

# ASF Regulation CIR (EU) 2023/594 and ASF Guidelines

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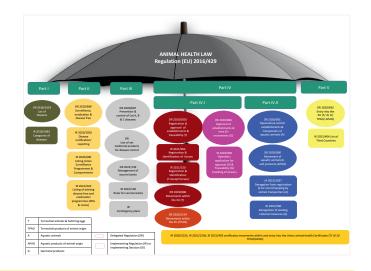
#### Outline

- Main EU legislation on ASF
- ASF Regulation
  - Main changes
  - Main principles
  - 'Compliant establishments'
  - Movements of pig within and outside restricted zones (RZ1, RZ2, RZ3)
  - Special health and identification marks
  - Annexes
- ASF guidelines



## Main EU legal framework for ASF

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



Commission **Delegated Regulation (EU) 2020/687** of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases

Commission Implementing Regulation (EU) 2023/594 of 16 March 2023 laying down special control measures for African swine fever

ASF Regulation 2021/605 has been repealed

Article 259 of AHL Commission emergency measures (if needed)

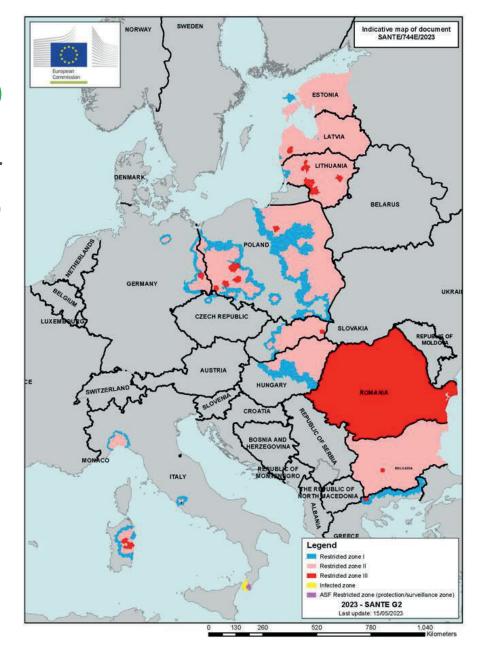


#### **Introduction**

## **ASF** Regulation

Commission Implementing Regulation (EU) 2023/594 ('ASF Regulation') laying down special disease control measures for African swine fever and repealing Implementing Regulation (EU) 2021/605

- Adopted by the Commission on 16 March 2023
- Published in the OJ on 17 March 2023
- Applies from 21 April 2023 (until 20 April 2028)
- EU regionalisation measures for ASF



## ASF Regulation (EU) 2023/594

- Takes account of the on the epidemiology of ASF latest experience and knowledge
- Ensures a continuous and consistent application of special disease control measures for ASF in the Union
- Provides for some <u>new</u> (additional) special disease control measures for ASF, such as
  - specific prohibitions and risk mitigating measures for the movements of consignments of kept porcine animals <u>within</u> restricted zones I, II and III
  - a <u>harmonised shape of special</u> health or, where relevant, identification <u>marks</u> for certain products of animal origin
  - national action plans for wild porcine animals in order to avoid the spread of ASF in the Union

# Main changes: 2023/594 vs 2021/605

New provisions in ASF Regulation (2023/594)	Relevant Article(s) in ASF Regulation	Main justification
specific prohibitions and risk mitigating measures for the movements of consignments of kept porcine animals within restricted zones and extension of the scope of the special disease control measures in Union rules accordingly	9 – specific prohibitions 14 – general conditions 15, 16, 17 – additional general conditions 22 – specific conditions (RZ1) 23, 24 – specific conditions (RZ2) 28, 29, 30 – specific conditions (RZ3) 44 – special designation Annex III – reinforced biosecurity measures	Avoid lengthy persistence and risks of ASF in long-lasting restricted zones  Sustainability of pig farms in the EU in the long term
an obligation on the Member States to establish National action plans for wild porcine animals in order to avoid the spread of African swine fever in the Union (with minimum requirements for the national action plans)	56 - National action plans Annex IV – minimum requirements for the plans	Coordinated and consistent approach across the MSs to address ASF risks (movements of wild boar or human mediated spread)
new Annex II with the list of areas identified at Union level as protection and surveillance zones or, in the case of wild porcine animals, as an infected zone (with the duration of that regionalisation) in a previously disease-free Member States or zones	6(2) – outbreak in wild porcine animals in a previously disease-free* MS or zone 7(2) – outbreak in kept porcine animals in a previously disease-free* MS or zone Annex II – list of areas  * 2(f) 'previously disease-free Member State or zone' means a Member State or zone of a Member State, where African swine fever has not been confirmed either in kept or in wild porcine animals during the preceding period of twelve months	to ensure clarity and transparency of Union rules (in the past, such areas were identified through separate (standalone) legislative acts)  European Commission

## Main changes: 2023/594 vs 2021/605

New provisions in ASF Regulation (2023/594)	Relevant Article(s) in ASF Regulation	Main justification
reference to the general conditions to grant derogations from prohibitions in the protection zone of Article 28 of Delegated Regulation (EU) 2020/687 replaced by a reference to the general conditions for granting derogations from prohibitions relevant to the surveillance zone of Article 43 of that Delegated Regulation, that requires, among other, that all authorised movements are performed prioritising major highways or mainline railways.	14(1)(a) – general conditions	Avoid unnecessary restrictions ('exclusively via designated routes')  Other risk mitigating measures in place (e.g. 'compliant farms')
A possible derogation from the general condition to only authorise movements of kept porcine animals without unloading or stopping, until the unloading in the establishment of destination within the same Member State concerned for the purpose of immediate slaughter of porcine animals kept in restricted zones I and II  Commission Implementing Regulation (EU) 2023/835 of 19 April 2023 (amendment of ASF Regulation)	14(4) – general conditions, new paragraph. 22(3) – specific conditions (RZ1), new paragraph 24(4) – specific conditions (RZ2), new paragraph	Avoid unnecessary restrictions  Specific logistical arrangements for the movements of kept porcine animals in place in some MSs
Possibility to exempt from prohibitions movements of porcine animals (and their germinal products) kept in confined establishments in RZ1, RZ2, RZ3 for the movements to another confined establishment within the same Member State (following the risk assessment by the competent authority; ASF risk negligble)	9(2)(b) – specific prohibitions and a possible exemption for porcine animals kept in confined establishments  10(2)(a) – specific prohibitions and a possible exemption for germinal products	Avoid unnecessary restrictions  Limited movements within confined establishments

# Main changes: 2023/594 vs 2021/605

New provisions in ASF Regulation (2023/594)	Relevant Article(s) in ASF Regulation	Main justification
specific conditions for derogations authorising movements of consignments of germinal products obtained from porcine animals kept in a restricted zone III from that restricted zone in the territory of the same Member State	33 – specific conditions for derogations authorising movements of consignments of germinal products	Avoid unnecessary restrictions to the approved establishments (high level of biosecurity)
specific conditions for authorising movements of consignments of Category 3 materials obtained from porcine animals kept in a restricted zone III outside that restricted zone within the same Member State for the purpose of the processing of animal byproducts by pressure sterilisation or certain alternative methods, the manufacturing of pet food and for the transformation of animal byproducts and derived products into biogas or compost	40 - specific conditions for authorising movements of consignments of Category 3 materials obtained from porcine animals kept in restricted zones III outside that restricted zone within the same MS	'safe' derogations business continuity
a concrete shape of special health or identification marks relevant for movements within or from restricted zones within the same Member State only of certain consignments of fresh meat and meat products obtained from kept or wild porcine animals	47 - special health or identification marks	harmonisation



# Main changes: 2023/594 vs 2021/605 concerning wild boar

ASF Regulation Changes (4)

New provisions in ASF Regulation (2023/594)	Relevant Article(s) in ASF Regulation	Main justification
in the case of an outbreak in wild porcine animals, an obligation on the competent authorities of the Member States to immediately establish an infected zone in accordance with Article 63 of Delegated Regulation (EU) 2020/687	3 - special rules for the immediate establishment of restricted and infected zones in the event of an outbreak of African swine fever in kept or wild porcine animals	To ensure <b>immediate response</b> to risks
an obligation on the Member States to establish National action plans for wild porcine animals in order to avoid the spread of African swine fever in the Union (with minimum requirements for the national action plans)	56 - National action plans Annex IV – minimum requirements for the plans	coordinated and consistent approach across the MSs to address ASF risks (movements of wild boar or human mediated spread)
possibility for the competent authority to allow derogation from each single testing of wild boar with pathogen identification tests for movements of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption,  - within and from RZ1; and  - within RZ2 and RZ3	52(3) – specific conditions for derogations (risk assessment on the basis of appropriate and continuous surveillance, for movements within the same MS as near as possible where the wild boar was hunted and for private domestic use only)	additional flexibility based on specific (favourable) ASF situation in the particular restricted zone or in the part of it



# Specific prohibitions of movements of consignments of:

- 9(1). Porcine animals kept in restricted zones I, II and III within and outside those zones.
- 10. Germinal products obtained from porcine animals kept in restricted zones II and III outside those zones.
- 11(1). ABPs obtained from porcine animals kept in restricted zones II and III outside those zones.
- 12(1). Fresh meat, meat products, including casings, obtained from porcine animals kept in restricted zones II and III outside those zones

Exemptions and derogations from prohibitions may be possible



#### **Exemptions from prohibitions for:**

#### The competent authority **may decide** to exempt from prohibitions:

- 9(2)(a). Porcine animals kept in the restricted zone I for the movements to establishments within the same Member State
- <u>new 9(2)(b). Porcine animals kept in confined establishments in RZ1, RZ2, RZ3 for the movements to another confined establishment within the same Member State (risk assessment)</u>
- <u>new</u> **10(2). Germinal products** from porcine animals kept in **confined establishments** in RZ2, RZ3 for the movements **to another confined establishment within the same Member State** (risk assessment)
- 11(2). ABPs obtained from porcine animals kept outside RZ II and III and slaughtered in slaughterhouses in RZ II and III, provided [conditions on separation].....
- 12(2). Meat products, including casings which have undergone the relevant treatment in accordance with Annex VII of Regulation (EU) 2020/687 in designated establishments (new treatment available in Annex VII of DR 2020/687; 70°C for a minimum of 30 minutes)

# Operator's obligations with regard to animal health certificates for movements outside restricted zones I, II and III

- Horizontal requirements (+ exemptions\*) provided for in AHL
- ASF Regulation special attestations required for:
  - Article 18 porcine animals; (+ exemptions\*)
  - Article 19 fresh meat, meat products obtained from porcine animals; (+ exemptions\*)
  - Article 20 germinal products obtained from porcine animals; (+ exemptions\*)
  - Article 21 **ABPs** obtained from porcine animals (AH certificate of Annex VIII to Regulation (EU) 142/2011). (+ exemptions as provided in Art. 22(6) of DR 2020/687)
- The competent authority may decide that such a certificate does not have to be issued for movements of [...] <u>within the Member State</u> concerned when that authority considers that an <u>alternative system is in place</u> ensuring that the consignment of such [...] is <u>traceable</u> and that those [...] <u>comply with the animal health requirements</u> for such movement.

# **'Compliant establishment' Articles of ASF Regulation**

#### - specific

ASF Regulation Compliant establishment

In general, the competent authority of the Member State concerned may authorise movements of kept porcine animals within and outside restricted zones in cases defined by ASF Regulation from 'compliant establishments'

#### 14(1)(a). General conditions as per Article 43 (2) to (7) of Regulation (EU) 2020/687

prioritising major highways or mainline railways; avoiding the vicinity of establishments keeping animals of listed species

without unloading or stopping, until the unloading in the establishment of destination (derogation possible)

Designated establishment of destination

Verification on the designation and acceptance of consignment

A clinical & if necessary, laboratory examination

Outcome of visits by official veterinarians

Separation from not eligible animals/products

Supplementary biosecurity measures



#### Additional general conditions as per Art. 14, 15, 16 of ASF Regulation

14(2). assessment of risk

15(1)(a). **residency period** for kept porcine animals *(does not apply for immediate slaughter)* 

15(1)(b). a **clinical examination** within 24h period prior to the movement by an official veterinarian

15(1)(c). if necessary (competent authority decides), **PCR tests of porcine animals** (establishment, consignment)

16(1)(a). **regular visits by official veterinarians** (at least 2 X year in RZ I/II; 1 X every three months in RZ III)

16(1)(b). **biosecurity requirements** (Annex III (EU) + national)

16(1)(c). continuous **passive surveillance**: PCR testing of dead animals = early detection of ASF!

17. **means of transport** (construction, maintenance, cleaning and disinfection under the control or supervision of the competent authority)

## Movements of pigs within and outside RZ1

- Art. 9(2) + 22(1): The competent authority may exempt from prohibition movements within the same MS of pigs outside or within the RZ1 (including from confined establishments to another confined establishments within the same MS (Art. 9(2)(b)). It can also decide to apply Art. 22 (conditions).
- Art. 9(3) + 22(2): Compliant establishments: The competent authority may authorize movements of pigs from RZ1 to other MSs (or third countries)
- Art. 9(1): Specific prohibition applies. The competent authority cannot authorize movements of pigs to other MSs or third countries <u>from 'non-compliant' establishments</u>. No derogation in Art. 22.
- Art. 10/11/12: No specific prohibitions for germinal products / ABPs / meat & products obtained from pigs kept in RZ1.

#### Movements of pigs within and outside RZ2

#### **From compliant establishments**:

- Art. 9(3) + ...: The competent authority may authorize movements of pigs within RZ2 or from that zone:
  - Art. 23: to other establishments in the same MS (same or another RZ2, also RZ1 or RZ3 and free areas) + monitoring period Annex II of DR 2020/687 = 15 days in the establishment of destination
  - Art. 25, 26, 27: to other establishments in RZ2 or RZ3 of other MSs (channeling procedure, monitoring period or immediate slaughter, lists and information in the PAFF, except when movements is only through continuous RZs)
  - Art. 24(1)(2): for immediate slaughter in the same MS (within or outside that RZ2)
  - Art. 25, 26, 27: for immediate slaughter in RZ2 or RZ3 of other MSs (channeling procedure)
- germinal products as per Art. 32 (within the same MS) or Art. 34 (to RZ2 or RZ3 in another MS, only from approved establishment, conditions, lists)
- <u>ABPs</u> as per Section 9 (**Art. 35-39**)
- <u>meat & products</u> as per Section 10 (**Art. 41-42**) can be moved within or outside (to other MSs or third countries as well)

#### Movements within and outside RZ2

#### From non-compliant establishments:

- Art. 9(3) + ...: The competent authority may authorize movements of pigs:
  - Art. 24(3): for immediate slaughter in the same MS risk assessment, cascade:
    - as near as possible within the same or another RZ2, or
      - if not possible in RZ1 or RZ3 within the same MS
        - in areas outside RZ1, RZ2, RZ3 in the territory of the same Member State, where it is not possible to slaughter the animals in the RZ1, RZ2, RZ3
- Germinal products
- <u>ABPs</u> as per Art. 35-39
- meat & products as per Art. 41(2)(b)
  - fresh meat marked and sent for processing (treatments of Annex VII of DR 2020/687); or
  - marked with special health/ID mark (Art. 47) (not intended to other MSs/third countries).



#### Movements within and outside RZ3

#### **From compliant establishments**:

**Art. 9(3) + 28:** The competent authority may *(exceptionally, due to AW!)* authorize movements <u>within and outside RZ3 to other establishments</u> (cascade, monitoring period, same supply chain):

- to an establishment located in a restricted zone II, or,
  - in the absence of such a restricted zone II in that MS, in a restricted zone I, in the same MS
- Art. 9(3) + 29(1)-(4): The competent authority may (exceptionally, due to AW + logistic limitations or absence of slaughterhouses!) authorize movements of pigs outside from RZ3 for immediate slaughter:
  - in a restricted zone II;
    - in a restricted zone I, where it is not possible to slaughter the animals in the restricted zone II;
      - outside of restricted zones I, II and III, where it is not possible to slaughter the animals in those restricted zones.
- Art. 9(3) + 30(1)-(2): The competent authority may authorize movements within RZ3 to for immediate slaughter:
- Germinal products as per Art. 33
- <u>ABPs</u> as per Art. 35-40
- meat & products as per 41(2)(b)
  - fresh meat marked and sent for processing (treatments of Annex VII of DR 2020/687); or
  - marked with special health/ID mark (Art. 47) (not intended to other MSs/third countries).



#### Movements within and outside RZ3

#### From non-compliant establishments:

- Art. 9(3) + ...: The competent authority may authorize movements of pigs:
  - Art. 29(5): for immediate slaughter outside RZ3 in the same MS risk assessment, cascade:
    - in another restricted zone III in the territory of the same MS, as near as possible to the establishment of dispatch;
      - in restricted zones II or I in the territory of the same MS, as near as possible to the establishment of dispatch, where it is not possible to slaughter the animals in the restricted zone III;
        - in areas outside restricted zones I, II and III in the territory of the same MS, where it is not possible to slaughter the animals in the restricted zones I, II or III;
  - Art. 30(3): for immediate slaughter within that RZ3 in the same MS risk assessment, as near as possible within that zone
- Germinal products
- ABPs as per Art. 35, 38, 40
- <u>meat</u> as per Art. 41(2)(b)(i)
  - fresh meat marked and sent for processing (treatments of Annex VII of DR 2020/687) or marked with special health/ID mark (Art. 47) (not intended to other MSs/third countries).



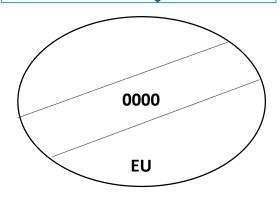
## Special health or identification marks

- Art. 47 The competent authority of the Member State concerned shall ensure that the following products of animal origin are marked\*:
- (a) the fresh meat and meat products, including casings, obtained **from porcine** animals kept in a restricted zone III, as provided for in Article 43, point (d)(ii);
- (b) the fresh meat and meat products, including casings, obtained from porcine animals kept in a restricted zone II, where the specific conditions for authorising movements of consignments of those commodities outside the restricted zone II provided for in Article 41(1) are not met, as provided for in Articles 24(3), point (e), and 41(2), point (b)(ii);
- (c) the fresh meat and meat products from wild porcine animals moved within a restricted zone I or outside that restricted zone from the establishment designated in accordance with Article 44(1), as provided for in Article 52(1), point (c)(iii), first indent.
- \*a health mark or, where relevant, an identification mark as provided for in Article 5(1) of Regulation (EC) No 853/2004 with two additional diagonal parallel lines is applied and intended for movement only within the same Member State concerned

There is no visual sample in the EU legislation how the special health/id mark referred to in IR 2023/594 should look like.

Therefore, the MSs should follow the Article 47 of that Regulation and design the special mark on the basis of those legal provisions.

Possible example?





#### Annexes



- Annex I list of ASF restricted zones (I, II and III) differentiated by the epidemiological situation of that disease
  - last amendment: IR 2023/947 of 11 May 2023
- <u>new:</u> Annex II list of areas subject to Commission emergency measures
- Annex III reinforced biosecurity measures for establishments of kept porcine animals located in restricted zones I, II and III
- <u>new:</u> Annex IV Minimum requirements for national actions plans for wild porcine animals in order to avoid the spread of ASF in the Union



#### Review of EU guidelines related to ASF

Work in progress

**Strategic** approach to the management of African swine fever for the EU





the prevention, control and swine fever in the Union ('ASF guidelines)

**Principles and** criteria for geographically defining ASF regionalisation

[draft] Guidelines on eradication of African

#### Draft chapters

- GENERAL (EU LEGISLATION).
- KEPT PORCINE.
- WILD PORCINE.
- IV. PRINCIPLES AND CRITERIA FOR REGIONALISATION.

#### **ANNEXES**

- 1. Key messages for awareness raising.
- 2. Biosecurity requirements for hunters and for searching/handling carcasses of wild porcine.
- 3. Sampling and removal of carcases of wild porcine.
- 4. Summary recommendations for the management of wild porcine.

# Thank you for your attention

# Questions?



European



https://ec.europa.eu/food/animals/animal-health/animal-health-law\_en

https://food.ec.europa.eu/animals/animal-diseases/diseases-and-control-measures/african-swine-fever\_en

https://rr-europe.woah.org/en/Projects/gf-tads-europe/standing-groups-of-experts-on-african-swine-fever-in-europe/