



*Ministero della Salute*

**Direzione generale della sanità animale e dei farmaci veterinari**

Country reports: Italy  
success stories and challenges  
regarding aquatic disease management  
Workshop for WOA National Focal Points  
for Aquatic Animals in Europe – Chioggia (Venice) - Italy  
October 18 - 20, 2023

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**Ministry of Health**

**General Directorate of animal health**

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# Summary

- **Background to EU Regulation 429/2016 (New Animal Health Law - AHL)**
- **New elements in the AHL**
- **Ongoing activities in Italy concening the application of AHL**

# Background of Regulation 2020/429

- ❖ Huge disease outbreaks in EU in between the end of 1990 and beginning of 2000 (terrestrial animal sector involved not aquaculture )
- ❖ Economical, social and environmental losses
- ❖ Deep analysis of the causes involved
- ❖ Need of a new approach related to prevention

# ***Main Horizontal pillars of Regulation 2016/429***

## **1) Biosecurity**

- ✓ **Need to enforce and update measures to reduce the risk of introducing and spread the diseases in the establishments.**

## **2) Training**

- ✓ **Compulsory training of operators ( knowledge of infectious diseases , prevention, early warning)**
- ✓ **Private veterinarians should be regularly updated on the rules of regulation.**

## **3) Enhanced Role of private veterinarians**

- ✓ ***Veterinarians should perform “animal health visit” and give instructions to the breeders on biosecurity, early warning and drug resistance.***

# *Main Horizontal pillars of Regulation 2016/429*

## 4) Responsibilities

Clear responsibilities of operators and veterinarians in the prevention and notification

## 5) Surveillance

- Surveillance health visits by veterinarians + official veterinarians
- Notification of diseases by operators according to defined times (early warning)
- Notification of abnormal mortalities and lower feed intake (emergent disease)

# Main vertical pillars of Regulation 2016/429

## 1) Selection and classification of diseases:

- ✓ Transparent procedure to select and classify diseases in relation to risk (spread and economic consequences, zoonotic) .
- ✓ More focus on “emerging diseases” .
- ✓ Different level of involvement of the official veterinary services in the managing of the diseases.

Five groups of diseases :

**A immediate eradication (i.e epizootic hematopoietic necrosis, infection with *M. Infezione da Mikrocytos mackini*)**

**B eradication compulsory in due time**

**C voluntary eradication (viral hemorrhagic septicemia, infectious hematopoietic necrosis)**

**D protect the spread between Member states**

**E surveillance**

# What is really new for aquaculture ?

In relation to the new provision of Regulation 2020/429 the aquaculture sector was already one step ahead for certain aspect...

In fact the aquaculture sector has long been subjected to measure which are now introduced in the terrestrial sector.

For instance..

Surveillance:

- Surveillance has been carried out by private Veterinarians and other professional figures together with Official veterinarians and based on risk .
- Biosecurity is already applied in Fish farms in order to be approved

The regulation 429 mainly request un update of those measures in the aquaculture sector

## What has changed ?

- Italy doesn't recognize anymore other professional figure other than veterinarians (animal health visit etc)
- Over the recognition of zone and compartment free of listed diseases a new classification of farms has been introduced “establishments which are not participating in the eradication program but demonstrating with a specific surveillance plan that are not infected of VHS and IHN”
- For fish diseases which are classified in C group eradication measures are applied only in compartment or zone free or subject to specific surveillance to demonstrate “not to be infected”
- the rest of fish farm should focus on surveillance to emergent diseases and A group diseases
- For C diseases detected outside the eradication area no measure to manage outbreaks are currently applied.



# Ongoing application of AHL in Italy

**A national working group coordinated by the Ministry of Health:**

- Regional competent authorities
- National reference laboratory
- Italian aquaculture producers associations
- Aquaculture experts



**National guidelines for application of Animal Health law with reference to (*In Progress*):**

- Information System, data management and and traceability
- Disease free status recognition
- Management of Cat C diseases in aquaculture establishment
- Biosecurity
- Disease awareness

## Ongoing application of AHL in Italy

- Ongoing approval of national decree regarding aquatic animal establishments (requirements for granting approval of aquaculture establishments in relation to biosecurity measures) according to Commission Delegated Regulation (EU) 2020/691:
  - facilities and equipment
  - good management practices
- Manual for the application of biosecurity measures for farmers: in preparation

## **Disease awareness**

**National training courses for regional and local veterinary authorities and veterinarians implemented since 2022 regarding all the aspects related to AHL application in aquaculture establishments with particular reference to:**


- ✓ prevention of diseases**
- ✓ early detection**
- ✓ eradication**
- ✓ surveillance**

**Online training sessions, exercise at farm level with the help of the National reference laboratory for aquatic animal diseases .**

# Disease awareness

National provision regarding the training of operators in progress on:

- animal diseases, including those that are transmissible to humans;
- biosecurity principles;
- the interaction between animal health, animal welfare and human health;
- good practice of animal husbandry for the animal species under their care;
- resistance to treatments, including antimicrobial resistance, and its implications



# **Information system and data management**

## **Updating national database of aquaculture establishments (NDB) 2**

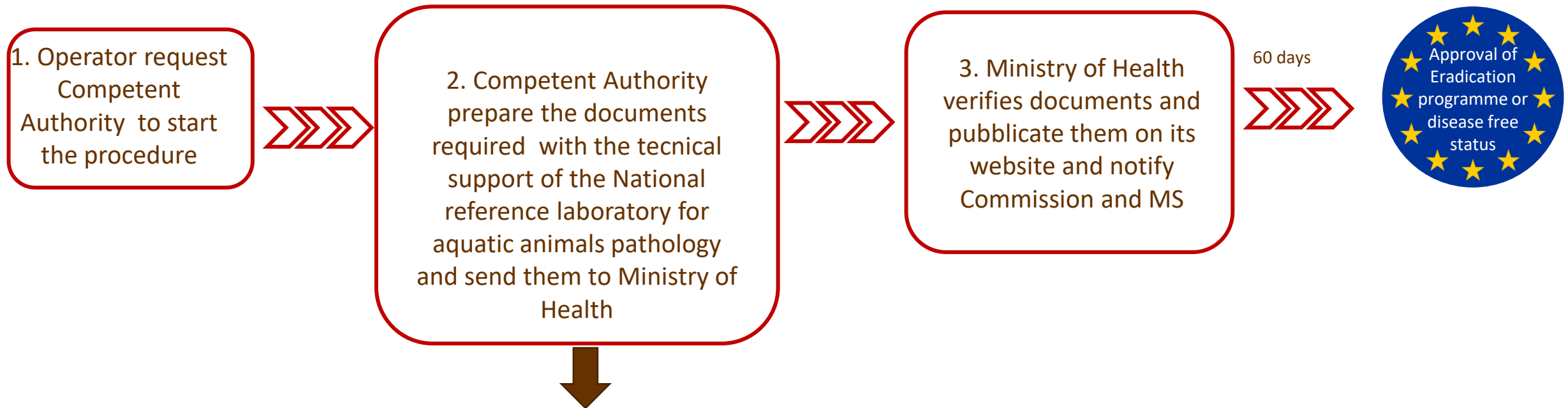
**Updating approval of establishments in the NDB according to new requirements and registration**

**Updating the categorization of establishments in NDB according to new requirements and registration**

**Electronic traceability of aquaculture animal movements within Italian territory: national traceability electronic system implemented**

# Disease free status recognition - 1

- National procedure established according to prescriptions provided in for Art. 83 of CDR 2020/689



Formats based on prescription of Art 10 and 11 of CIR  
2020/2002 (Italian/English)

# Disease free status recognition - 3

SUBMISSION OF ERADICATION PROGRAMMES FOR CATEGORY C DISEASES OF AQUATIC ANIMALS

in accordance with Chapter 3 of Part II of Regulation (EU) 2020/689 and Article 10 of Commission Implementing Regulation (EU) 2020/2002

Modello per la presentazione di programmi di eradicazione per le malattie di Categoria C degli Animali Acquatici redatto sulla base di quanto previsto dal Capo 3, Parte II del Regolamento Delegato (UE) 2020/689 e dall'articolo 10 del Regolamento di Esecuzione (UE) 2020/2002

1. General informations - Informazioni generali	
1.1. Date of submission - Data di presentazione <i>Data di caricamento sul sito a cura del Ministero</i>	
1.2. Declaring Member State - Stato Membro dichiarante	
Italy	
1.3. Diseases - Malattie <i>Barrare le caselle delle malattie per cui si intende avviare il programma di eradicazione</i>	
1.3.a. Fish - Pesci	<input type="checkbox"/> VHS (SEV - Setticemia Emorragica Virale) <input type="checkbox"/> IHN (NEI - Necrosi Ematopoietica Infettiva)
1.3.b. Molluscs - Molluschi	<input type="checkbox"/> Infection with <i>Marteilia refringens</i> <i>Infezione da Marteilia refringens</i> <input type="checkbox"/> Infection with <i>Bonamia ostreae</i> <i>Infezione da Bonamia ostreae</i> <input type="checkbox"/> Infection with <i>Bonamia exitiosa</i> <i>Infezione da Bonamia exitiosa</i>
1.3.c. Crustaceans - Crostacei	<input type="checkbox"/> White spot disease - Malattia dei punti bianchi
<input type="checkbox"/> Other - Altro (specificare)	
1.4. Contact details – Referente del documento	
Name - Nominativo	Dr Maroni Ponti Andrea
Role within the Competent Authority – Ruolo istituzionale	Aquaculture referent Ministry of Health, Directorate General for the hygiene and food safety and nutrition - Office II
E-mail:	a.maroni@sanita.it
1.5. Local Competent Authority - Autorità Competente Locale <i>Indicare l'Azienda sanitaria competente per territorio, indirizzo, numero di telefono, Fax, e-mail e il Veterinario di riferimento</i>	
1.6. Laboratory in charge of analysis - Laboratorio di riferimento <i>Indicare il laboratorio (IIZZSS) che ha analizzato i campioni prelevati dall'Autorità Competente Locale e la persona di riferimento (nominativo, telefono e indirizzo email)</i>	

- Formats based on prescription of Art 10 and 11 of CIR 2020/2002 (Italian/English)



Model for declarations of disease-free status  
in accordance with Article 11 of Commission Implementing Regulation (EU) 2020/2002  
Modello per la dichiarazione relativa allo status di "indenne da malattia" redatto sulla base dell'articolo 11 del Regolamento di Esecuzione (UE) 2020/2002

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2. Area covered - Zona interessata <i>Scegliere una sola delle seguenti 5 opzioni (da 2.1 a 2.5) in base al caso di riferimento (dichiarazione per tutto lo stato membro, zona, intero bacino, oppure singola azienda)</i>	

# Disease free status recognition - 4

1. Operator request Competent Authority to start the procedure



2. Competent Authority prepare the documents required with the technical support of NRL and send them to Ministry of Health



3. Ministry of Health publicates documents on its website and notify Commission and MS

60 days



**NON MI ABBANDONARE SIAMO INSEPARABILI**  
I nostri amici animali meritano amore e cure ogni giorno

**Riconoscimento comunitario di indennità a determinate malattie (SEV e NEI) aziende e zone indenni**

Uno Stato membro dell'Unione Europea può richiedere alla Commissione, il riconoscimento dello status di Indennità per una o più malattie elencate nel gruppo C del Reg. di esecuzione (UE) 2010/1882 per tutto il suo territorio o per una o più zone o compartimenti. La Setticemia emorragica virale (SEV) e la Necrosi ematopoietica infettiva (NEI) rientrano nel gruppo di malattie per le quali è possibile richiedere il riconoscimento di indennità.

La domanda può essere fatta nelle seguenti casistiche:

- nessuna delle specie sensibili per la malattia oggetto della domanda è presente nel territorio interessato
- l'agente patogeno è notoriamente non in grado di sopravvivere nel territorio oggetto della domanda
- lo status di indenne è stato dimostrato tramite un programma di eradicazione
- il compartimento introduce solo animali provenienti da stabilimenti dichiarati indenni ed è indipendente dallo stato sanitario delle acque circostanti.

Gli Stati membri devono presentare un vero e proprio dossier preparato dallo stabilimento che ne fa richiesta di concerto con la ASL territorialmente competente.

Per approfondire consulta la scheda servizi:  
Riconoscimento all'Unione europea dello status di indennità di stabilimenti di acquacoltura o di zone da Setticemia emorragica virale e Necrosi ematopoietica infettiva

Di seguito le aziende o zone, vengono pubblicate per un periodo di 60 giorni per la presentazione di un piano di eradicazione o per ottenere il riconoscimento di azienda o zona indenne da una delle malattie del gruppo C del Regolamento (UE) 2020/689 ed in particolare la Setticemia emorragica virale (SEV) e la Necrosi ematopoietica infettiva (NEI).

Nel caso la Commissione e gli Stati membri concordino, possono assistere entro il termine dei 60 giorni evidenziando problematiche relative alla richiesta, a sostegno della dichiarazione il sottosegretario di Stato, collegando di ulteriori 60 giorni, la data in cui la richiesta è stata effettuata.

According to article 83 (1) of Regulation 2020/689/UE the provisional declaration of freedom for VHS and IHN of the compartment "Stazione di Idrobiologia Alpina Valli di Sant'Antonio - Incubatoio Ittico di Valle" code 0638214/1 and "Alto Nera zone" are hereby attached.  
The day of publication starts from July 17 2023.

According to article 83 (1) of Regulation 2020/689/UE the provisional declaration of freedom for VHS and IHN of the hatchery "Incubatoio di Volle" code IT07971009 are hereby attached.  
The day of publication start from September 11 2023.

For any request you can contact the following e-mail address: [marion@sanita.it](mailto:marion@sanita.it)

- Complete and correct documents are published on website
- After 60 days, Ministry of Health communicates to Competent Authority the officiality of the disease free status

## 7 provisional declaration published in 2023

- Updating national category 1 establishments in the national and the EU website



# Critical points in the application of the AHL

- ✓ Re-organization of NDB aquaculture for the different type of production (finfish, shellfish, crustacean)
- ✓ Assignment of farms with surveillance to demonstrate that are not infected in relation to a not uniform application of AHL in EU
- ✓ The previous aquaculture professional figures are no longer delegated
- ✓ Need of high training activities for competent veterinary authority and operators related to:
  - the knowledge on new NDB and correct data entry process
  - the knowledge on the application of AHL in the different type of production (finfish, shellfish, crustacean) in relation to high staff turnover
- ✓ Surveillance doesn't provide information on prevalence and incidence of group C diseases outside the eradication zones

*Thanks for your attention..*