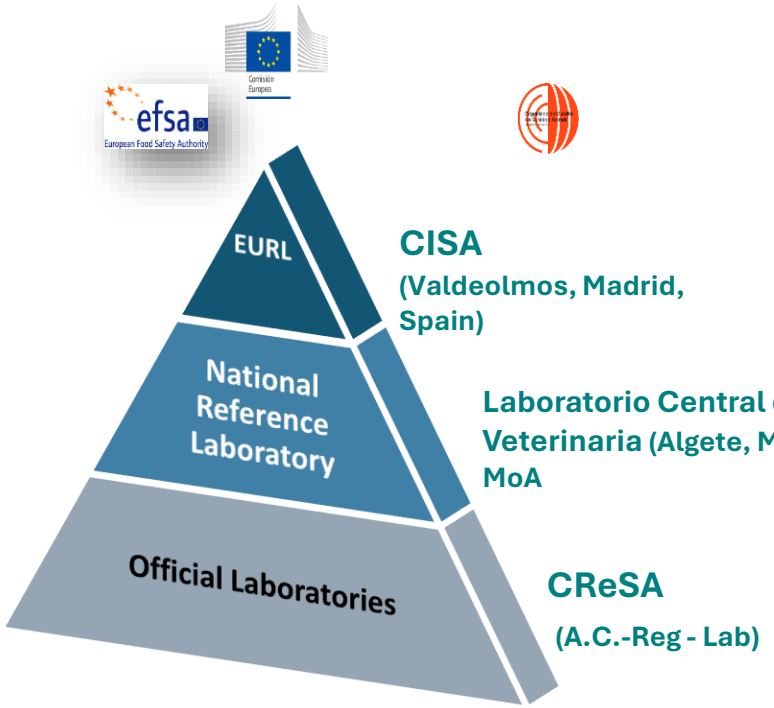
African Swine Fever (ASF) confirmatory diagnosis and molecular characterization at the EU-Reference Laboratory for ASF



CISA
(Valdeolmos, Madrid, Spain)

Laboratorio Central de Veterinaria (Algete, Madrid) - MoA

CReSA
(A.C.-Reg - Lab)

Regulation (EU) 2017/625

1. **First report** on 5 December 2025. A more extensive report is still pending. (confidential, virus sequence will be made available at due time).

2. **Main findings and conclusion**:

- ✓ **Confirmation** of NRL results (real time PCR)
- ✓ Virus **sequencing** (Sanger & WGS):
  - **Genotype II** (= genotype currently circulating in EU Member States)
  - **Genetic group 29** (similar to genetic group1: Georgia 2007), different from known genetic groups currently circulating in EU Member States

Measures taken by the Ministry of Agriculture (Central Competent Authority) in response to EURL report`s findings.

1. Hyphotesis of **origin** :
   - Unknown virus strain currently circulating in EU or Europe and Asia third countries (**fomites?)**
   - Biological containment facility in Spain or abroad (**laboratory leak?)**

2. **Fact:** Proximity of a BSL 3 laboratory near the first two outbreaks of the disease

3. **Response**: opening of a **complementary epidemiological investigation** according to art. 57.2 del Reglamento (UE) 2016/429 (Animal Health Law).
   - Ask the European Commission for technical assistance: **EU vet team** of **laboratory experts**

EUvet team –lab experts visit. 11-12 December 2025

1. **Meeting venue:** Animal Health Research Center of Catalunya (**IRTA-CReSA**)

2. **Participants:**

   - **EUvet team members**
   - Representatives of the **EU Reference Laboratory** (CISA-Valdeolmos, Spain)
   - Representatives of the **Central Competent Authority** (MoA)
     - Representative of the National Reference Laboratory (LCV, Algete – Madrid)
   - Representatives of the **Regional Competent Authority** (Generalitat de Catalunya)
   - Representatives of IRTA-CReSA
   - Representatives of a **private pharmaceutical company** operating on CReSA's premises

EUvet team lab expert visit. 11-12 December 2025

3. Main topics:

- **Description of level 3 biological containment facilities**. Photo report and videos of the facilities (for safety and time reasons, the level 3 biological containment facilities was not visited).
- **Biosafety management protocols**.
- **System for authorizing personnel** working directly or indirectly with the ASF virus.
- **Inventory (list) of ASF** virus strains stored at CReSA.
- Records of **virus strains entries and exits** (origin/destination/volume/purpose).
- **List of *in vivo* trials** conducted in the facilities with the Georgia 2007 ASFv strain in the last two years.
- **Assessment of critical points in the facility or protocols** that could have led to a hypothetical virus leak.

EUvet team lab expert visit. 11-12 December 2025

4. Main conclusions (I)

- The **analyses carried out** by the reference laboratories (**NRL, EURL**) are of **high-level and relevant.**
- The EURL conducted sequence analysis, including the Whole Genome Sequencing (WGS), which led to a **detailed genetic characterization of the outbreak ASFv strain**.
- **Comparison** of these sequence to sequences publicly available was performed. These analyses **do not allow identification of the origin of the virus** due to lack of closely related strains in the databases.
- These analysis allowed **identification of genetic markers** in the viral genomes sequenced. These markers could **help to trace** the origin of the virus if other sequence data become available.

EUvet team lab expert visit. 11-12 December 2025 (II)

4. Main conclusions (II)

- The **laboratory (CReSA) biosecurity measures** presented are **adequate** and well established.
- The **laboratory is aware** of the risks of virus escape from the facility and **has established assessment of critical points** in the facility or protocols.

*Based on the data presented, the **EUVET team could not identify any obvious route by which the virus could have been released from the IRTA-CReSA facilities**.*

EUvet team lab expert visit. 11-12 December 2025 (II)

5. Main Recommendations

- **Continue sequencing viruses detected in disease outbreaks** (ongoing by the NRL)
- Perform **sequencing** of relevant **viruses available in IRTA-CReSA** and **in the private company** operating in CReSA's premises (ongoing: NRL & EURL)

정말 감사합니다

どうもありがとうございます

非常感谢