

Competent Authority response to recommendations in draft report, received 16 March 2022

Response of the competent authorities of Italy to the recommendations of report ref. DG (SANTE) 2021-7344 of the audit carried out from 09 November 2021 to 19 November 2021 in order to evaluate the implementation of animal health controls in relation to African swine fever

N°	Recommendation	Action Proposed by the competent authority
1	<p>To take action to improve compliance with the requirements on identification and registration of pigs and the ones for keeping free-range pigs, in particular as regards:</p> <ul style="list-style-type: none"> a. adequate keeping of records in the holding registers of all new-born of pigs and their notification to the competent authority, and b. the prohibition on keeping pigs outside registered semi-enclosed or enclosed premises. <p>Articles 84, 93, 101, 102(1)(3) and 115 of Regulation (EU) 2016/429. Articles 23 and 52 of Regulation (EU) 2019/2035. Articles 3(1), 9 and 15 of Regulation (EU) 2021/520. Recommendation based on conclusion No. REF_Ref88820651 \r \h 2. Associated findings No. REF_Ref88742840 \r \h * MERGEFORMAT 5 and REF_Ref89355691 \r \h 12.</p>	<p>The competent authority will take the following measures:</p> <ul style="list-style-type: none"> a) In application to the Recommendation based on conclusion No. REF_Ref88820651 \r \h 2., a new procedure has been implemented in addition to the records of the new-born of pigs in the holding registers. The procedure is included in the II provision of the Extraordinary ASF Eradication Program (https://www.regione.sardegna.it/j/v/2644?s=1&v=9&c=390&c1=13680&id=98492), containing rules about the control of the disease in pigs and pig meat productions for the 2022-2023. The provision has been issued on 11/03/2022 by the ASF Project Unit (UdP) and provides for: <ul style="list-style-type: none"> - The farmers are required to register the new-born of pigs in the National Database (BDN), at least three times per year (Art. 6, par. 5 of the II provision) (phase 1: census registration in BDN). - Every six months, the Veterinary Epidemiological Regional Observatory (OEVR) will performs appropriate checks aimed at highlight, measuring and monitoring any discrepancies in pig reproductive parameters. This phase requires the implementation of a specific algorithm with the official data from BDN by the OEVR (phase 2: assessment of conformity of the reproductive parameters) - If non-conformities are detected, the OEVR notified them by means of specific alerts in the Datawarehouse (DWH) to the competent authorities. Subsequently, the competent authorities will carry on the appropriate checks and possible prescriptions in those farms where non-conformities are found (phase 3: alert and official controls).

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		<ul style="list-style-type: none"> - If the non-conformities detected are not heal within the expected time period, the competent authorities apply the relevant measures aim at slaughtering and/or depopulating the farm (Art. 6, par. 8, and Art. 25 of the II provision) (phase 4: slaughtering and/or depopulating measures). b) In Sardinia it is forbidden to raise pigs outside registered semi-enclosed or enclosed premises. This phenomenon is currently under control thanks to the specific monitoring procedures that provides for: <ul style="list-style-type: none"> - Daily inspections by the 82 Forestry Corps of Enviromental Surveillance (CFVA) local units all over the region, aimed even at illegal free-ranging pigs sightings (phase 1: illegal free-ranging pigs surveillance and control). - If illegal free-ranging pigs are sighted, the number of these pigs and the geolocation (lat and long) are notified by specific survey form (see Annex 1) to the OEVR, which collect and input the information in the DWH (phase 2: sightings notification and data collection in DWH). - Specific checks, verification and intelligence actions are carried out to evaluate the existence of illegal free-ranging pigs owner and the safety of the area where these pigs were sighted (phase 3: measure of intelligence). - If no owner is identify, the competent authorities carried out the depopulation actions and the laboratory tests for ASFV on the illegal pigs (phase 4: depopulation and ASF laboratory tests). <p>Furthermore, in order to further strengthen the control measures related to the identification and registration of pigs, the new second provision established restrictive deadlines for the non-conformities heal. If the non-conformities are not heal within the expected time period, the competent authorities apply the relevant measures aim at depopulating the herd (Art. 5, par. 5 of the II provision).</p>

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2	<p>To ensure that holdings with seropositive pigs are considered as confirmed ASF outbreaks and notified to the Commission and Member States.</p> <p>Article 1 (2)(c) of Commission Decision 2003/422/EC, Article 58 of Regulation (EU) 2016/429 and Article 9 (1) of Regulation (EU) 2020/689</p> <p>Recommendation based on conclusion No. REF_Ref88820798 \r \h 4.</p> <p>Associated findings No. REF_Ref90460051 \r \h 45, REF_Ref90460057 \r \h 46 and REF_Ref90460064 \r \h 47.</p>	<p>Considering the observations arising from the dialogue between the Auditors, the UdP and the regional and national competent authorities during the audit of 9-19 November 2021, the Recommendation 2 has been already transposed and the relevant legislation has been applied starting from December 2021, as can be seen from the notification of the ASF outbreaks in SIMAN and ADIS.</p>
3	<p>To carry out effective epidemiological investigations in cases where ASF is confirmed, ensuring that they provide accurate and timely conclusions on the possible origin of the disease and the likely duration of its presence in the affected holding.</p> <p>Article 57 (2)(a) and (b) of Regulation (EU) 2016/429.</p> <p>Recommendation based on conclusion No. REF_Ref88820744 \r \h 5.</p> <p>Associated finding No. REF_Ref88742944 \r \h 65.</p>	<p>As stated in the II provision of the Extraordinary ASF Eradication Program (Art. 13, par. 6), the OEVR in collaboration with of the National Reference Centre for ASF, supports the veterinary services in carrying out the epidemiological investigation, evaluating its completeness, timeliness and exhaustiveness.</p> <p>Furthermore, the digital compilation of the epidemiological investigations on the SIMAN database (via input screen) allows the official veterinarians to highlight any discrepancy with the official health data sources.</p> <p>In addition, specific training courses will be planned and organized for the staff of the veterinary services.</p>
4	<p>To ensure that passive surveillance covers and is representative for the entire kept porcine population and meets the objectives of early detection of the presence of ASF virus in this population.</p> <p>Articles 26 and 27 of Regulation (EU) 2016/429.</p> <p>Article 3(1) of Regulation (EU) 2020/689.</p> <p>Recommendation based on conclusion No. REF_Ref88820798 \r \h 4.</p> <p>Associated finding No. REF_Ref88752935 \r \h 42 and REF_Ref88743091 \r \h 69.</p>	<p>The new procedure on passive surveillance in domestic pigs was adopted with UdP note prot. 77 del 09/02/2022 (Annex 2) and is included in the II provision of the Extraordinary ASF Eradication Program. Base on this, the national and regional informative systems have been lined up.</p> <p>The procedure is aim at ensure adequate and uniform passive surveillance all over the region. The procedure is based on a sample size representative of the expected dead pigs population, aim at detect a disease prevalence less than 0.5% (confidence level 95%).</p> <p>Particularly, the procedure provides for:</p> <ul style="list-style-type: none"> - The UdP notifies to the ASLs the yearly expected number of dead pigs to be tested for ASF, by the note prot. 77 del 09/02/2022 (phase 1: sample size assignment and notification).

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		<ul style="list-style-type: none"> - The Veterinary services are required to send to the IZS local laboratories the samples collected from the dead pigs in farms, to perform the ASF laboratory tests. Samples have to be send with specific data sheet (phase 2: domestic pig passive surveillance sampling). - During the acceptance of the sample by IZS, the data about farm (i.e., farm code, fiscal code, type of farm, farming practice, municipality, province and location), age and sex of the dead pig, date of death, sample type and data of sampling are included in the data sheet and upload on the national official data system for passive surveillance (SINVSA) (phase 3: domestic pig passive surveillance data upload). - The OEVR is already performing every month the data mining on ASF passive surveillance in domestic pigs. Data about the samples tested for ASF passive surveillance in domestic pigs are directly extracted from SINVSA (phase 4: domestic pig passive surveillance data collection). - The OEVR is already notifying every month to the ASLs a specific summary report about the sampling program with information about: the monthly number of expected dead pigs to be tested for ASF, the number of dead pigs already tested for ASF, the number of those yet to be tested (phase 5: domestic pigs passive surveillance reporting). - On the base of the reports, the OEVR, in collaboration with the National Reference Centre for ASF, evaluates the state-of-play of the passive surveillance in domestic pigs and any modification needed to guarantee the representativeness of the sample (phase 6: sample representativeness evaluation).
5	To ensure practical arrangements are put in place to increase the number of dead wild boar sampled and tested for ASF in order to make passive surveillance representative for the entire wild	The wild boar passive surveillance is already in place throughout the region and will be ensured and strengthened. The OEVR has already delivered a specific procedure for implementing the EFSA Exit strategy for Sardinia, on which the operational phases of passive surveillance are based. The UdP is implementing a

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	<p>porcine population and meet the objectives of early detection of the presence of ASF virus in this population. Articles 26 and 27 of Regulation (EU) 2016/429. Article 3(1) of Regulation (EU) 2020/689. Recommendation based on conclusion No. REF_Ref88820798 \r \h 4. Associated findings No. REF_Ref88753519 \r \h 51 and REF_Ref88753527 \r \h 52.</p>	<p>specific intervention plan, in collaboration with the Veterinary Services, the IZS, the CFVA, the regional agency of Forestas, and the hunting and dog associations. This plan makes it possible to enhance the search for wild boar carcasses throughout the region, according to EFSA guidelines, in order to provide a representative view of the health status of the entire wild boar population, inside and outside the area considered infected by the competent authorities of Sardinia, including protected areas where the hunt is forbidden.</p> <p>The 2022 wild boar passive surveillance plan includes the following phases:</p> <ul style="list-style-type: none"> - Yearly, the OEVR plans the wild boar passive surveillance goals, based on EFSA Exit strategy (phase 1: planning of the wild boar passive surveillance). - Annual scheduling of the on field inspections aimed at actively searching for wild boar carcasses throughout the region (infected and non-infected area, including protected areas where the hunt is forbidden). The OEVR notified with specific reports the area where carcasses search should be performed, to comply with the Exit strategy. On field activities are coordinated by the OEVR, in collaboration with CFVA, the regional agency of Forestas, and the hunting and dog associations (phase 2: scheduling of the wild boar passive surveillance activities). - Starting from January 2022, the OEVR performs the data mining from SINVSA on the number and geolocation of the wild boar carcasses sampled and tested for ASF producing and updating a specific database (phase 3: wild boar passive surveillance data mining). - The OEVR evaluates the number and location of the carcasses collected and tested for ASF compare to those expected by the EFSA Exit strategy, every two months and based on the screening or the confirmatory phase (phase 4: update of the Exit strategy).

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		<ul style="list-style-type: none">- The OEVR provides to the competent authorities a two months report from the DWH with the number of carcasses to be found, the deadline and the area where these carcasses have to be found to complete the screening or the confirmatory phase, guarantying the overdispersion of the passive surveillance. Particular attention is paid to those areas where the hunt is forbidden (phase 5: wild boar passive surveillance reporting).- The Veterinary services are required to send the samples collected from wild boar carcasses to the IZS local laboratories to perform the ASF laboratory tests. Samples have to be send with specific data sheet (phase 6: laboratory testing).- Data about carcasses (i.e., location, hypothesis of dead wild boar or killed by road traffic accident, state of conservation of the carcasses) are upload on the National informative system SINVSA. These information costantly implement the phase 3 database (phase 7: wild boar passive surveillance data upload).