



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

**Training course: Surveillance, eradication,
disease freedom**

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- Legal frame
- Disease notification
- Surveillance
- Eradication
- Free status



1. Disease notification and reporting

2. Surveillance

- Operator's obligations
 - observe health, changes in the production parameters, abnormal mortalities
 - Animal health visits for the purpose of prevention
- CA's obligation
 - Presence of listed and emerging diseases

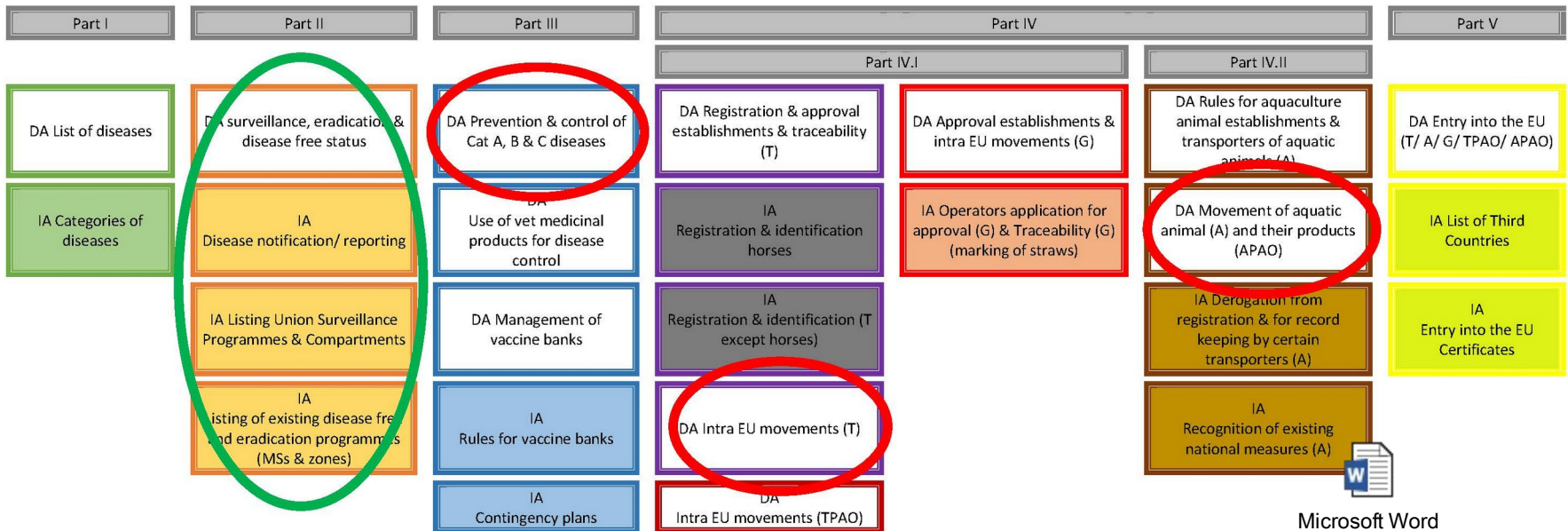
3. Eradication programmes

4. Disease free status

AHL - legal frame



AHL Regulation (EU) 2016/429



Microsoft Word Document

T	Terrestrial animals & hatching eggs
TPAO	Terrestrial products of animal origin
A	Aquatic animals
APAO	Aquatic products of animal origin
G	Germinal products
DA	Delegated Act (DA)
IA	Implementing Act (IA)

Relations with other delegated acts



- Regulation (EU) 2020/688 & Regulation (EU) 2020/990
- **Movement regime** for diseases **subject to eradication** programmes
- **conditions to move** animals **into a disease-free** area or one under a programme
- **conditions to certify** a movement **from a MS to another MS** (disease-free, under a programme or without status)
- Regulation (EU) 2020/687
- **Disease control measures**
 - under a programme
 - in disease free areas

Complementing implementing acts



- 1. CIR (EU) 2020/2002 on reporting and notification
 - Disease **notification and reporting**: diseases, deadlines, notification regions
 - Submission and reporting of **eradication programmes**, Union surveillance programmes
 - Applications for **disease freedom**
 - The **computerised information system** for Union notification and Union reporting of diseases
- 2. CIR (EU) 2020/690 laying down rules as regards the listed diseases subject to **USP**, their geographical scope and the listed diseases for which the disease-free status of compartments may be established
 - 1. USP: Avian influenza (HPAI and LPAI viruses)
 - 2. Compartments: diseases of aquatic animals
- 3. CIR (EU) 2021/620 listing **disease free areas** and areas with an approved programme

Acts repealed by this DA



- Diagnostic methods
 - Decision 2000/428/EC: diagnostic methods SVD
 - Decision 2002/126/EC: diagnostic manual CSF
 - Decision 2002/127/EC: diagnostic manual ASF
 - Decision 2002/128/EC: diagnostic manual BSE
 - Implementing Regulation (EU) No 1181/2011: diagnostic methods for aquatic animals
- Surveillance
 - Regulation (EC) No 1260/2007: surveillance of aquatic animals
 - Decision 2008/896/EC: surveillance of aquatic animals
- Acts listing free trade zones
 - Repealed by Commission Decision (EU) 2019/1000 listing diseases of aquatic animals programme

From April 2021



- Regulation (EU) 2020/689 Article 3(1)(a) & 3(2)(a)
- Obligation of the CA: Design the surveillance for listed and emerging diseases
- General requirements:
 - Notification
 - Investigation of increased mortalities, decreased production rates, signs, suspicion of Category E diseases or emerging diseases
 - Contribution of official controls-other official activities



- Regulation (EU) 2020/689 Article 3(1)(b) & 3(2)(b)
- Specific surveillance requirements in the following circumstances:
 - Union surveillance programmes (terrestrial only)
 - Compulsory or optional eradication programmes plus maintenance of disease freedom
 - Disease control measures
 - Movements (trade-imports)
 - Approval of establishments
 - Risk-based surveillance (aquatic only)
 - Voluntary surveillance programmes for Cat C diseases (aquatic only)



- Regulation (EU) 2020/689 Article 6
- From a prescriptive approach to a more flexible approach
- Specific legislation and guidance which will be made available in the websites of the EURL and COM
- OIE Manuals
- Art 34 of OCR
 - National rules. In absence of national rules, relevant methods recommended by NRL validated in accordance with international standards or
 - Relevant methods validated with inter or intra-laboratory methods validation studies
 - In case of urgency, NRL (in absence, other designated lab) may use methods which have not been validated
- 4. Diagnostic methods for granting and maintaining disease freedom are laid down in Annexes III and VI



- Regulation (EU) 2020/689 Annexes I & VI
- General definition
 - Suspicion
 - Clinical, post mortem, laboratory examinations or results from a diagnostic method which are indicative of a particular disease
 - Epidemiological link with a confirmed case
- Confirmation
 - Isolation (excluding vaccine strains)
 - Animal with clinical signs or with an epidemiological link with a suspected or confirmed case where:
 - Antigen or nucleic acid (excluding vaccine strains) is identified or
 - Positive to an indirect diagnostic method (excluding vaccinations strains)
- Specific definitions: HPAI, LPAI, NC in Annex I /Aquatic diseases in Annex VI

Union surveillance programmes



- Regulation (EU) 2020/689 Article 10 - 11
- **Obligation of the CA** to perform surveillance for diseases that are relevant for the Union (Art 28 of AHL)
- For the time being, **only HPAI** (and LPAI) and
- **Submitted** to the Commission, but no need for approval (Art 28 of AHL)
- **Content** of the AI Union surveillance programme: Annex II to Regulation (EU) 2020/689
- **Information** for the submission of the programmes and reporting obligations (Art 11 of Regulation (EU) 2020/689)
- **Deadlines** are in CIR (EU) 2020/2002 on reporting and notification
 - Submission: 31 May
 - Reporting: 15 March



- Regulation (EU) 2020/689 Annex II
- **Early detection** of HPAI in poultry
- Early detection of HPAI in wild birds: targeted populations in EURL web
- Detection of HPAI in poultry species **not showing significant clinical signs**: targeted populations defined
- **Detection of LPAI** that may spread between flocks: targeted populations defined
- Contribution to increase the knowledge of **zoonotic risks**
- Sampling and laboratory testing methods



- Regulation (EU) 2020/689 Article 3(2)(b)(i) & Annex VI, Part I
- Risk-based surveillance
- Applied in certain **approved aquaculture establishments and groups of approved** aquaculture establishments approved in accordance with Regulation (EU) 2020/691
- Objective is to detect increased mortality, listed diseases, emerging diseases
- Depends on the risk the establishment poses in relation to contracting and spreading disease => **applies to listed and non-listed diseases**
- **Ranking of establishments:** High / Medium/ Low
- Maybe **combined** with health visits and sampling as part of:
 - Eradication programmes
 - Maintenance of freedom
 - Surveillance programmes



- Regulation (EU) 2020/689 Article 3(2)(b)(iv) & Annex VI, Part III
- Surveillance programmes
 - Establishment level
 - Not participating in an eradication programme but **do not wish to trade with infected establishments**
 - **Targeted surveillance** but at a lower level than for an eradication programme
 - Details set out in Chapters 1 to 6 of Part III of Annex VI, depending on the disease
 - **General requirements** – health visits and sampling
 - **Specific requirements** for each Cat C disease to:
 - Demonstrate the implementation of the surveillance programme
 - Re-start a surveillance programme after a disease outbreak

Eradication programmes



- Regulation (EU) 2020/689 Article 12 - 13, AHL Article 4 def. 35 (b)
- For category B diseases (compulsory) and category C diseases (optional)
- Territorial scope: Member State, Zone(s) or compartment (aquaculture only)
 - Zone (terrestrial): administrative unit of more than 2000 km² including at least one notification and reporting region-possible derogations
 - Zone (aquatic): contiguous hydrological system with a distinct health status with respect to a specific disease or specific diseases that forms an area that is referred to in one of the following:
 - An entire water catchment from source to the estuary or lake
 - More than one water catchment
 - Part of a catchment from the source to a barrier that prevents the introduction of disease(s)
 - Part of a coastal area with a precise geographical delimitation
 - An estuary with a precise geographical delimitation



- AHL, Article 4 Def. 37
- Compartment:
 - animal sub-population
 - contained in one or more aquaculture establishments
 - common biosecurity management system
 - distinct health status for specific disease(s)
 - subject to appropriate disease control and biosecurity measures
- May be independent of surrounding waters or dependent on the health status of surrounding waters



- AHL Part II, Chapter 3, Regulation (EU) 2020/689, Article 14 & 15 (T) 48 & 49 (AQ)
- **Targets:** intermediate and final to show progress towards eradication or its achievement
- **Duration:** for optional programmes maximum of 6 years
- **Deadlines** CIR (EU) 2020/2002 on reporting and notification
 - Submission: 31 May 2021 (compulsory) - any time (optional)
 - Reporting: 30 April
- **Content** of submitted programmes and reports (CIR (EU) 2020/2002)



- Based on granting disease free status at the level of establishments
 - Cat B diseases (terrestrial): MTBC, infection with *Brucella abortus*, *B. melitensis* and *B. suis*
 - Cat C diseases (terrestrial): EBL, IBR/IPV, ADV, BVD
- Based on granting the disease free status at an area level
 - Cat B diseases: infection with RABV
 - Cat C diseases: infection with BTV



- Regulation (EU) 2020/689 Article 16-31
- Targeted population + additional animal populations
- Obligations of operators
 - General: surveillance ordered by the CA, introductions into their establishment, vaccination, disease control measures, any other additional measure
 - Disease specific: detailed rules for each disease in the annexes
- Obligation of competent authorities
 - Commence, maintain or withdraw the eradication programme
 - Grant, suspend and withdraw disease free status
 - Specify maximum period of time for a suspension
 - Define epidemiological units (in peace time)

Disease control measures



- Suspicion and confirmation
- Movement restrictions and derogations
- Suspicion and confirmation in wildlife
- Management of products
- Cleaning and disinfection
- Risk mitigating measures to prevent reinfection
- Testing regime and removal of animals
 - To complete the epidemiological enquiry
 - To restore the free status
 - Any additional testing
 - Slaughter-killing of confirmed cases (suspicion) in a maximum period of time to be determined



- Regulation (EU) 2020/689 Annex IV, Part I, Chapter 1, section 1
- Granting the status at establishment level
 - No cases in 12 months
 - No vaccination in the past 3 years
 - All bovine animals over 12 months and all ovine and caprine animals over 6 months comes from BRC free establishments with or without vaccination, not vaccinated and has been tested twice with (-) result
 - First test 3 months after infection
 - Second test between 6 and 12 months after the first test
 - Animals with clinical signs are investigated with negative results,
 - All newly introduced ruminates after the start of the testing (first test) are from BRC free establishments with or without vaccination and have not been vaccinated. They are all at age when it can be tested and they are tested negative or they are post-parturient females.
 - Rules for germinal products.
 - Fast track for granting free status.



- Regulation (EU) 2020/689 Annex IV, Part I, Chapter 1 section 2
- Maintenance of status at establishment level
 - Conditions for granting are kept.
 - Testing regime less frequent and finally risk based
- Suspension and restoring:
 - Conditions for maintenance are not kept
 - Suspicion
- Withdrawal
 - Suspension period elapsed
 - Confirmation or BRC cannot be ruled out
 - Case is confirmed
 - Justified to control BRC

Annex: BRC with vaccination



- Regulation (EU) 2020/689 Annex IV, Part I, Chapter 2, Section 1
- Granting the status at establishment level
 - Rules for BRC without vaccination (excluding 3 year period without vaccination)
 - All bovine animals over 12 month and all ovine and caprine animals over 6 months comes from BRC free establishments with or without vaccination, and has been tested twice with (-) result
 - They are all at age when it can be tested and they are tested negative or they are pot-parturient females.
 - Rules for germinal products.
 - Fast track for granting free status.
- Maintenance of status at establishment level
- Suspension and restoring:
- Withdrawal
- Regaining: fast track possible



- Regulation (EU) 2020/689 Annex IV, Part II
- Granting the status at establishment level
 - No cases in 12 months+ two tests + introduction from free establishments (if not from free areas pre-movement testing) + free germinal products
 - Fast track for new establishments
- Maintenance of status at establishment level
 - Conditions for granting are kept. Testing regime less frequent and finally risk based
- Suspension and restoring:
 - Conditions for maintenance are not kept
 - Suspicion
- Withdrawal
 - Suspension period elapsed
 - Confirmation or MTBC cannot be ruled out
 - Justified to control MTBC
- Regaining: fast track possible



- Regulation (EU) 2020/689 Annex IV, Part II
- Granting of the status at MS or zone level
 - Last three years 99.8% of establishments keeping 99.9% of population MTBC free
 - Incidence rate during the year not exceed 0.1%
 - Surveillance including at least
 - Ante and post-mortem surveillance
 - Investigation of any lesion
- Maintenance at MS or zone level
 - After two years of MTBC freedom, switch to a risk based approach



- Regulation (EU) 2020/689 Articles 32-36 Annex V, Part I
- Mostly focused on foxes
- Obligations of CA
 - Surveillance
 - Disease control measures
 - Vaccination
 - In kept animals
 - In wild animals: regular campaigns, bait distribution, control-GIS, monitoring
- MS or zones rabies free
 - General surveillance in the last 24 months and 24 months without cases



- Regulation (EU) 2020/689, Article, 37-45 Annex V, Part II
- To eradicate all serotypes
- All MS or minimum of 150 km around infected establishment (derogations)
- Based on vaccination (unless risk assessment justifies the contrary)
- Disease control measures
- Movement restrictions into areas free or under a programme
 - Movements that always are to be accepted
 - Movements that may be accepted: no bilateral agreements
- Annex
 - Surveillance
 - Movement requirements
 - Granting and maintaining the status



- Regulation (EU) 2020/689 Part II, Chapter 3
- Territorial scope: MS/ zone/compartment
- Species to be included: All establishments keeping relevant listed species
- By way of derogation, establishments may be excluded if:
 - they do not pose a significant risk to the success of the programme &
 - are exempted from the requirement for approval
- Establishments keeping only vector species may also be excluded from the programme based on a risk assessment
- Intermediate and final targets to show progress towards eradication, or its achievement



- Regulation (EU) 2020/689 Part II, Chapter 3 & Annex VI
- Obligations of operators
 - General: surveillance ordered by the CA, introductions into their establishment, notification, vaccination (where relevant), disease control measures, any additional measures
 - Disease specific: detailed rules for each Cat C disease in Annex VI
 - Comply with the above until the programme has been successfully completed or is withdrawn
- Obligation of competent authorities
 - Commence, maintain or withdraw the eradication programme
 - Inform operators on evolution of programme

Eradication programmes (aquatic)



- Regulation (EU) 2020/689, Articles 55 to 65
- Disease control measures
- Suspicion and confirmation of Cat B or relevant Cat C disease (Ref Annex VI)
- Movement restrictions – animals & products
- Certain derogations & risk mitigating measures
- Possible extension of disease control measures
- Removal of animals (slaughter or killing)
- Cleaning, disinfection, fallowing
- Risk mitigating measures to prevent reinfection
- Complete the epidemiological enquiry
- Restore the free status



- Regulation (EU) 2020/689, Annex IV
- Requirements for health visits and sampling for all Cat C diseases of aquatic animals
 - Fish: VHS, IHN, infection with HPR-deleted ISAV
 - Molluscs: infection with *Marteilia refringens*, infection with *Bonamia exitiosa*, infection with *Bonamia ostreae*
 - Crustaceans: infection with WSSV
- Specific requirements for each disease
 - number of health visits per year
 - number & category of animals to be tested
 - period of time to run the programme
 - Organs and tissue material to be sampled
 - Diagnostic methods to be used

Example: VHS /IHN



- Regulation (EU) 2020/689, Annex VI, Part II, Chapter 1
- General requirements for health visits & sampling (water temp, intervals between samples, selection of animals to be tested, sampling in the wild where necessary)
- Granting of disease- free status in MS/zone/compartment with an unknown health status (2 year model or 4 year model, number of health visits/ year, timing of health visits, number of samples per year, categories of animals to be tested, number of animals per sample, number of fish per pool)
- Granting of disease -free status in MS/zone/compartment known to be infected (as above plus disease control measures)
- Surveillance required to maintain disease-free status
- Diagnostic methods to be used
- **NB:** Similar structural approach is taken to all Cat C diseases as set out in Chapters 1 to 6, Part II, Annex VI



- AHL Part II, Chapter 4,
- Regulation (EU) 2020/689, Part II, Chapter 4
- MS, zone or compartment level (only aquatic animals)
- Several pathways
 - Absence of listed species
 - Disease agent's incapacity to survive
 - Incapacity to survive of listed vectors for listed diseases of terrestrial animals
 - Based on historical and surveillance data
 - Based on eradication programmes
 - Specific rules for certain aquatic compartments which are independent of surrounding waters
- Details for the submission in CIR (EU) 2020/2002 on reporting and notification



- Regulation (EU) 2020/689 Articles 70 &76
- Never reported or was eradicated more than 25 years ago
- Reported in the last 25 years and eradicated in accordance with the eradication criteria of this Regulation
- Only possible in a new MS or for a newly categorised disease for a period of 2 years
- Particular cases:
 - Rabies and infection with BTV
 - Varroa and status free from infections with Newcastle virus without vaccination
 - BVD, infection with *Bonamia exitiosa*, Infection with WSSV

specific rules for independent aquatic compartments



- Regulation (EU) 2020/689, Articles 79 & 80
- An independent compartment which commences or re-commences aquaculture activities after a break is considered to be disease-free when it:
 - Has never had a Cat B or Cat C disease
 - It has been cleaned, disinfected and fallowed if necessary, prior to re-population
 - It is re-stocked with animals from a disease-free MS/zone/compartiment
- An independent compartment which re-commences aquaculture activities after an outbreak of a Cat B or Cat C disease is considered to be disease-free when:
 - It has been cleaned, disinfected and fallowed prior to re-population
 - It is re-stocked with animals from a disease-free MS/zone/compartiment
 - The first cohort is sampled 3-12 months after re-population using a sample size that ensures the detection of the relevant pathogen with a 95% confidence if the targeted prevalence is 2%



- Regulation (EU) 2020/689 Articles 81 & 82
- Maintenance:
 - General principles: surveillance, biosecurity
 - Specific disease requirements: reference to the annexes
- Suspension
 - Intermediate step before withdrawal
 - Can be used as a transitional measure after suspicion or confirmation
 - It provides time to manage the situation informing regularly MS and the Commission



- Free from infestation with *Varroa spp.*, and Status free from infection with Newcastle disease without vaccination
- No provisions for eradication programmes
- Requirements in Annex V to grant the status
- *Echinococcus multilocularis*
- Provisions for freedom based on Regulation 576/2013 are valid until 2026

Transitional provisions



- Regulation (EU) 2020/689 Article 83 & 84
- Existing disease free areas
 - They are considered as free areas under the provisions of this Delegated Regulation
 - They are listed in CIR 2021/620
 - MS must ensure that the conditions of maintenance conform with the provisions of this Delegated Regulation
- Existing eradication or surveillance programmes
 - They are considered as approved under the provisions of this Delegated Regulation for 6 years
 - They are listed in CIR 2021/620
 - MS must ensure that the measures conform with the provisions of this Delegated Regulation



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THANK YOU FOR YOUR ATTENTION



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