stable that six-monthly reporting will satisfy the obligation of the Member Country,
 - For each event notified, a final report should be submitted;
- **six-monthly** reports on the absence and evolution of listed diseases
- **annual** reports concerning any other information of significance

Notification of emerging disease



- Through the WAHIS, fax or e-mail
- Periodic reports subsequent to a notification of an emerging disease:
 - For the time necessary to have reasonable certainty that:
 - ❖ the infection or infestation has been eradicated; or
 - ❖ the situation has become stable;
 - OR
 - until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.;
- A final report once point above has been complied with
- *any other disease (other than listed or emerging) can be reported on a voluntary basis

Listing of diseases



- Each listed disease normally has a **corresponding chapter** that assists MS in the **harmonisation** of disease detection, prevention and control and provides standards for safe international trade in animals and their products.
- **Chapter 1.3.** - Diseases, infections and infestations listed by the OIE
- https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmlfile=chapitre_oie_listed_disease.htm

Criteria for listing of diseases



- **International spread** of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.
- AND
- **At least one country has demonstrated** freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.
- AND
- **Reliable means of detection** and diagnosis exist and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations.
- AND

Criteria for listing of diseases



- **Natural transmission to humans has been proven**, and human infection is associated with severe consequences.
- OR
- The disease has been shown to have a **significant impact** on the **health of domestic animals** at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.
- OR
- The disease has been shown to, or scientific evidence indicates that it **would, have a significant impact on the health of wildlife taking** into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population.

What is early warning system?



- means a system for the timely detection, reporting and communication of occurrence, incursion or emergence of diseases, infections or infestations in a country, zone or compartment.



“It’s an early warning system , it picks up my wife”


Elements of the early warning systems



- timely detection, reporting and communication of occurrence, incursion or emergence of diseases
- integral component of emergency preparedness
- It includes:
 - appropriate access to, and authority over, the target animal populations by the Veterinary Services
 - access to laboratories capable of diagnosing and differentiating relevant infections or infestations
 - training and awareness programmes for veterinarians,
 - a legal obligation by veterinarians and other relevant stakeholders to report suspected cases or cases of notifiable diseases or emerging diseases
 - epidemiological investigations of suspected cases and cases
 - effective systems of communication
 - a national chain of command

Listing of disease in EU



- AHL Regulation (EU) 2016/429 - **Article 5**
- A disease shall be included on the list if it has been **assessed** in accordance with Article 7 and it meets:
 - (a) all of the following criteria:
 - (i) scientific evidence indicates that the disease is **transmissible**;
 - (ii) animal **species** are either susceptible to the disease or **vectors** and reservoirs thereof **exist in the Union**;
 - (iii) the disease **causes negative effects** on animal health or poses a risk to public health due to its zoonotic character;
 - (iv) **diagnostic tools are available** for the disease; and
 - (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**;
- **AND** 

Listing of disease in EU



- (b) at least one of the following criteria:
 - (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;
 - (ii) the disease agent has **developed resistance to treatments** which poses a significant danger to public and/or animal health in the Union;
 - (iii) the disease causes or could cause a **significant negative economic** impact affecting agriculture or aquaculture production in the Union;
 - (iv) the disease has the potential to **generate a crisis** or the disease agent could **be used for the purpose of bioterrorism**;
or
 - (v) the disease has or could have a **significant negative impact on the environment, including biodiversity**, of the Union.



AHL Regulation (EU) 2016/429 - **Article 6**

- 2. A disease other than a listed disease shall be considered to be an emerging disease ('emerging disease') provided it has the potential to meet the criteria for listing diseases provided for in Article 5(3) and:
 - (a) results from the evolution or change of an existing disease agent;
 - (b) is a known disease spreading to a new geographic area, species or population;
 - (c) is diagnosed for the first time in the Union; or
 - (d) is caused by an unrecognised or a previously unrecognised disease agent.



Emerging diseases - Article 6

- 1. The rules for the **prevention and control** of diseases **shall apply** to emerging diseases as provided for in this Regulation
- 3. **The Commission shall, by means of implementing acts**, take the necessary **measures** regarding an emerging disease
- 4. On **duly justified imperative grounds of urgency** relating to a disease representing an emerging risk having a highly significant impact, the **Commission shall adopt immediately applicable implementing acts**
- 5. Any **obligation on operators** in respect of an emerging disease, as set out in this Regulation, shall only apply if the **Commission has adopted an implementing act** for that disease in accordance with paragraph 3 of this Article or if the disease is covered by a **contingency plan**

Assessment parameters



- AHL Regulation (EU) 2016/429 - **Article 7**
- (a) the **disease profile**, which shall comprise the following:
 - (i) the animal **species** concerned by the disease;
 - (ii) the **morbidity and mortality** rates of the disease in animal populations;
 - (iii) the **zoonotic character** of the disease;
 - (iv) the **resistance to treatments**, including antimicrobial resistance;
 - (v) the **persistence** of the disease in an animal population or in the environment;
 - (vi) the **routes and speed of transmission** of the disease between animals and, when relevant, between animals and humans;
 - (vii) the **absence or presence** and distribution of the disease **in the Union**, and, where the disease is not present in the Union, the **risk of its introduction into the Union**;
 - (viii) the **existence of diagnostic and disease control tools**;



Assessment parameters



- (b) the **impact** of the disease on:
 - (i) **agricultural and aquaculture** production and other parts of the economy, as regards:
 - the **level of presence** of the disease in the Union;
 - the **loss of production** due to the disease;
 - other **losses**;
 - (ii) **human health**, as regards:
 - **transmissibility** between **animals and humans**;
 - **transmissibility** between **humans**;
 - the **severity of human forms** of the disease;
 - the **availability of effective prevention** or medical treatment in humans;
 - (iii) **animal welfare**;
 - (iv) **biodiversity and the environment**;





- (c) its potential to generate a **crisis situation and its potential use in bioterrorism**;
- (d) the feasibility, availability and effectiveness of the following disease **prevention and control** measures:
 - (i) **diagnostic** tools and capacities;
 - (ii) **vaccination**;
 - (iii) medical **treatments**;
 - (iv) **biosecurity** measures;
 - (v) **restrictions** on the movement of animals and products;
 - (vi) **killing** of animals;
 - (vii) **disposal of carcasses** and other relevant animal by-products;



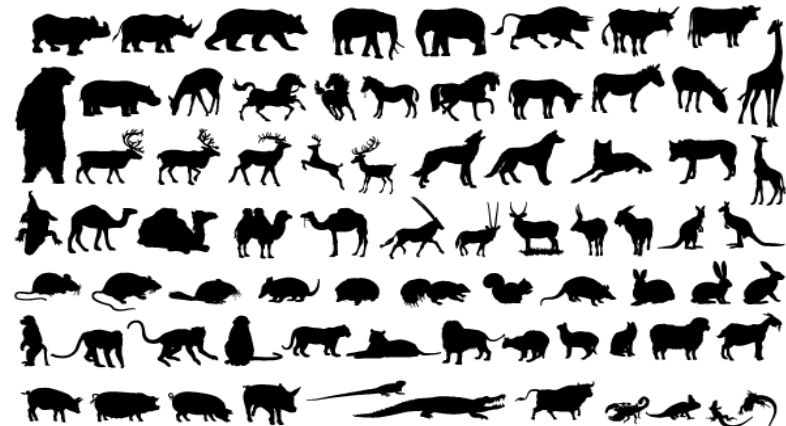


- (e) the **impact** of disease prevention and control measures, as regards:
 - (i) the **direct and indirect costs** for the affected sectors and the economy as a whole;
 - (ii) their **societal acceptance**;
 - (iii) the **welfare** of affected subpopulations of kept and wild animals;
 - (iv) the **environment and biodiversity**.

Listing of species



- AHL Regulation (EU) 2016/429 - Article 8
- 3. Animal species or groups of animal species shall be added to the list if they are affected or if they pose a risk for the spread of a specific listed disease because:
 - (a) they are **susceptible** to a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
 - (b) they are **vector species** or **reservoirs** for that disease, or scientific evidence indicates that such role is likely.



Listing of diseases



- AHL Regulation (EU) 2016/429 - **Article 5**
- (a) the following listed diseases:
 - (i) foot and mouth disease;
 - (ii) classical swine fever;
 - (iii) African swine fever;
 - (iv) highly pathogenic avian influenza;
 - (v) African horse sickness; and
- (b) the listed diseases set out in the list in **Annex II**.

Categories of listed disease



- AHL Regulation (EU) 2016/429 – Annex IV – Criteria for **categories** of disease in respect of the **prevention and control rules**
- The process of categorisation shall take into account the **profile of the disease** in question, the level of the **impact** of that disease on **animal and public health**, animal **welfare** and the **economy**, and the availability, feasibility and effectiveness of the **diagnostic tools** and different sets of **disease prevention and control measures** provided for in this Regulation with respect to the disease.

Criteria for A disease



- **most severe** animal health, public health, economic, social or environmental impacts on the Union. Those diseases need to fulfil the following criteria:
 - (a) the disease in question is:
 - (i) **not present** in the territory of the Union;
 - (ii) **present only in exceptional** cases (irregular introductions); or
 - (iii) present in only **in a very limited** part of the territory of the Union; and
 - (b) the disease in question is **highly transmissible**; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector-borne spread. The disease **may affect multiple species** of kept and wild animals, or a single species of kept animals of economic importance, and may result in high morbidity and significant mortality rates.




Criteria for A disease



- **one or more** of the following criteria:
 - (c) the disease in question has a **zoonotic potential** with **significant consequences** for public health, including epidemic or pandemic potential or possible significant threats to food safety;
 - (d) the disease in question has a significant impact on the **economy** of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals;
 - (e) the disease in question has a significant impact on one or more of the following:
 - (i) **society**, with in particular an impact on **labour** markets;
 - (ii) animal **welfare**, by causing suffering to large numbers of animals;
 - (iii) the **environment**, due to the direct impact of the disease or due to the measures taken to control it;
 - (iv) in the long term, **biodiversity** or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

Criteria for B disease



- with the **goal of eradicating** them throughout the Union:
- (a) the disease in question is **endemic in nature** and is present in the whole or part of the Union territory. However, several Member States or zones of the Union are free of the disease; and
- (b) the disease is **moderately to highly transmissible**; in addition to direct and indirect transmission, there may also be **possibilities of airborne, waterborne or vector-borne spread**. It may affect single or multiple animal species and may result in high morbidity, with in general low mortality.
- In addition **one or more** 

Criteria for B disease



- (c) the disease in question has a **zoonotic** potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety;
- (d) the disease in question has a significant impact on the **economy** of the Union causing substantial costs, mainly related to its direct impact on the health and productivity of animals;
- (e) the disease has a significant impact on **one or more** of the following:
 - (i) **society**, with in particular an impact on **labour** markets;
 - (ii) animal **welfare**, by causing suffering to large numbers of animals;
 - (iii) the **environment**, due to the direct impact of the disease or due to the measures taken to control it;
 - (iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.
- If A disease **has not been successfully and promptly eradicated** in a part of the Union, and has, in that part of the Union, **obtained an endemic character**, **may be subject to disease prevention** and control measures under point (b) of Article 9(1), in that part of the Union.

Criteria for C disease



- are of **relevance** to some MS and measures are needed to **prevent them from spreading** to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease in question.
 - (a) in terrestrial animals, the disease in question is **endemic** in nature and is present in the whole or part of the Union territory; or in aquatic animals, several MS or zones of the Union are free of the disease; and
 - (b) (i) in terrestrial animals, the disease in question is **moderately to highly transmissible**, mainly through direct and indirect transmission. The disease mainly affects multiple or single animal species, usually does not result in high morbidity, and has a negligible or no mortality rate. Often the most observed effect is production loss;
 - (ii) in aquatic animals, the disease is **moderately to highly transmissible**, mainly through direct and indirect transmission. The disease affects multiple or single animal species and may result in high morbidity and usually low mortality. Often the most observed effect is production loss.



Criteria for C disease



- (c) the disease in question has a **zoonotic** potential with significant consequences for public health, or possible threats to food safety;
- (d) the disease in question has a significant impact on the **economy** of parts of the Union, mainly related to its direct impact on certain types of animal production systems.
- (e) the disease in question has a significant **impact** on one or more of the following:
 - (i) **society**, with, in particular, an impact on **labour** markets;
 - (ii) animal **welfare**, by causing suffering to large numbers of animals;
 - (iii) the **environment**, due to the direct impact of the disease or of the measures taken to control it;
 - (iv) in the long term, **biodiversity** or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

Criteria for D disease



- The disease **prevention and control rules** referred to in point (d) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Section 1, 2 or 3 and to other diseases fulfilling the criteria set out in **Section 5** where the risk posed by the disease in question can be **effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread.**

Criteria for E disease



- The disease prevention and control rules referred to in point (e) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Sections 1, 2 or 3 and to other diseases where **surveillance of the disease is necessary** for reasons relating to animal health, animal welfare, human health, the economy, society or the environment.



Notification within MS



- AHL Regulation (EU) 2016/429 - Article 18
- MS shall ensure that operators and other relevant natural or legal persons:
 - (a) **immediately** notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease of **category A**, or where the presence of such a disease is detected in animals;
 - (b) **as soon as practicable notify** the competent authority where there are any reasons to suspect the presence in animals of a listed disease of **category E** other than those of **category A**, or where the presence of such a disease is detected in animals;
 - (c) **notify a veterinarian** of abnormal mortalities and other signs of serious disease or significant decreased production rates with an undetermined cause, for further investigation, including sampling for laboratory examination when the situation so requires.

Union notification



- AHL Regulation (EU) 2016/429 – Article 19
- MS shall **immediately notify** the Commission and the other MS of any outbreaks of listed diseases of **category E** for which an **immediate notification** is required in order to ensure the timely implementation of necessary risk management measures, taking into account the disease profile.
- 2.The notification shall contain the following information on the **outbreak**:
 - (a) the disease **agent** and, where relevant, the **subtype**;
 - (b) the relevant **dates**, in particular those of the **suspicion** and the **confirmation** of the outbreak;
 - (c) the **type and location** of the outbreak;
 - (d) any **related** outbreaks;
 - (e) the **animals involved** in the outbreak;
 - (f) any disease **control measures** taken in relation to the outbreak;
 - (g) the possible or **known origin** of the listed disease;
 - (h) the **diagnostic methods** used.

Union reporting



- AHL Regulation (EU) 2016/429 – Article 20
- MS shall report to the Commission and to the other MS the information on listed diseases of **category E** for which:
 - (a) **immediate notification** of an **outbreak** is **NOT** required;
 - (b) **immediate notification** of an outbreak is required, but additional information is required to be reported to the Commission and the other MS on:
 - (i) **surveillance**;
 - (ii) an **eradication programme**;



- Regulation (EU) 2020/2002

Union reporting



- The reports shall include information on:
- (a) the **detection** of the listed diseases;
- (b) the results of **surveillance**;
- (c) the results of **surveillance programmes**;
- (d) **eradication programmes**.



Listing of diseases



- Regulation (EU) 2016/429 - Article 21
- The MS shall establish notification and **reporting regions**.

- Regulation (EU) 2016/429 - Article 22
- The **Commission** shall set up and manage a computerised information system for the operation of the mechanisms and tools for the notification and reporting requirements.





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THANK YOU FOR YOUR ATTENTION



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