



Draft Implementing Regulation

**Union notification, Union reporting,
Computerised information system,
eradication programmes and
the disease-free status**

PAFF

21-22 November 2019

Animal Health Law – Part II –

disease notification and reporting, surveillance, eradication programmes, disease-free status



Delegated Regulation

on

surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases



Implementing Regulation

on

Union notification, Union reporting, the computerised information system, eradication programmes and the disease-free status

Updated draft Implementing Regulation

following the Working Group meeting of 30 September 2019

- **table of contents – modifications**
- **Articles/Annexes – modifications & explanations**
- **completed points**

Table of contents

Table of contents – modifications

- *Chapter 2: no more sections*
- *Article 7: shortened, change of title*
- *Order of Articles unchanged*

Table of contents of the Implementing Regulation

Chapter 1 general provisions

- **Article 1 - subject matter and scope**
- **Article 2 - definitions**

Chapter 2 Union notification and Union reporting

- **Article 3 - Union notification**
(Annex I - list of diseases, Annex II - notification information)
- **Article 4 - Union reporting on the detection of listed diseases**
(Annex III - reporting information)
- **Article 5 - Union reporting on the results of Union surveillance programmes**
- **Article 6 - Union reporting on the results of the implementation of approved eradication programmes (Annex V - reporting information)**
- **Article 7 - notification and reporting regions**
(Annex IV – list of notification and reporting regions)

Table of contents of the Implementing Regulation

Chapter 3 Submission of Union surveillance programmes and eradication programmes

- **Article 8 - Submission of Union surveillance programmes**
- **Article 9 - Submission of eradication programmes**
(Annex VI - submission information)

Chapter 4 Application for recognition of disease-free status and exchange of information

- **Article 10 - Application for recognition of disease-free status of Member States and zones as regards diseases of terrestrial and aquatic animals and disease-free status of compartments as regards diseases of aquatic animals (Annex VII – information for disease-free status)**
- **Article 11 – exchange of information on the disease-free Member States, zones and compartments**

Chapter 5 Transitional measures

- **Article 12 – Transitional measures for migration of data**
- **Article 13 – Entry into force and date of application**

Articles/Annexes

modifications & explanations

modifications/explanations

Article 2 - Definitions

- point 1 'primary outbreak'
 - ➔ unchanged: first outbreak occurring in another region has to be notified as primary outbreak
- points 2, 4, 5 and 6 - disease categories
 - ➔ deleted/ replaced by reference to Regulation (EU) 2018/1882
- point 10 'suspect or indicator animals'
 - ➔ deleted

explanation

region - zone – territory/territorial scope

- **‘Notification and reporting regions’**
(Article 21 **AHL**)

The Member States shall establish notification and reporting regions for the purpose of the notification and reporting provided for in Articles 19 and 20.

explanation

region - **zone** – territory/territorial scope

- '**zone**' (Article 4(35) **AHL**) means
 - (a) for **terrestrial animals**, an area of a Member State, third country or territory with a precise geographical delimitation, containing an **animal subpopulation with a distinct health status** with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;
 - (b) for **aquatic animals**, a **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...'

explanation

region - zone – **territory/territorial scope**

- ‘**Territorial scope and animal populations**’
(Article 13 **Delegated Regulation**)
 2. The territory covered by the eradication programme referred to in point (a) of paragraph 1 shall be:
 - (a) the **entire territory** of the Member State; or
 - (b) **one or several zones**, provided that **each zone** corresponds to administrative unit(s) of at least 2000 km² and **includes at least one of the regions** established in accordance with **Article 21** of Regulation (EU) 2016/429

explanation

region - zone – **territory/territorial scope**

- ‘**Territorial scope and animal populations**’
(Article 47 **Delegated Regulation**)
 2. The territory covered by the eradication programme referred to in point (a) of paragraph 1 may be:
 - (a) the **entire territory** of the Member State;
 - (b) **one or several zones**; or
 - (c) the **geographical location** of the establishments of which the compartment or compartments are comprised.

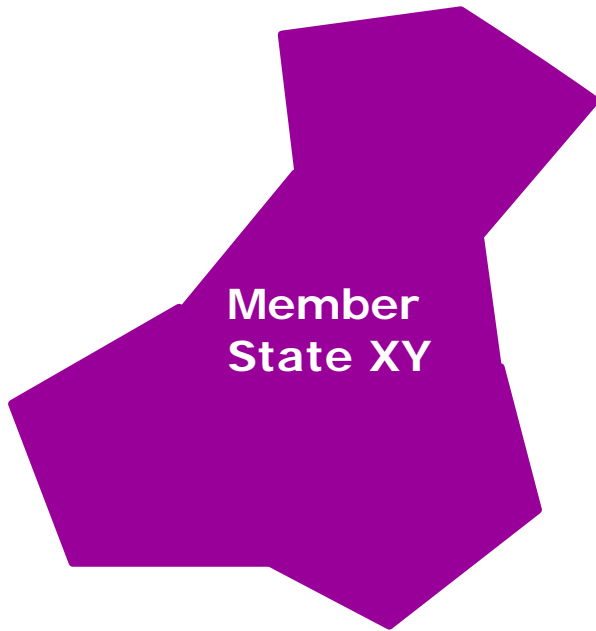
explanation

region - zone – territory/territorial scope

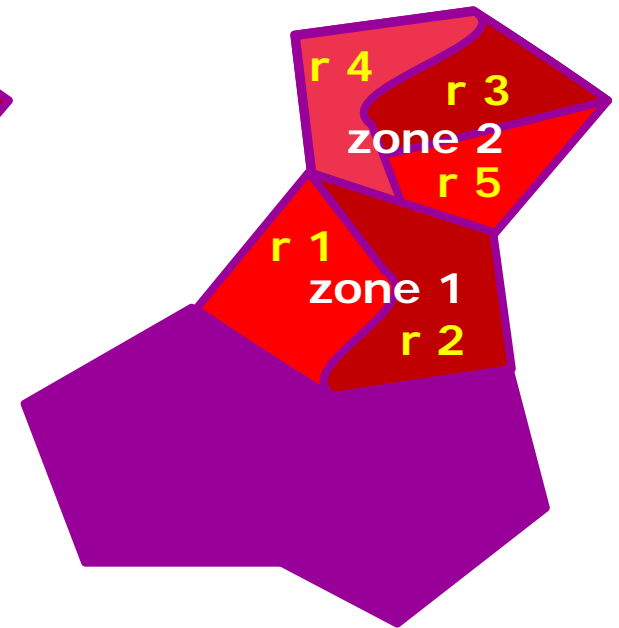
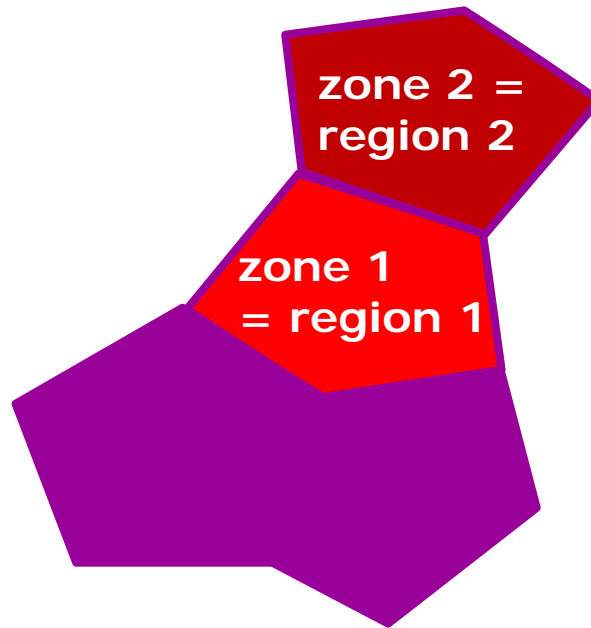
- ‘**primary outbreak**’ (Article 2 **Implementing Regulation**) means
 1. an outbreak not epidemiologically linked with a previous outbreak in the same **region** of a Member State as provided for in **Article 7** or the first outbreak in a different region of the same Member State;
- ‘**Territorial scope**’ (Article 2 **Implementing Regulation**) means
 3. the **territory** in accordance with **Article 13 of Delegated Regulation** (EU) 2016/429 as regards terrestrial animals and in accordance with **Article 47 of that Regulation** as regards aquatic animals.

Territorial scope of an eradication programme

one or more zones



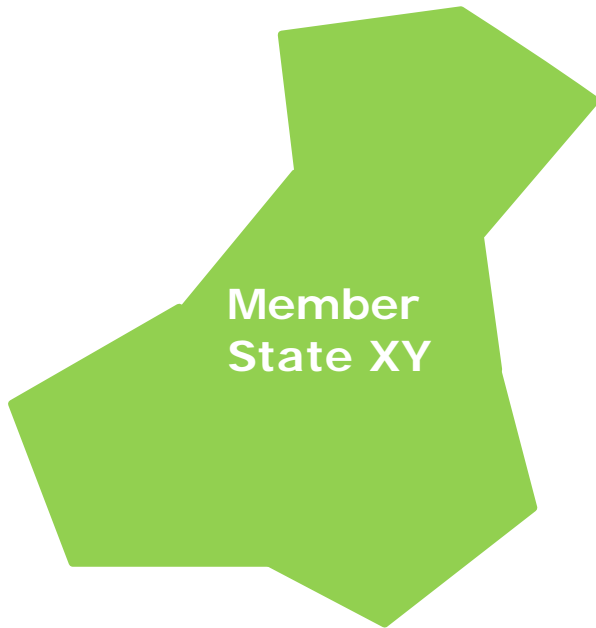
entire territory of MS



a zone must include
at least one region

Territorial scope of an eradication programme

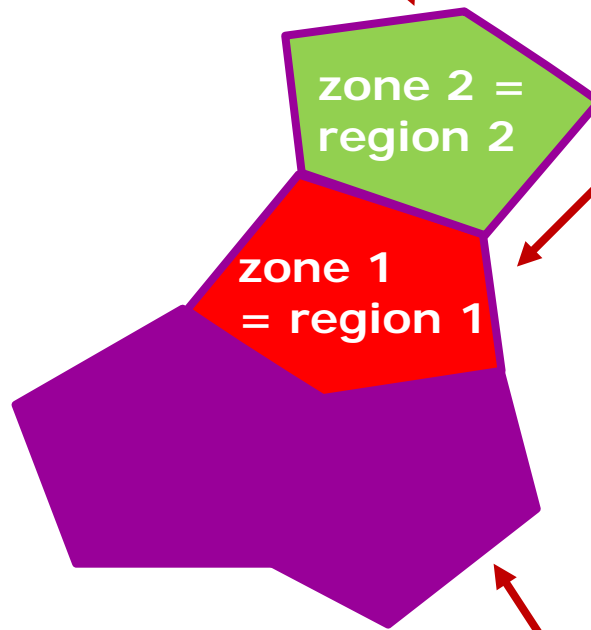
disease-free status
entire territory of MS



⇒ immediate notification
of ALL outbreaks

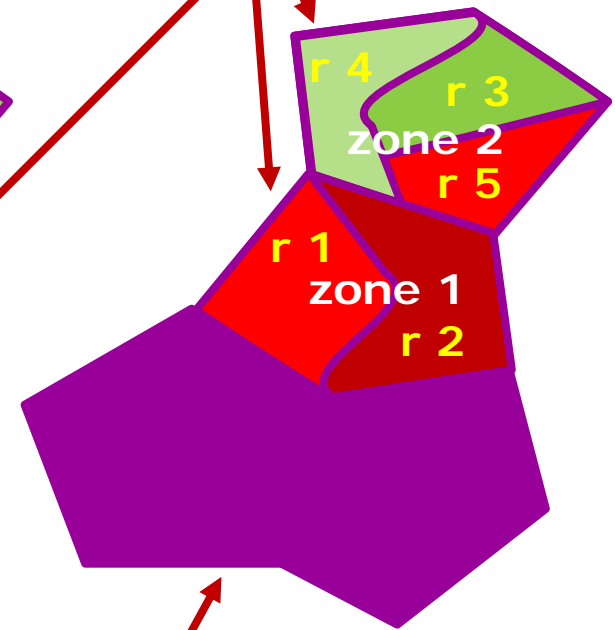
(Annex I point 2: targeted animal species!)

disease-free zone
⇒ immediate notification of outbreaks

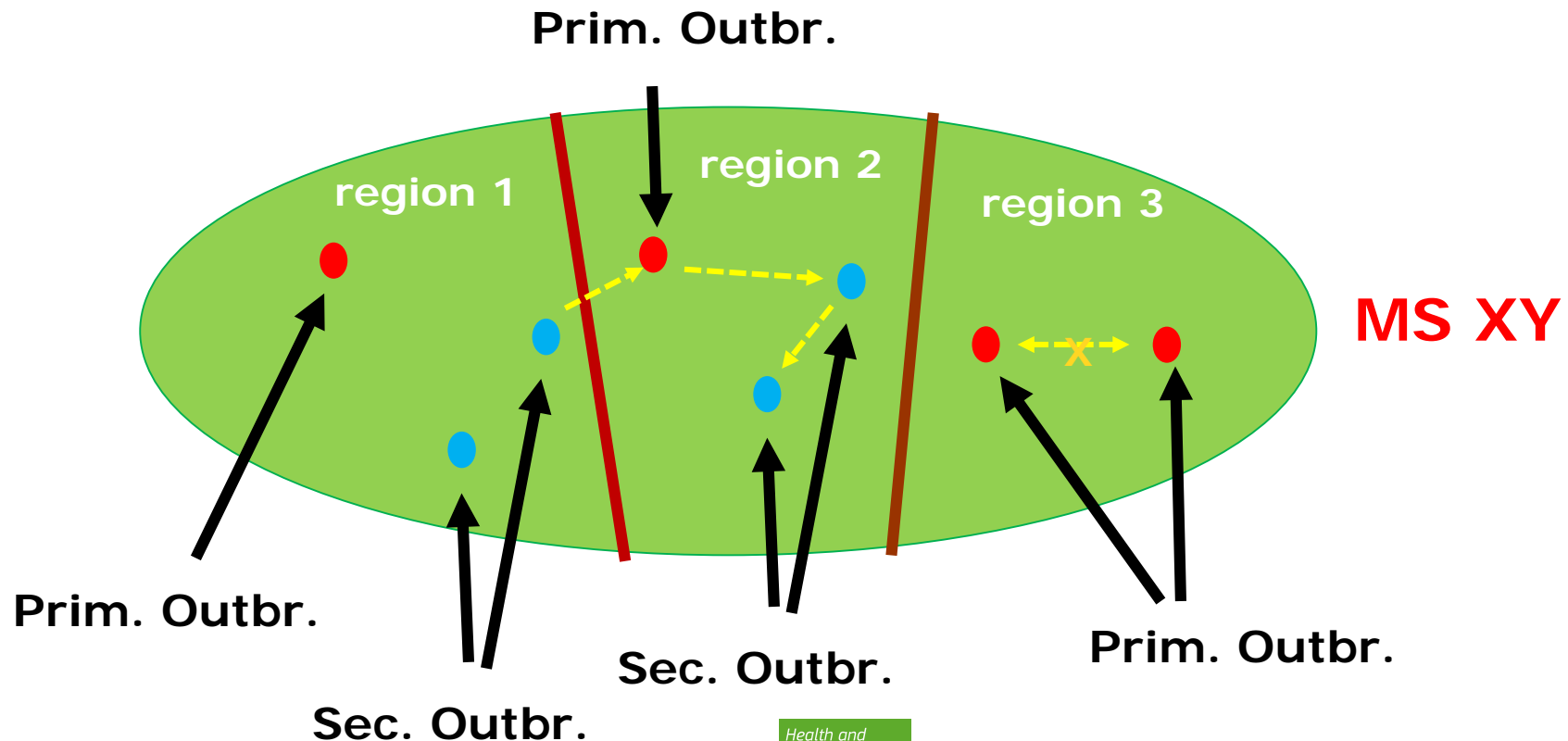


territory not under EP
⇒ reporting on detection of disease

zone under EP
⇒ reporting on results of EP



'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** or the first outbreak in a different region of the same Member State;



modifications/explanations

Article 3 – Union notification

- Deadline for immediate notification (24 hours/weekly)
 - unchanged: in case of B-/C-diseases (point 2 and points 3.1 and 3.2 of Annex I)
 - once officially confirmed, notification of outbreaks within 24 hours should be no problem
 - **no reporting** on results of surveillance **in disease-free MS/zones/compartments** under new rules (currently, annual reporting in accordance with Directive 64/432)
 - disease-free status not recognised by OIE – sufficiently stable diseases do not require a WAHIS immediate notification

modifications/explanations

Article 3 – Union notification

Suggestion: allow 'clustering' / take into account already established restriction zones

- ➔ unchanged: notification of clusters not feasible, control measures related to outbreak establishments
- ➔ multiple cases (e. g. ASF in wild boar) detected in the same restriction zone/same population could be considered as epidemiologically linked ⇒ bundled notification weekly

modifications/explanations

Annex I – list of diseases

- point 1.1 West Nile fever / Rabies

➡ unchanged

- WNF: listed species (birds transmit WNF virus, horses are dead end hosts)
- Rabies: listing under 1.1 (public health issue)

- point 3.1 BTV

➡ unchanged: immediate notification (by serotype), when outbreaks are confirmed in disease-free MS/zone

- point 4 American foulbrood

➡ deleted

modifications/explanations

Annex II – notification information

- Point 14 (ii) 'subclinically infected animals'

➔ OIE (notification guidance doc):

'For a subclinical infection, the date of the first collection of samples which resulted in positive results can be an estimate of the date of start of the outbreak' (date of suspicion)

modifications/explanations

Annex II – notification information

- Point 14 (iv) and (v) number of animals killed / slaughtered
 - ➡ if unknown by the time of notification ⇒ information to be updated asap
 - ➡ OIE (notification guidance doc):
 - Killed: animal(s) killed for disease control purposes and subjected to disposal
 - Slaughtered: animal(s) killed for disease control purposes and intended for commercial use or own use

modifications/explanations

Annex II – notification information

- point 15

'Date of ~~completion of killing and preliminary cleaning and disinfection~~ (where applicable)'

➔ Date of preliminary cleaning and disinfection needed in the context of disease control (movements/repopulation)

modifications/explanations

Article 4 – Reporting on detection of listed diseases

- Deadline for reporting on detection of listed diseases
 - ➔ changed: 30 April (in line with reporting on results of eradication programmes/Union funding)
- Suggestion
 - ➔ Tbd: Recital on ADIS/internal data transfer to avoid double reporting of outbreaks of listed diseases

modifications/explanations

Annex III – information on detection of listed diseases

- point 5

'Number of outbreaks by listed animal species or group of species during the reporting period'

- ➡ Number of outbreaks that have been detected/are known to have occurred (not necessarily each infected animal)
- ➡ MS collect outbreak data in national data bases
- ➡ Obligation to confirm outbreaks in the context of Article 8 DA surveillance

modifications/explanations

Article 5 – Reporting on Union surveillance programmes (USP)

- Deadline for reporting results of USP
 - ➔ Unchanged: 31 January (one of the currently used two deadlines)
 - ➔ Tbd: 15 March - new proposal supported by EFSA / D4
 - ⇒ by 30 April information needed for Union funding – most of the USP data could be used (plus additional data for financial part)

modifications/explanations

Article 6 – Reporting on eradication programmes (EP)

- Deadline for reporting on results of EP
 - ➔ unchanged: 30 April – alignment with Union funding (deadline for technical report in accordance with Regulation 652/2014)
 - ➔ No double reporting! Data entered into the system in the context of annual reporting (small data set) does not need to be re-entered. Additional data included in the large data set to be provided every six years (C-diseases: upon completion of programme!) must be entered into the system covering the entire period

modifications/explanations

Article 7 – notification and reporting regions

- ➔ title changed: former title 'ADIS' (information on ADIS included in Articles 3 to 6)
- ➔ introduction of Annex IV (list of notification and reporting regions)

modifications/explanations

Annex IV – list of notification and reporting regions

- administrative regions for notification and reporting
 - ➡ changed: SE, FI, LV, DE, NL, DK
- FR: problem of overseas departments

modifications/explanations

Article 8 – Submission of Union surveillance programmes

- Deadline for submission of USP
 - ➔ 31 May 2021 for programmes due to start 2022
 - ➔ In case of substantial modifications,
31 May for programmes due to start the following year

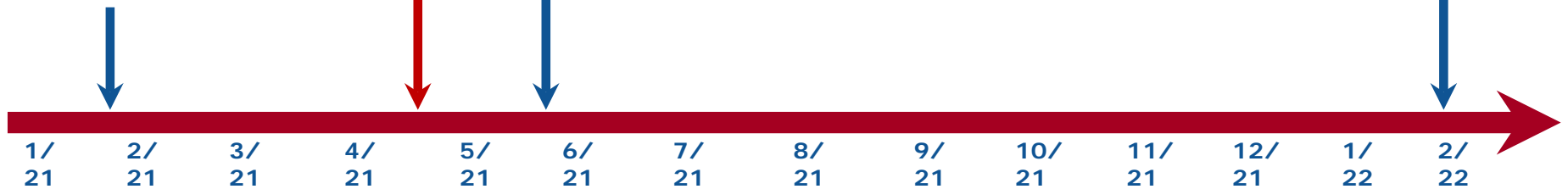
AI surveillance - what happens in 2021?

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~~
15 March 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



modifications/explanations

Article 9 – Submission of eradication programmes

- Paragraph 1 deadline for submission
 - ➔ 31 May 2021: compulsory eradication programmes due to start 2022
 - AND: eradication programmes for EBL that should continue (no grandfathers rights!)
 - ➔ At any time: optional eradication programmes

modifications/explanations/ completion of points

Article 10 – Application for recognition of disease-free status

➡ unchanged: Article 10

Annex VII – Information for applications for recognition of the disease-free status)

➡ Modifications/
completed points: Section 5 (disease-free status based on historical and surveillance data),
Section 6 (disease-free status based on eradication programmes)

modifications/explanations/ completion of points

Annex VII – Section 5 - disease-free status based on historical and surveillance data

- point 1 diseases that have never been reported
 - ➔ Changed: point 2b) (*Varroa*) shifted to point 1, reference to Annex V of Delegated Regulation on surveillance
- point 2 diseases that have been eradicated
 - ➔ Completed: point 2a) (BVD), point 2b) (*Bonamia exitiosa*), point 2c) (White spot syndrome virus)
 - ➔ Changed: point 3 (Newcastle disease) ⇒ reference to Annex V of DA surveillance

modifications/explanations/ completion of points

Background: *B.exitiosa* and WSSV

- Draft which has been circulated covers information to be included in applications for the recognition of disease-free status based on **historical and surveillance data in Para 2 of Section 5** and uses a framework similar to that which is used for **BVD**
- Not all of the requirements that are listed in the current draft with respect of *B.exitiosa* and WSSV are appropriate, given the history of these diseases
- *B.exitiosa* – listed as an exotic disease in Directive 2006/88/EC – **11 detections in 4 MSs in past 10 years** – Cat C disease under CIR 2018/1882
- WSSV – listed as non-exotic disease in Directive 2006/88/EC but **no reports from any MS in past 10 years**

modifications/explanations/ completion of points

B.exitiosa and WSSV have been:

- listed for >10 years
- subject to surveillance – passive / investigation of increased mortality

However, it would be prudent to carry out some **targeted testing** in establishments / groups of establishments who apply for historical freedom

modifications/explanations/ completion of points

It is proposed therefore, that the text should be modified as follows in relation to *B.exitiosa*:

- (b) if recognition of the status free from infection with *Bonamia exitiosa* is requested:
 - (i) for at least one year, all establishments or groups of establishments keeping listed species within the Member State, zone or compartment, and where required, sampling points in wild populations, have been tested using a sample size that allows detection of infection with *Bonamia exitiosa* with a 95% level of confidence, if the disease agent is present in the population at a prevalence rate of 2%
 - (ii) measures applied to prevent the introduction of *Bonamia exitiosa* into the territory concerned
 - (iii) disease control measures applied in the event of an outbreak

modifications/explanations/ completion of points

....and it is proposed that the text should be modified as follows in relation to WSSV:

- (b) if recognition of the status free from infection with white spot syndrome virus is requested:
- (i) for at least one year, all establishments or groups of establishments keeping listed species within the Member State, zone or compartment, and where required, sampling points in wild populations, have been tested using a sample size that allows detection of infection with WSSV with a 95% level of confidence, if the disease agent is present in the population at a prevalence rate of 2%
 - (ii) measures applied to prevent the introduction of WSSV into the territory concerned
 - (iii) disease control measures applied in the event of an outbreak

modifications/explanations

Annex VII – Section 6 disease-free status based on eradication programmes

- point 1 - infection with *B. bovis*, *B. melitensis*, *B. suis* (bovine)
 - ➔ simplified: results on serological tests (blood/milk samples), investigation of abortion
 - ➔ deleted: *B. suis* biovar 2
 - ➔ modified: date of last vaccination (instead of date of prohibition of vaccination)

modifications/explanations

Annex VII – Section 6 disease-free status based on eradication programmes

- point 4 – enzootic bovine leukosis
 - ➔ simplified: number of tested establishments/animals
 - ➔ deleted: suspect cases in the context of introduction of animals
 - ➔ modified: investigation of suspect cases in the context of post-mortem examination (instead of laboratory examination of tumours)

modifications/explanations

Annex VII – Section 6 disease-free status based on eradication programmes

- point 8 - infection with RABV
 - ➔ modified: vaccination of kept animals, healthy hunted animals, stray dogs

modifications/explanations

Article 11 – Exchange of information

- Deadline for upload of updated list of MS/zones/ compartments in case of
 - ➔ Unchanged: within 2 [5] days
 - ➔ No withdrawal intended in cases of limited outbreaks ('self suspension' of the status disease-free)



Finished 😊

Notification and reporting regions

Notification and reporting regions

Implementing Regulation – Annex IV:

Member State:	administrative region:	Member State:	administrative region:
Belgium	province —provincie	Malta	entire country
Bulgaria	област	Netherlands	entire country
Czechia	kraj	Austria	Bezirk
Denmark	veterinary units or municipalities	Poland	powiat
Germany	Bundesland	Portugal	continente: distrito, and other parts of the territory: região autónoma
Estonia	maakond	Romania	judet
Ireland	county	Slovenia	območje
Greece	νομός	Slovakia	kraj
Spain	provincia	Finland	maakunta/landskap
France	département	Sweden	kommun
Croatia	županija	United Kingdom	England, Wales and Northern Ireland: county; Scotland: district or island area
Italy	provincia		
Cyprus	επαρχία (district)		
Latvia	novads		
Lithuania	apskritis		
Luxembourg	entire country		
Hungary	megye		

Current legislation:

Article 2 of Directive 64/432

*(p) **region** means that part of a Member State's territory which is at least 2000 km² in area and which is subject to inspection by the competent authorities and includes at least one of the following administrative regions:*

- Belgium: province —provincie
- Germany: Regierungsbezirk
- Denmark: amt or island
- France: département
- Italy: provincia
- Luxemburg —
- Netherlands: rrv-kring
- United Kingdom: England, Wales and Northern Ireland:
county
Scotland: district or island area

— Ireland:	county	— Lithuania:	apskritis
— Greece:	νομός	— Hungary:	megye
— Spain:	provincia	— Malta:	—
— Portugal:	continente: distrito, and other parts of Portugal's territory: região autónoma	— Poland:	powiat
— Austria:	Bezirk	— Slovenia:	območje
— Sweden:	län	— Bulgaria:	област
— Finland:	lääni/län	— Romania:	judet
— Czech Republic:	kraj	— Croatia:	županija;
— Estonia:	maakond		
— Cyprus:	επαρχία (district)		
— Latvia:	rajons		