Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°.	Recommendation	Action Proposed by the Competent Authority
1		According to art. 51 of Law on the Veterinary Activity all animal holdings are subject to obligatory registration and all animals kept in - to identification. The BFSA maintains an Integrated Information System (electronic database) – VetIS with all data for holdings, identified animals and animal movements.
		As additional guaranty that all pigs holdings including backyards are registered and the register is kept up to date a new instruction was issued (Order № RD 11-365/26.03.2013 of the Executive Director of BFSA) for implementation of measures for control of classical swine fever in Bulgaria and the recommendations of the FVO Audit carried out in Bulgaria from 19 to 26.11.2012. in order to assess the measures for control of classical swine fever(DG (SANCO) /2012-6602),
		http://babh.government.bg/uploads/File/Zdraveopazvane/Zarazni_bolesti/Klasicheska_chuma_svine/Instruction%20CSF%20program_final.pdf
		In p. I of this instruction are defined the rules and timetable for the control to be applied on the registration of pig holdings and animal identification, the obligations of official veterinarians at municipal level, of Heads of Animal Health Departments at the RFSD-s and AHAW directorate at the HQ of the BFSA as well as the sanctions in case of noncompliance with the relevant legislation.
2	Ensure that all pig movements, including those relating to	In order to ensure that all pig movements, including those to backyards,

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°.		Recommendation	Action Proposed by the Competent Authority
	personal farms at back-yard locations, are reby Article 4 of Council Directive 2008/71/EC.		are recorded as required by Article 4 of Council Directive 2008/71/EC, it was ordered all guidelines of p. II of the new instruction (approved by Order of Executive Director of BFSA № RD 11-365/26.03.2013.) for implementation of measures for control of classical swine fever in Bulgaria and the recommendations of the FVO Audit carried out in Bulgaria from 19 to 26.11.2012 in order to assess the measures for control of classical swine fever(DG (SANCO) /2012-6602), to be strictly followed. http://babh.government.bg/uploads/File/Zdraveopazvane/Zarazni_bolesti/Klasicheska_chuma_svine/Instruction%20CSF%20program_final.pdf According to this point the following has to be performed: 1. Official municipal veterinarians together with police officers carry out regular inspections on farms and on during the journey of animals the documentation issued for their movements. The inspections are carried out according to the timetable specified in section I. p.1. 2. The joint inspections with police officials are carried out in accordance with the provisions of Ordinance № 24/28.12.2009 which determines the rules for interaction between the veterinary experts and
			thus from the Ministry of internal affairs. 3. Penalties are imposed under art. 417 and art.420a of the Law on Vetarinary. Activities in case of violeties of the requirements set out in
			Veterinary Activities in case of violation of the requirements set out in art.132 (1) p.11 and art.139 (1) p.1 and 3 of the same act.

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°.	Recommendation	Action Proposed by the Competent Authority
		4. Facilitation for movements of individual animals at backyards for personal use is regulated by Art. 168, § 2 of the LVA. 5. Head of Animal Health Department at the Regional Food Safety Directorate sends to AHAW Directorate at the HQ of BFSA report (in accordance with the template in the annex of this program) concerning checks carried out on a quarterly basis, the noncompliance detected and the sanctions imposed for the period. 6. The AHAW Directorate at the HQ of BFSA analyzes the reports under p. 5, controls the execution of inspections according to the timetable and annually inspected 30% of the 28 RFSD-s. The experts from the HQ examined the work done by the experts on the spot for the implementation of the measures under p. II.
3	Ensure that the requirements in Article 11(a) of Commission Decision 2008/855/EC are enforced on all holdings for domestic pigs.	To ensure that the requirements in Article 11(a) of Commission Decision 2008/855/EC are enforced on all holdings for domestic pigs the following measures under section III of the Instruction (approved by Order of Executive Director of BFSA № RD 11-365/26.03.2013) for implementation of measures for control of classical swine fever in Bulgaria and the recommendations of the FVO Audit carried out in Bulgaria from 19 to 26.11.2012. in order to assess the measures for control of classical swine fever(DG (SANCO) /2012-6602), http://babh.government.bg/uploads/File/Zdraveopazvane/Zarazni_bolesti/Klasicheska_chuma_svine/Instruction%20CSF%20program_final.pdf are applied:

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

P. Recommendation	Action Proposed by the Competent Authority
Recommendation	1. Municipal Official veterinarian carries out checks on pig farms for biosecurity level pursuant to Art. 11 of Ordinance № 44 of April 20, 2006 on animal health requirements for holdings 2. Municipal Official veterinarian carries out checks for the implementation of the provisions of Ordinance № 6 of 20 March 2007 on the conditions and procedure for pasture breeding of East-Balkans pigs and their crossbreds. 3. Municipal Official veterinarian carries out checks for the implementation of Order RD 09-27 / 15.01.2010 of MAF and Order RD 11-45 / 26.01.2010. 4. The checks under points 1-3 are performed by Municipal Official veterinarian quarterly according to a schedule pursuant to this Instruction 5. In case of noncompliance detected during the inspections under point 1 action are taken for re-categorization of the farm in the relevant group and/or imposing of sanctions provided in the LVA. All actions performed are recorded in the VetIS electron database of BFSA. 6. In case of noncompliance detected during the inspections under point 2-3 actions are taken and/or sanctions are imposed pursuant to the LVA. All actions performed are recorded in the VetIS. 7. Head of Animal Health Department at the Regional Food Safety Directorate sends to AHAW Directorate at the HQ of BFSA report (in
	accordance with the template in the Annex of this program) about the checks carried out on a quarterly basis, the noncompliance detected and the sanction imposed for the period.
	°. Recommendation

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°	Recommendation	Action Proposed by the Competent Authority
		http://babh.government.bg/uploads/File/Zdraveopazvane/Zarazni_bolesti/Klasicheska_chuma_svine/Instruction%20CSF%20program_final.pdf 8. The AHAW Directorate at HQ of BFSA analyzes the reports under p. 7, controls the execution of the inspections according to the timetable and within one year carries out checks on the spot of 30% of the 28 RFSDs for the implementation of the measures under p. III.
4	Ensure that procedures are in place to verify that the monitoring and control measures in domestic pigs meet the targets laid down, also at herd level, in the 2013 CSF monitoring and control plan approved by Commission Implementing Decision 2012/761/EC.	The head of AH department at RFSD and the AHAW Directorate at the HQ of BFSA carry out periodical checks of the lower levels pursuant to the provisions of new Instruction on the check of the effectiveness of the official control in the scope of Animal Health and Welfare in accordance with art. 8, point 3 of Regulation 882/2004 (approved by Order № RD 11-343/20.03.2013 of the Executive Director of BFSA) http://babh.government.bg/uploads/File/Zdraveopazvane/Humanno_otnoshenie/Instruction_official%20control_AHWD_final.pdf to ensure that monitoring and control measures for domestic pigs meet the targets laid down in the annual CSF control programme The Regional Food Safety Directorate sends to AHAW Directorate at the HQ of BFSA report (in accordance with the template in the Annex of this program) about the checks carried out on a quarterly basis, the noncompliance detected and the sanctions imposed for the period. This is described in p. IV of the new Instruction for implementation of measures for control of classical swine fever in Bulgaria and the

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

1	Recommendation	Action Proposed by the Competent Authority
		recommendations of the FVO Audit carried out in Bulgaria from 19 to 26.11.2012. in order to assess the measures for control of classical swine fever(DG (SANCO) /2012-6602) (approved with Order of Executive Director of BFSA № RD 11-365/26.03.2013) http://babh.government.bg/uploads/File/Zdraveopazvane/Zarazni_bolesti/Klasicheska_chuma_svine/Instruction%20CSF%20program_final.pdf
5	Ensure that the sampling of feral pig populations takes into account the guidelines in Point H, Chapter IV of the Annex to Commission Decision 2002/106/EC.	A new Instruction for targeted sampling of wild boar in the framework of the annual CSF control program was approved by Order № RD 11-365/26.03.2013 of the Executive Director of BFSA. http://babh.government.bg/uploads/File/Zdraveopazvane/Zarazni_bolesti/Klasicheska_chuma_svine/Instruction%20CSF%20WB%20sampling_final.pdf For the purpose of targeted survey of the CSF health status of wild boar
		in this instruction the whole territory of Bulgaria is divided into 80 zones, 15 of them (along the North and West borders) classified as high risk and the remaining 65 as low risk for CSF.
		The population of the wild boar in each of the zones (1 to 80) is approximately between 350 and 1,600 heads (Executive Forestry Agency, 2012).
		Pursuant to the Instruction a sampling scheme of 59 heads is planned for each zone (1-80) to detect the disease at 5% prevalence with 95%

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°.	Recommendation	Action Proposed by the Competent Authority
		confidence for the goals of the annual CSF surveillance in wild boar. The plan is in line with the recommendations of EFSA: "Control and eradication of CSF in wild boar". The EFSA Journal (2009) 932 The sampling of the wild boar population in each of the zones is planned according to the guidelines in Chapter IV, of Annex to Commission Decision 2002/106/EC i.e. 50% of the tested wild boar should be up to 1 year of age, 35% between 1 and 2 years old and 15% over 2 years. This strategy will be also used in the planning of the 2014 CSF control
6	Ensure that an expert group is appointed in line with the requirements of Article 15(2)(a) of Council Directive 2001/89/EC and that a system is established in order that this group can review on a regular basis the results of the vaccination campaign in wild boar as required by Article 20(2)(k) of this Directive.	By Order № RD 11-363/25.03.2013 of the Executive Director of BFSA a five-member expert group is nominated in line with the requirements of Article 15(2)(a) of Council Directive 2001/89/EC to review on a regular basis the results of the vaccination campaigns in wild boar as required by Article 20(2) (k) of this Directive and to analyses their effects on the immune status of the wild boar population. The expert group submits the analysis to the CVO, specify the deficiencies found and propose corrective actions, if needed.
7	Ensure that any amendments to the 2013 CSF monitoring and control plan approved by Commission Implementing Decision 2012/761/EC, are submitted to the Commission for approval as required under Article 27(6) of Council Decision 2009/470/EC.	The AHAW Directorate at the headquarter of BFSA has always reported the state of play and will report and submit for approval to the Commission any amendment of the annual control program for CSF

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°.	Recommendation	Action Proposed by the Competent Authority
		 In April (16 17.04.2013) CSF TASKFORCE meeting in Bucharest, Romania, will be held and the Commission also will be present. During the session BFSA will report about the: implementation of the CSF control programs in 2012 and 2013; measures taken on the recommendations of the FVO Audit carried out in Bulgaria from 19 to 26.11.2012 assessed the measures for control of classical swine fever(DG (SANCO) /2012-6602); planned targeted sampling for CSF surveillance in wild boar. Until 04/30/2013 BFSA will submit to the European Commission for approval the 2014 CSF control program.
8	Ensure that all analytical methods used for official samples are included in the scope of accreditation in order to meet the requirements of Article 12(2) of Regulation (EC) No 882/2004.	During 26-28.03.2013, the NRL for CSF was audited by the Bulgarian Accreditation Service (BAS) in conjunction with re-accreditation of the analytical methods and the extension of the real time PCR (letter № 69/227 19.03.2013 of BAS). The audit was successfully finalized with a positive evaluation and within one month from the date of the audit the Research Laboratory for Exotic and Emergency Contagious disease within the National Diagnostic and Reasearch Veterinary Institute (NRL for CSF is within its' scope) will receive an official extension from the BAS. As next step documentation will be submitted to BAS for further extension of the scope of accredited methods (which according to Bulgarian law is 30% of the already accredited methods) for VNT for

Response of the Competent Authorities of Bulgaria to the recommendations of Report ref. DG(SANCO)/2012-6602-MR of an audit carried out from 19 to 26 November 2012 in order to evaluate the animal health controls on classical swine fever

N°.	Recommendation	Action Proposed by the Competent Authority
		CSF and VNT to distinguish antibodies against Bovine Viral Diarrhea – Mucosal Disease and Border disease. It is expected that the documentation will be submitted to BAS by the end of September 2013 and the procedure will be finalized in March 2014.
9	and monitoring plan have adequate resources for reliable testing of official samples for CSF virus and antigen as indicated in the plan and in order to meet the requirements of Article 4(2)(c) of Regulation (EC) No 882/2204.	Director of the National Diagnostic and Research Veterinary Institute at BFSA has declared the need for timely purchase of 100 doses of diagnostic kit for real time PCR (report ref. № 4147/22.03.2013), which will be sufficient till the completion of an ongoing tender for the purchase of diagnostic kits expected to be finalized in May 2013. The report is approved by the CVO and the laboratory will be collateralized to carry out the necessary tests.