

New regulatory framework for Animal Health in the EU



Novo quadro regulamentar da Saúde Animal na União Europeia

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**JORNADAS TÉCNICAS
DA FESASS 2019**





Summary

- The purpose of the “Animal Health Law”
- Steps for the implementation
- The delegated acts
- The entry into application
- Conclusions



The purpose of “AH law”



Reg. (EU) 2016/429 of the European Parliament and of the Council of 9 March on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

*"The aim of this Regulation is to implement the commitments and visions for Animal Health Strategy, including the 'One health' principle, and to consolidate the legal framework for a common Union animal health policy through a **single, simplified and flexible** regulatory framework for animal health".*

The purpose of “AHL”



Article 10 - Responsibilities for animal health

1. **Operators, animal professionals and pet keepers shall:**
 - a) as regards kept animals and products under their responsibility, be responsible for:
 - (i) the health of kept animals;
 - (ii) prudent and responsible use of veterinary medicines, without prejudice to the role and responsibility of veterinarians,
 - (iii) minimizing the risk of the spread of diseases;
 - (iv) good animal husbandry;



The purpose of “AHL”



Article 10 - Responsibilities for animal health

Operators, animal professionals and pet keepers shall:

1. b) where appropriate, take such **biosecurity measures** regarding kept animals, and products under their responsibility, as are appropriate for:
 - (i) the species and categories of kept animals and products;
 - (ii) the type of production; and
 - (iii) the risks involved, taking into account: — geographical location and climatic conditions; and — local circumstances and practices;
- 1.c) where appropriate, take biosecurity measures regarding **wild animals**.
2. Animal professionals **shall take action to minimize the risk** of the spread of diseases in the context of their occupational relationship with animals and products.



The purpose of “AHL”

Article 11 - Knowledge of animal health

1. Operators and animal professionals shall have adequate knowledge of:
 - (a) animal diseases, including those that are transmissible to humans;
 - (b) **biosecurity principles**;
 - (c) the interaction between animal health, animal **welfare** and human **health**;
 - (d) good practice of animal **husbandry** for the animal species under their care;
 - (e) resistance to treatments, including **antimicrobial resistance**, and its implications.

The purpose of “AHL”



Article 10 - Responsibilities for animal health

Operators, animal professionals and pet keepers shall:

4. The biosecurity measures referred to in point b shall be implemented, as appropriate, through:

(a) physical protection measures, which may include:

(i) enclosing, fencing, roofing, netting, as appropriate;

(ii) cleaning, disinfection and control of insects and rodents;

(iii) in the case of aquatic animals, where appropriate: — measures concerning the water supply and discharge; — natural or artificial barriers, ... including measures against flooding or infiltration of water from surrounding water courses;



The purpose of “AHL”



Article 12. Responsibilities of veterinarians

1. Veterinarians shall, in the course of their activities, which fall within the scope of this Regulation:
 - (a) take all appropriate measures to prevent the introduction, development and spread of diseases;
 - (b) take action to ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease;
 - (c) play an active role in:
 - (i) raising animal health awareness, and awareness of the interaction between animal health, animal welfare and human health;
 - (ii) disease prevention;
 - (iii) the early detection of, and rapid response to, diseases.
 - (iv) raising awareness of resistance to treatments, including antimicrobial resistance, and its implications;
 - (d) cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation.

The purpose of “AHL”



Article 13 - Member States' responsibilities

1. In order to ensure that the competent authority for animal health has the capability to take the necessary and appropriate measures, and to carry out the activities, required by this Regulation, each Member State shall, at the appropriate administrative level, ensure that competent authority has:
 - (a) **qualified personnel**, facilities, equipment, **financial resources** and an effective organisation covering the whole territory of the Member State;
 - (b) access to **laboratories** with the qualified personnel, facilities, equipment and **financial resources** needed to ensure the rapid and accurate diagnosis and differential diagnosis of listed diseases and emerging diseases;
 - (c) sufficiently **trained veterinarians** involved in performing the activities referred to in Art.12. 2. **Member States shall encourage operators and animal professionals to acquire, maintain and develop the adequate knowledge of animal health** provided for in Art. 11 through relevant programmes in agricultural or aquaculture sectors or formal education.

The purpose of “AHL



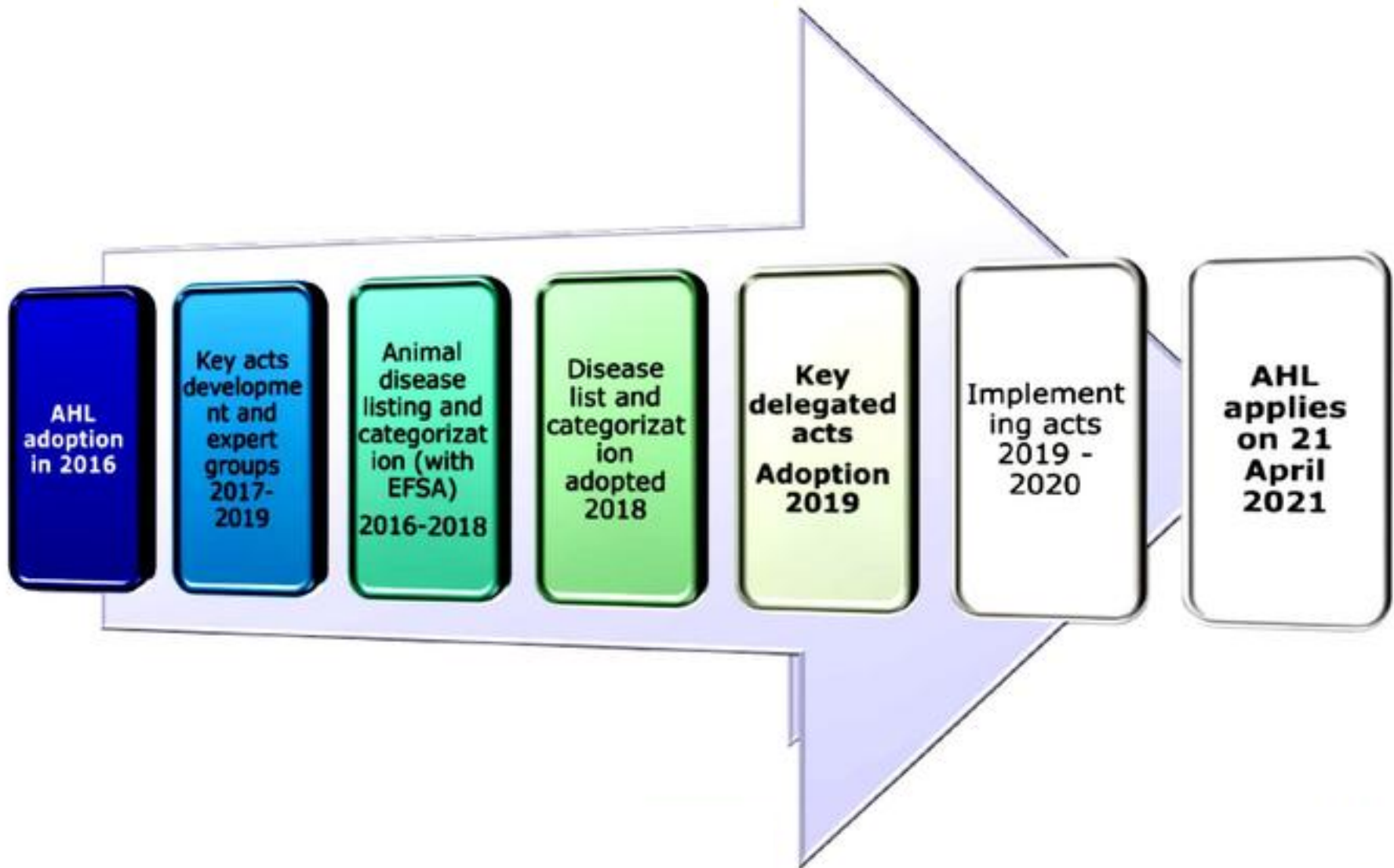
Article 14 - Delegation by a competent authority of official activities

3. The **Commission** shall be empowered to adopt **delegated acts** in accordance with Article 264 concerning other activities which may be delegated to veterinarians in addition to those provided for in paragraph 1, and, as appropriate, to prescribe the necessary circumstances and conditions for such delegation.

The **Commission** shall take account of the nature of those activities and of relevant international standards when adopting those **delegated acts**.



Steps for the implementation



Overview of priority drafts



Part AHL	Act	Status
1	DA on list of animal diseases	COMPLETED
	IA on categorisation of diseases	COMPLETED
2	DA on surveillance	FINALISATION
3	DA on disease control	FINALISATION
4/1	DA on establishments and I&R of animals	FINAL STAGE/PUBLIC FEEDBACK
	IA on I&R of animals	FINAL STAGE (ON HOLD)
	DA on Germinal Products (establishments, traceability, movements)	FINALISED/TRANSLATION
	IA on Germinal Products (traceability, movements)	FINAL STAGE (ON HOLD)
	DA on movements of terrestrial animals	FINALISATION
	DA on movements of products of animal origin	ONGOING
4/2	DA on aquaculture establishments	ONGOING
	DA on movements of aquatic animal	ONGOING
5	DA on entry into the EU	FINALISATION



New delegated acts under construction

Together with terrestrial animals

- On surveillance, eradication and freedom
- On animal identification, movements, registration and approval of establishments
- On control measures
- Entry into the Union

Only aquaculture

- Registration and approval of establishments
- Movements within the Union

List of animal diseases, disease categories, list of animal species



Act	Status
DA on list of animal diseases	COMPLETED
IA on categorisation of diseases	COMPLETED

Regulation (EU) 2018/1629 published on 31/10/2018 List of animal diseases :
63 animal diseases listed

Regulation (EU) 2018/1882 published on 4/12/2018 Categorisation of
diseases and listed species

Union notification point 1.1. (article 19)

Annex I -diseases of terrestrial animals



64

- Foot and mouth disease
- Infection with rinderpest virus
- Infection with Rift Valley fever virus
- Infection/*B. abortus*, *B. melitensis*, *B. suis*
- Infection with *Myc. tuberculosis* complex
- Infection with rabies virus
- African swine fever
- African horse sickness
- Infection with bluetongue virus 1-24
- Infestation with *Echin. multilocularis*
- Infection with epizootic haemorrhagic disease virus
- Anthrax
- Surra (*Trypanosoma evansi*)
- Ebola virus disease
- Paratuberculosis
- Japanese encephalitis
- West Nile fever
- Q fever
- Infection with lumpy skin disease virus
- Contagious bovine pleuropneumonia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Bovine viral diarrhoea
- Bovine genital campylobacteriosis
- Trichomonosis
- Enzootic bovine leukosis
- . Classical swine fever
- . Sheep pox and goat pox
- . Infection with PPR virus
- . Contagious caprine pleuropneumonia
- . Ovine epididymitis (*Brucella ovis*)
- . Infection with *Burkholderia mallei*
- . Infection with equine arteritis virus
- . Equine infectious anaemia
- . Dourine
- . Venezuelan equine encephalomyelitis
- . Contagious equine metritis
- . Equine encephalomyelitis (East. & West.)
- . Infection with Aujeszky's disease virus
- . Infection with porcine reproductive and respiratory syndrome virus
- . Infection with Newcastle disease virus
- . Avian mycoplasmosis
- . Infection with *S. Pullorum*, *S. Gallinarum* and *S. arizonae*
- . Infection with highly or low pathogenic avian influenza viruses
- . Avian chlamydiosis
- . Infestation with *Varroa* spp. (Varroosis)
- . Infestation with *Aethina tumida* (Small hive beetle)
- . American foulbrood



Union notification point 1.1. (article 19)

Annex I -diseases of aquatic animals

Confirmation of listed disease (24 hrs / 1week)

point 1.2 of Annex I -diseases of aquatic animals

- Epizootic haematopoietic necrosis
- Infection with *Mikrocytosmackini*
- Infection with *Perkinsusmarinus*
- Infection with Taura syndrome virus
- Infection with yellow head disease virus

Not listed under 1.2.of Annex I

- Infection with HPR deleted infectious salmon anaemia virus
- Infectious haematopoietic necrosis
- Infection with *Marteiliarefringens*
- Infection with *Bonamiaexitiosa*
- Viral haemorrhagic septicaemia
- Infection with white spot disease virus
- Infection with Koi Herpes virus (to be reported)



IMPLEMENTING REGULATION (EU) 2018/1882 of 3/12

application of certain prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed



Art.1st. Categorisation of diseases

A : a disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected,

B : a disease which must be controlled in all Member States with the goal of eradicating it throughout the Union,

C : a disease which is of relevance to some Member States and for which measures are needed to prevent it from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned.

D : a listed disease for which measures are needed to prevent it from spreading on account of its entry into the Union or movements between Member States;

E : means a listed disease for which there is a need for surveillance within the Union

Aquatic animals- registration and approval of establishments, movements



Act	Status
DA on aquaculture establishments	ONGOING
DA on movements of aquatic animal	ONGOING

Delegated act on registration and approval of establishments

Delegated act on movements of aquatic animals

✓ *State of play*

✓ *Technical discussion with MSs ongoing (1 meeting 6/06/2019)*

Surveillance, eradication programmes, disease freedom



<i>Act</i>	<i>Status</i>
DA on surveillance	FINALISATION

State of play:

- End of technical discussions
- Last meetings on 28/01/2019 for terrestrial and 28/02/2019 for aquatic animals
- Under internal consultation

Article 20. Union reporting of AHL



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

Article 4 Implementing Regulation



Union reporting on the detection of listed diseases

MS shall report

- by 31 January each year, covering the previous calendar year (*first time: 31 January 2022*)
- detection of Category E-diseases
Annex III (information to be reported)
- data submission via ADIS

Union reporting on the detection of listed diseases



Annex III -Information to be reported:

- *Date of report*
- *Reporting period*
- *Name of the country*
- *Name of disease and type of pathogen, where appropriate*
- *Number of outbreaks by listed animal species or group of species*
- *Date of confirmation [notification] of the last outbreak*



Notification and reporting regions

Current legislation:

Directive 82/894 - Definitions (Article 2):

*'**primary outbreak**' means an outbreak not epizootiologically linked with a previous outbreak in the same **region** of a Member State as defined in **Article 2 of Directive 64/432/EEC** or the first outbreak in a different region of the same Member State.*

Implementing Regulation – Definitions (Article 2):

*'**primary outbreak**': means an outbreak not epidemiologically linked with a previous outbreak in the same **region** of a Member State as provided for in **Article 7(3)** or the first outbreak in a different region of the same Member State;*

➡ **refers to list of notification and reporting regions (Annex IV)**

Article 20. Union reporting of AHL



MS shall report to the Commission and to the other MS information on listed diseases for which:

- (a) immediate notification is not required*
- (b) immediate notification is required, but additional information is required on:*
 - (i) surveillance*
 - (ii) an eradication programme*

Article 21. Computerised information system for Union notification and reporting of diseases



Article 21 of Regulation 2016/429

*The Commission shall set up and manage a computerised information system – **ADIS** – for the operation of the mechanisms and tools for the notification and reporting requirements provided for in Articles 19, 20 and 21.*



Article 7. Implementing Regulation



ADIS – Animal Disease Notification System

- enables systematic data collection
- provides data fields and upload options for
 - **immediate notifications**
 - **reporting on detection of listed diseases**
 - **reporting on Union surveillance programmes**
 - **reporting on eradication programmes**
- notification and reporting regions apply (**Annex IV**)

Article 19 of AHL - Union notification



Notification information

Member States shall immediately notify the Commission and the other Member States of any outbreaks of listed diseases

- (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 notification



Implementing Regulation - Article 3:

Deadlines and frequencies for **immediate notification** of listed diseases:

1. **primary** outbreaks within 24 hrs of confirmation and **secondary** outbreaks weekly (at least on the first working day of each week covering the previous week until midnight on Sunday)
2. **primary** outbreaks within 1 week of confirmation and **secondary** outbreaks monthly

Union reporting on the results of approved eradication programmes



Implementing Regulation – Article 6:

MS shall submit reports

- each year by [date], results of on-going EPs:
 - every year “small data set” (**Annex V**) covering the previous calendar year (B- and C-diseases)
 - every six years “large data set” (**Annex VII, Section 6**) covering the previous six years (B-diseases)

Union reporting on the results of Union surveillance programmes



Implementing Regulation – Article 5:

MS shall report

- by 31 January, covering the previous calendar year
- Data on results of their USPs in accordance with Article 11(2) of DA surveillance (AI specific information in Annex II → based on and replacing 'AI surveillance Decision' 2010/367)

Brucellosis, Tb, rabies, EBL eradication – what happens in 2021?



21 April 2021:
entry into application
AHL legal acts

31 May 2021:
annual reporting on
results of the year
2020 in accordance
with Directive 64/432

30 April 2022:
annual reporting
on results of the
year **2021** in
accordance with
AHL

30 April 2023:
annual reporting
on results of the
year **2022** in
accordance with
AHL

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assessment

AHL approved eradication programme

31 May 2021:
submission of eradication
programme for approval
in accordance with AHL

1 January 2022:
approval of eradication
programme

Avian Influenza (exemple) – What will happen in 2021 ?

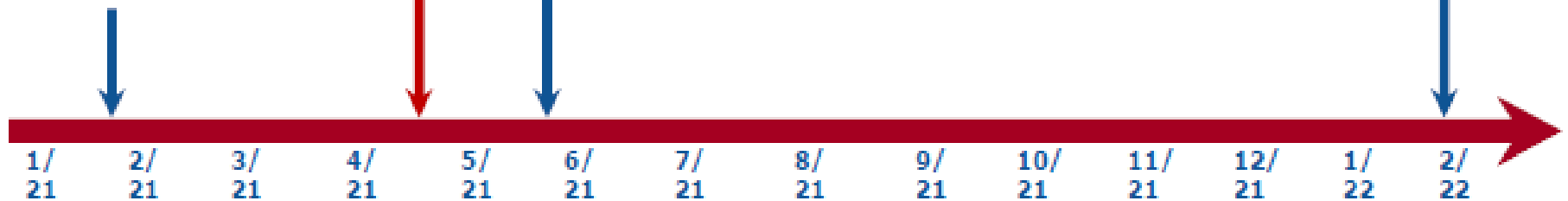


21 April 2021:
entry into application
AHL legal acts

31 May 2021:
submission of Union surveillance
programmes for information in
accordance with AHL (approval for
co-financing, if relevant, as from
2022)

31 January 2022:
reporting on results
of the year 2021 in
accordance with AHL

31 January 2021:
reporting on
results of second
half of 2020 in
accordance with
Decision 2010/367



2021: AI surveillance programme

Submission of eradication programmes

Article 33 of Regulation n°. 2016/429



Information to be included in submission of EPs for approval

- (a) *a description of the epidemiological situation of the listed disease covered by the EP;*
- (b) *a description and demarcation of the geographical and administrative area or the compartment covered by the EP;*
- (c) *a description of the disease control measures of the EP programme as provided for in DA surveillance*
- (d) *a description of the organisation, supervision and roles of the parties involved in the EP;*
- (e) *the estimated duration of the EP;*
- (f) *the intermediate targets of, and the disease control strategies for implementing, the EP.*



Submission of Union Surveillance programmes

Implementing Regulation – Article 8:

MS shall submit for information

- USPs in accordance with Article 11(1) of DA surveillance
- Listed for USPs: Avian influenza (AI specific information in Annex II → based on and replacing 'AI surveillance Decision' 2010/367)
- by use of standard electronic templates
- or: as technical part of a programme in accordance with Article 12 of Regulation 652/2014

Submission of Union surveillance programmes



Current legislation:

- *Directive 2005/94: no provisions as regards submission of surveillance programmes for AI*
- *AI eligible for co-financing: submission of AI surveillance programmes in accordance with Article 12 of Regulation 652/2014*
- *deadline for submission: 31 May*
- *technical information based on Decision 2010/367 (to be updated in case of substantial changes / for each programme)*

AHL- Article 9

Submission of eradication programmes



MS shall submit for approval

- by [date], their compulsory EPs
- where relevant, optional EPs
- information laid down in Article 33 of Regulation 2016/429, specified more detailed in **Annex VI** (4 sets of information):
 - **B- and C-diseases** (eradication at establishment level)
 - **Rabies**
 - **Bluetongue**
 - **B and C diseases of aquatic animals**

AHL- Article 9

Submission of eradication programmes



Current legislation:

- *Submission of national control programmes (Article 9, Directive 64/432) to achieve additional guarantees*
 - **IBR, Aujeszky's disease**
- *Submission of national control programmes (Article 12, Regulation 652/2014) for co-financing*
 - **Tuberculosis, Brucellosis, rabies**
 - **Deadline for submission 31 May**

Union reporting on the results of approved eradication programmes



Current legislation:

- *Reporting on results (Article 8, Directive 64/432)*
 - ***templates for reporting (Decision 2003/886)***
 - ***deadline for submission: 31 May***
- *Submission of national control programmes (Article 14, Regulation 652/2014) for co-financing*
 - ***standard electronic templates (Decision 2016/969)***
 - ***deadline for submission: 30 April***

Union reporting on the results of approved eradication programmes



Implementing Regulation – Article 6:

MS shall submit final reports

- within [period] of completion of their EPs:
 - B-diseases: "large data set" (**Annex VII, Section 6**) covering the period from last submission of this set until completion
 - C-diseases: "large data set" (**Annex VII, Section 6**) covering the entire period of application until completion



AHL- Annex V- “small data set”

B- and C-diseases that can be eradicated at establishment level

By zone or by region (if more than one region is included in a zone):

- number of establishments keeping animals of the targeted animal population at 31/12 (excl. Art. 19 DA surveillance derogations)
- number of animals of the targeted animal population kept there at 31/12
- number of establishments with disease-free status (including suspended) at 31/12
- number of animals kept there at 31/12
- Number of establishments with one or more confirmed cases at 31/12
- Number of outbreaks (reporting period)

Health and



European
Commission



AHL- Annex VII- “large data set” (section 6(1))

EP against infection with *B. abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals

By zone or by region (if more than one region is included in a zone):

- a) number of establishments keeping bovine animals + number of bovine animals at 31/12 (excl. Art. 19 DA surveillance derogations)
- b) number of disease-free establishments without vaccination and number of bovine animals kept there at 31/12
- c) number of establishments keeping bovine animals tested annually with a serological test on blood samples for the granting or for the maintenance of the status and number of bovine animals tested
- d) number of establishments keeping bovine animals tested annually with a serological test on milk samples for the granting or for the maintenance of the status and number of bovine animals tested
- e) number of establishments with suspicion following the testing referred to in point (c) and (d)
- f) number of bovine animals introduced in an establishment referred to in (a);
- g) number of bovine animals tested with a serological test in the context of introduction of a bovine animal

AHL, Article 38 - List of disease-free Member States zones or compartments



Each Member State shall establish and maintain an up-to-date list of its territory or zones with disease-free status as provided for in Article 36(1) and (3), and of its compartments with disease-free status as provided for in Article 37(1) and (2), when applicable.

Member States shall make those lists publicly available. The Commission shall assist the Member States in making the information contained in these lists available to the public by providing on its internet page the links to the internet-based information pages of the Member States.



European
Commission

Submission of application for recognition of disease-free status



Implementing Regulation – Article 10:

Information to be included specified in **Annex VII**:

- **Section 1:** general information & statement of compliance with general requirements
- Section 2: if application is based on absence of listed species
- Section 3: if application is based on disease agent's incapacity to survive
- Section 4: if application is based on the incapacity to survive of listed vectors for listed diseases of terrestrial animals

Submission of application for recognition of disease-free status



Implementing Regulation – Article 10:

Information to be included specified in **Annex VII**:

- Section 5: if application is based on historical and surveillance data
- Section 6: if application is based on EPs against infection point 1 with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals
- Section 6: if application is based on EPs against infection point 2 with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals

Submission of application for recognition of disease-free status



Implementing Regulation – Article 10:

Information to be included specified in **Annex VII**:

- Section 6: if application is based on EPs against infection point 3 with MTBC
- Section 6: if application is based on EPs against EBL point 4
- Section 6: if application is based on EPs against IBR/IPV point 5
- Section 6: if application is based on EPs against infection point 3 with ADV



COMMISSION DELEGATED REGULATION (EU)
.../...of XXX supplementing Regulation (EU)
2016/429 of the European Parliament and of the
Council, as regards **registration obligations** of
certain **transporters**, requirements for granting
approval of certain establishments **keeping**
terrestrial animals and **hatcheries**, registers to be
kept by the competent authorities, record-keeping
obligations of **registered establishments**,
transporters and **operators**, and of **approved**
establishments, **identification** and registration of
kept terrestrial animals and **traceability** of
hatching eggs

Delegated act - movements



Presentation of a draft delegated act under Part IV, Title II, Chapter 2 of the Animal Health Law concerning intra Union movements.

This draft delegated act covers requirements for **movements** of aquatic animals, **animal health certificates**, self-declaration documents, **movement notification** and requirements for movements of products of animal origin from aquatic animals, other than live aquatic animals



Conclusions

- Like the “Food Law”, the new “Animal Health Law” (AHL) represents a starting basis for future legislation or acts on the protection of animal health
- The aim of AHL is to make sure that the EU internal market will be safe and so will be the trade in live animals, while avoiding movement restrictions imposed by the national veterinary laws of single member states
- The list of notifiable diseases provided for by AHL has the effect of indirectly but immediately modifying all the lists of infectious diseases contained in the existing European directives and decisions, and also the laws of member states on the same issue, with the aim to address uniform conditions for the health status of animals in the European union, Animal health was regulated so messy, confusing and not harmonized, divided between directives and decisions, and animal health rules of the individual member states, which, depending on the internal health problems, autonomously decided which infectious diseases should be notifiable and which were the restrictive health measures on animal movements AHL, which shall apply from 21 April 2021, impacts on EU animal health legislation, because it will supplement existing provisions on food safety, even with regard to the management of bio-security in animal breeding and derived products.
- According to this regulation, animal health will no longer be governed by individual member states but the European union itself will directly order measures to fight against transmissible diseases of animals