



STATE VETERINARY ADMINISTRATION OF THE CZECH REPUBLIC  
Slezská 7, 120 56 PRAHA 2  
Phone : (+420 ) 227 010 184  
Fax.: (+420 ) 227 010 198

Web : www.svs-cr.cz  
Email: zahr@svs-cr.cz

Your letter d/d : Attachment : Enclosures, five topics  
Your reference : File handled by : Dr. J. Kuna, DVM  
Our reference : ZAH1036/usda/04 Department : Foreign Relations

Dr. John R. Clifford  
Deputy Administrator  
USDA/APHIS, Veterinary Services, NCIE  
4700 River Road  
Riverdale, MD 20737  
USA

Prague : October 6, 2004

Attn.to : primary contact for the project : Dr. Chip Wells,  
Regionalization Evaluation Services Staff, Unit 38  
APHIS, VS, NCIE,

**Re: Request for the on-site visit/s.**

**Rulemaking exercise to implement Article 6 of the EC/US Veterinary Agreement.**

**Recognition of the EU animal health status for the "EU 25" – risk analysis.**

Dear Dr. Clifford,

This is in reference to your letter of 6 August, 2004 forwarded to Mr. Checchi Lang, Director, Directorate E, DG-SANCO, EC, Brussels, outlining first steps that the APHIS intends to take towards evaluating the CSF status of the 10 new EU Member States in conjunction with the EC/EU Veterinary Agreement.

As indicated in the said letter (Enclosure II) the APHIS, quote : "*could visit other MSs (apart from 4 "new" Member States already foreseen to be visited) if information on the five topics listed in Enclosure II is provided prior to the visit. APHIS could obtain the remaining eleven factor information necessary for its evaluation during the visit and/or at a later date*" unquote.

In this respect please be informed the State Veterinary Administration of the Czech Republic is ready to provide APHIS with any necessary information contributing to the recognition of its animal health status with the goal to open trade in swine and swine products between the United States and the entire EU. In enclosures you will find the information on the five topics listed in Enclosure II and requested by APHIS representatives prior to the site visit in the Czech Republic. Pending the positive response from your offices the remaining answers to 11

factors cited in Enclosure I will be generated and submitted to you either during the site visit or based on your recommendations at a later date.

We are fully aware that an initial data review is only one of the steps in the evaluation process and after the site visit in the Czech Republic the US public is going to have an opportunity to review and comment on proposed amendments created by APHIS in connection with a full implementation of Article 6 of the EC/US Veterinary Agreement.

Awaiting your kind reply we are at your disposal for any further queries.

Yours sincerely,



MVDr Milan Malena

Director General (CVO)

**Enclosures :**

- Information on the five topics required prior to the requested on-site visit.

**Note :**

*Structure of the SVA CR, staff, regions, laboratory diagnostics, geographic areas, situation prior to and after the EU admission date (1 May, 2004) etc. All the documents, as too capacious to be enclosed to this letter, have been provided electronically in a zipped form right to the primary contact person for this project :*

Dr. Chip Wells

USDA/APHIS, VS, NCIE, Regionalization Evaluation Services Staff, Unit 38  
[chip.j.wells@aphis.usda.gov](mailto:chip.j.wells@aphis.usda.gov)

c.c. : Mr. Lorenzo Terzi,

Directorate E, SANCO, European Commission, Brussels, [lorenzo.terzi@cec.eu.int](mailto:lorenzo.terzi@cec.eu.int)

**Request for the on-site visit/s in the Czech Republic – information on the five topics.**

**Topics :**

1. List of all legislation, applicable to the meat inspection system.(EU Regulations, Directives and Decisions) and reference to the appropriate national legislation  
Liste de toute législation pertinente du système d'inspection de la viande (Les Règlements, Directives et Décisions de L'ue) et la référence corespondante de la législatiion nationale

Name Nom	Corresponding Legislation of the Member State / Législation correspondante de l'état membre	Responsible enforcing agency/ministry Ministère/agence responsable de son application
Council Directive 64/433/EEC	<b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended	Ministry of Agriculture
	<b>Decree No. 202/2003</b> on veterinary requirements for fresh meat, minced meat, meat preparations and meat products	Ministry of Agriculture
	<b>Decree No. 201/2003</b> on veterinary requirements for fresh poultrymeat, rabbit meat, farmed game meat and wild game meat	Ministry of Agriculture
Council Directive 71/118/EEC	<b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended	Ministry of Agriculture
	<b>Decree No. 201/2003</b> on veterinary requirements for fresh poultrymeat, rabbit meat, farmed game meat and wild game meat	Ministry of Agriculture
	<b>Decree No. 383/2003</b> on veterinary conditions governing import from third countries of certain animal products	Ministry of Agriculture
Council Directive 77/96/EEC	<b>Decree No. 383/2003</b> on veterinary conditions governing import from third countries of certain animal products	Ministry of Agriculture
	<b>Methodical Instruction of the SVA No. 14/2000</b> - Trichinae examination	State Veterinary Administration

Council Directive 77/99/EEC	<p><b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended</p> <p><b>Decree No. 202/2003</b> on veterinary requirements for fresh meat, minced meat, meat preparations and meat products</p>	<p>Ministry of Agriculture</p> <p>Ministry of Agriculture</p>
Council Directive 98/83/EC	<p><b>Act No. 258/2000</b> on protection of public health and amending some related Acts</p> <p><b>Act No. 274/2001</b> on water-supply systems and canalisations for public need and amendments to some related Acts (Act on water-supply systems and canalisations)</p> <p><b>Act No. 254/2001</b> on water and amendment to some related Acts</p> <p><b>Decree No. 184/1997</b> on radiation protection requirements</p> <p><b>Decree No. 292/1997</b> on requirements for safety of bottled water</p> <p><b>Decree No. 428/2001</b> implementing Act No. 274/2001 on water-supply systems and canalisations for public need and amendments to some related Acts (Act on water-supply systems and canalisations)</p>	<p>Ministry of Health</p> <p>Ministry of Agriculture</p> <p>Ministry of Environment</p> <p>State Office for Nuclear Safety</p> <p>Ministry of Health</p> <p>Ministry of Agriculture</p>
Council Directive 91/495/EEC	<p><b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended</p> <p><b>Decree No. 201/2003</b> on veterinary requirements for fresh poultrymeat, rabbit meat, farmed game meat and wild game meat</p>	<p>Ministry of Agriculture</p> <p>Ministry of Agriculture</p>
Council Directive 92/118/EEC	<p><b>Decree No. 379/2003</b> on veterinary requirements for trade in animal products not covered by specific legal rules and on veterinary conditions</p>	<p>Ministry of Agriculture</p>

	governing their import from third countries	
Council Directive 94/65/EC	<b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended	Ministry of Agriculture
	<b>Decree No. 202/2003</b> on veterinary requirements for fresh meat, minced meat, meat preparations and meat products	Ministry of Agriculture
	<b>Decree No. 383/2003</b> on veterinary conditions governing import from third countries of certain animal products	Ministry of Agriculture
Council Directive 96/93/EC	<b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act) As amended	Ministry of Agriculture
	<b>Decree No. 296/2003</b> concerning animal health and its protection, animal movement and transportation and authorization and professional qualification for performance of certain professional veterinary activities	Ministry of Agriculture
	<b>Decree No. 372/2003</b> concerning veterinary checks applicable in trade in animals	Ministry of Agriculture
	<b>Decree No. 373/2003</b> concerning veterinary checks applicable in trade in animal products	Ministry of Agriculture
Commission Decision 2001/471/EC	<b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act) As amended	Ministry of Agriculture
	<b>Decree No. 201/2003</b> on veterinary requirements for fresh poultrymeat, rabbit meat, farmed game meat and wild game meat	Ministry of Agriculture
	<b>Decree No. 202/2003</b> on veterinary requirements for fresh meat, minced meat, meat preparations and meat products	Ministry of Agriculture
		State Veterinary Administration

	<p><b>Methodical Instruction of the SVA No. 18/2003</b> laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Decree No. 202/2003 on veterinary requirements for fresh meat, minced meat, meat preparations and meat products and Decree No. 201/2003 on veterinary requirements for fresh poultrymeat, rabbit meat, farmed game meat and wild game meat</p>	
1.1. Regulation (EC) No. 178/2002	<p><b>Act No. 110/1997</b> on foodstuffs and tobacco products and on amendments to some related Acts</p>	Ministry of Agriculture
Council Directive 86/363/EEC	<p><b>Act No. 110/1997</b> on foodstuffs and tobacco products and on amendments to some related Acts</p> <p><b>Decree No. 158/2004</b> laying down the maximum limits for pesticide residues in foodstuffs and food raw materials</p>	<p>Ministry of Agriculture</p> <p>Ministry of Health</p>
Council Regulation (EEC) No. 2377/90	<p><b>Act No. 79/1997</b> on medical products</p> <p><b>Act No. 110/1997</b> on foodstuffs and tobacco products and on amendments to some related Acts</p> <p><b>Decree No. 273/2000</b> establishing of maximum limits in foodstuffs and foodstuffs raw material of veterinary medicinal products and substances having a biological action used in stockfarming</p> <p><b>Act No. 166/1999</b> concerning veterinary care and amending some related laws (Veterinary Act)</p>	<p>Ministry of Health</p> <p>Ministry of Agriculture</p> <p>Ministry of Health</p> <p>Ministry of Agriculture</p>
Council Directive 96/22/EC	<p><b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended</p>	Ministry of Agriculture

	<b>Decree No. 291/2003</b> concerning the prohibition on the administration of certain substances to animals products of which are intended for human consumption, and the monitoring in animals and animal products of unauthorized substances, residues and contaminants which may render animal products harmful to human health	Ministry of Agriculture
Council Directive 96/23/EC	<b>Act No. 166/1999</b> concerning veterinary care and amending certain related laws (Veterinary Act), as amended  <b>Decree No. 291/2003</b> concerning the prohibition on the administration of certain substances to animals products of which are intended for human consumption, and the monitoring in animals and animal products of unauthorized substances, residues and contaminants which may render animal products harmful to human health	Ministry of Agriculture  Ministry of Agriculture
Commission Directive 98/53/EC	<b>Decree No. 211/2004</b> on methods of analyses and on taking and preparation of check samples	Ministry of Agriculture
Commission Directive 2001/22/EC	<b>Decree No. 211/2004</b> on methods of analyses and on taking and preparation of check samples	Ministry of Agriculture
Commission Regulation (EC) No. 466/2001	<b>Decree No. 53/2002</b> laying down the chemical requirements on health safety of individual kinds of foodstuffs and foodstuff raw materials, conditions of use of food additives, aid food processing substance and nutritional supplements	Ministry of Health
Commission Directive 2002/69/EC	<b>Decree No. 211/2004</b> on methods of analyses and on taking and preparation of check samples	Ministry of Agriculture
Commission Decision 2002/657/EC	<b>Methodical Instruction of the SVA No. 4/2004</b> implementing Decree No 291/2003 concerning the prohibition on	State Veterinary Administration

	the administration of certain substances to animals products of which are intended for human consumption, and the monitoring in animals and animal products of unauthorized substances, residues and contaminants which may render animal products harmful to human health, for animals and animal products as regards the performance of analytical methods and the interpretation of results	

**CSF related national legislation comparable to and reflecting the EU legislation.**

Council Decision 2001/89/EC / **Decree No. 299/2003** – from § 38 to § 58 – emergency plans, safeguard measures regarding CSF.

Commission Decision 2002/106/EC / **Methodical Instruction of the SVA CR No. 7/2003** – CSF diagnostics guideline in the scale of the CR national monitoring .

**Methodology of CSF national monitoring – general information :**

**Domestic pigs** – serological examination ( ELISA + NPLA)

- a) districts with CSF antibodies occurrence in wild boar – tests in slaughterhouses, percentage of tested domestic pigs from each consignment to the slaughterhouse is set by the SVA CR and based on antibodies positive findings in wild boar population in the relevant district.
- b) imports of breeding pigs from third countries – each imported animal older than 3 months tested not later than 1 month following the arrival to the destination place.
- c) imports of breeding pigs from the EU Member State/s with the CSF occurrence but where the intra-Community trade is allowed based on regionalization principles – each imported animal older than 3 months tested not later than 1 month following the arrival to the destination place
- d) each breeding boar prior to its admission to the Semen Collection Centre (SCC)
- e) each breeding boar in the SCC – once a year

**Wild boar population** – post-mortem examinations, test, samples

- a) districts neighbouring with Slovak Republic and Austria – 100% of hunted wild boar, adjacent districts 50% of hunted wild boar- based on risk analysis
- b) rest of districts on the state territory – 10% of hunted wild boar
- c) districts with CSF antibodies occurrence in wild boar – 50% of hunted animals for 6 months since the positive finding and 25% hunted animals next 6 months ( 12 months together)
- d) each wild boar animal found dead

Surveillance programs, data, tests, results, gov. subsidies for hunted boar, density of wild boar, border protective measures – see Topic 4

**Note :**

Because of the CSF situation in the Czech Republic the European Commission has not imposed on the CR any additional disease control measures concerning that disease – see Decision 2003/526/EC as last amended by Decision 2004/375/EC and Decision 2004/625/EC

**TOPIC 2**

Situation regarding the BIPs location prior to and after the admission date, i.e. May 1, 2004 , is described in the documents ( Structure of the SVA CR – 35 pages ) forwarded electronically in a zipped form to APHIS, Unit 38 (Dr. Chip Wells) – see the graphics.

Following the admission date, the Czech Republic is surrounded by the EU Member States (Germany, Austria, Slovak Republic, Poland) and the only entry point to the EU from non-EU countries is the airport BIP Praha-Ruzyně – see Commission Decision 2004/469/EC, page 13, SANCO/10142/ R1, Consolidated ANNEX . From the table therein provided the airport BIP has the equipment and is approved by the EC for equidae (E) and other live animals (O) but not for porcine species. It means the BIP is open, in this case, to traffic in swine products only – HC(2), NHC(2) – i.e. human, non-human consumption products.

Veterinary checks on incoming products ( samples, physical checks ) are carried out in full compliance with Commission Decision 94/360/EC plus according to the annual national plan on residues samples. Results are being forwarded to the European Commission on a regular basis.

Up to the recent time no positive findings from non-EU countries and no compliance problems with border controls have been found. Some consignments have been returned to the country of origin due to failures in documentation checks. Records are available during the on-site visit at this BIP.

**TOPIC 3**

The smallest administrative unit which APHIS can consider as the smallest administrative jurisdiction in the Czech Republic with effective oversight on animal movements into, out of, and within that jurisdiction and that, in association with central national veterinary authorities, has an effective control over animal movements and animal diseases locally is the region.

14 Regional Veterinary Administrations (RVAs) as the basic veterinary units are located in each from 14 regions of the CR. Each RVA is administratively composed of different number of district veterinary inspectorates ( see the map - Structure of the SVA CR) which inspectorates are historical and geographical entities subordinated to the RVA. Director of the RVA is appointed and responsible to the Director General (CVO) of the State Veterinary Administration of the Czech Republic (SVA CR – national central competent authority). In the sense of the Veterinary Act 166/1999 the RVA is in charge of government veterinary tasks on its territory.

Map of the regions, size and location – *see the zipped material herein electronically provided to the APHIS, Unit 38*

## TOPIC 4

### Surveillance data available on CSF :

**Exhaustive data 1999 – 2004** - i.e. serology/virology results, graphics, density of wild boar population in individual districts and regions, history of CSF, description and costs of eradication programs, government subsidies for hunted wild boar, safeguard measures close to the borders with the risk representing countries ... etc.

Materials, tables, graphics are too capacious to be enclosed here

*See the zipped material herein electronically provided to the APHIS, Unit 38*

### In general :

Measures and terms as regards the control of the disease are laid down in the Veterinary Act No. 166/1999 as amended by the Act 131/2003 and in the Decree No 299/2003.

Ministry of Agriculture of the Czech Republic determines main strategies in a veterinary care and carries out their control as laid down in the Veterinary Act No. 166/1999 Article 44, Point 1a. The Ministry of Agriculture specifies obligatory preventive and diagnostics campaigns in accordance with the Veterinary Act, Article 44, Point 1d, based on the epidemiological situation. Related details are laid down in the "Methodology of Animal Health Controls and Prophylaxis" approved by the Ministry of Agriculture and issued in its Official Journal. According to the legislation (Veterinary Act 166/1999) the SVA CR (CCA) has the legal power to supervise any action ordered by the "Methodology". Regional veterinary administrations execute the legal powers as to supervise private veterinarians over their actions in the professional field as ordered by the "Methodology".

Measures and controls of contagious diseases are laid down in the Veterinary Act No. 166/1999, Article 10 - 17. The preventative vaccination against CSF has been ceased in the Czech Republic in 1992. Conditions for vaccination of animals against contagious diseases are generally laid down in Decree No 299/2003, Article 10. Measures and the following control of classical swine fever are specified in the Chapter III, Article 38 – 58 in accordance with Council Directive 2001/89/EC. Conditions for vaccination against classical swine fever are stipulated in Articles 53 – 55.

### Testing scheme

The sero-surveillance programme (ELISA, NPLA methods) will be conducted according to the following plan:

#### Domestic pigs

##### CSF presence proved in wild boar:

a) In infected zone and in 10 km protection zone – examination of swine herds selected by the decision of the Regional Veterinary Administration (RVA) Director (i.e. 5-7 % of animals from the herd). Examination shall be carried out twice in 6-8 weeks during the period of ordered emergency veterinary measures. The examination shall be repeated after 6-8 weeks in the event of occurrence of new CSF cases.

b) In other areas of the districts concerned – examination of swine herds at risk (i.e. 5-7 % of animals from the herd). Examination shall be carried out once during the period of ordered emergency veterinary measures.

c) In selected (endangered) areas of adjoining districts and in selected areas of districts adjoining the Slovak Republic – examination of 50 % of swine herds (i.e. 5-7 % of animals from the herd). The areas and herds referred to in points b) and c) shall be selected by the RVA director.

#### Antibodies presence proved in wild boars:

Examination shall be carried out in districts with presence of antibodies in wild boar. Examination shall be carried out in 100 % of slaughtered (including emergency slaughtered) breeding sows and boar from particular consignments delivered to a slaughterhouse. Sampling shall be carried out by the RVA in slaughtering animals; blood sampling shall be carried out according to the origin of animals (i.e. the above mentioned districts with presence of antibodies in wild boar).

#### Wild boar

##### **A. CSF presence virus proved in wild boar:**

In designated districts where the presence of CSF virus was confirmed – examination of all hunted wild boar during 6 months following last positive virological finding, examination of 50 % of hunted wild boar during further 6 months.

In selected areas of districts adjoining districts with the presence of CSF virus (the areas shall be selected by the RVA) – examination of 50 % of hunted wild boar during 6 months following last positive virological finding in adjoining district.

##### **B. Antibodies presence proved in wild boar:**

In districts with the presence of antibodies – examination of approx. 50 % of hunted wild boar during 6 months following last finding of antibodies, examination of 25 % of hunted wild boar during further 6 months; in selected areas of districts adjoining districts with the presence of antibodies against CSF (the areas shall be selected by the RVA) – examination of 25 % of hunted wild boar during 6 months following last positive serological finding in adjoining district.

##### **C. In regions adjoining the Slovak Republic and Austria (without presence of the virus in the region concerned):**

In selected areas (districts Zlín, Vsetín and Břeclav) – examination of all of hunted wild boars during the entire year.

In selected areas of other districts adjoining the Slovak Republic and in selected areas of selected districts adjoining Austria (Znojmo, Jindřichův Hradec etc. according to the decision of the RVA) – examination of 50% of hunted wild boars during the entire year.

**Total number of examinations of domestic and wild boar in the Czech Republic in 1999**

Domestic pigs				wild boar			
CTB-ELISA		Virus isolation		CTB-ELISA		Virus isolation	
Examinations	Positive	Examinations	Positive	Examinations	Positive	Examinations	Positive
36 181	0	34	0	11 157	335	11 266	17
<b>Total in the CR</b>							

**Total number of examinations of domestic and wild boar in the Czech Republic in 2000**

Domestic pigs				wild boar			
CTB-ELISA		Virus isolation		CTB-ELISA		Virus isolation	
Examinations	Positive	Examinations	Positive	Examinations	Positive	Examinations	Positive
20 820	0	58	0	9 617	160	9 085	0
<b>Total in the CR</b>							

**Total number of examinations of domestic and wild boar in the Czech Republic in 2001**

Domestic pigs				wild boar			
CTB-ELISA		Virus isolation		CTB-ELISA		Virus isolation	
Examinations	Positive	Examinations	Positive	Examinations	Positive	Examinations	Positive
22 737	0	25	0	11 349	94	11 440	0
<b>Total in the CR</b>							

**Total number of examinations of domestic and wild boar in the Czech Republic in 2002**

Domestic pigs				wild boar			
CTB-ELISA		Virus isolation		CTB-ELISA		Virus isolation	
Examinations	Positive	Examinations	Positive	Examinations	Positive	Examinations	Positive
17 987	0	13	0	9 998	51	9 970	0
<b>Total in the CR</b>							

**Total number of examinations of domestic and wild boar in the Czech Republic in 2003**

Domestic pigs				wild boar			
CTB-ELISA		Virus isolation		CTB-ELISA		Virus isolation	
Examinations	Positive	Examinations	Positive	Examinations	Positive	Examinations	Positive
30 494	0	3	0	9 339	55	9 645	0
<b>Total in the CR</b>							

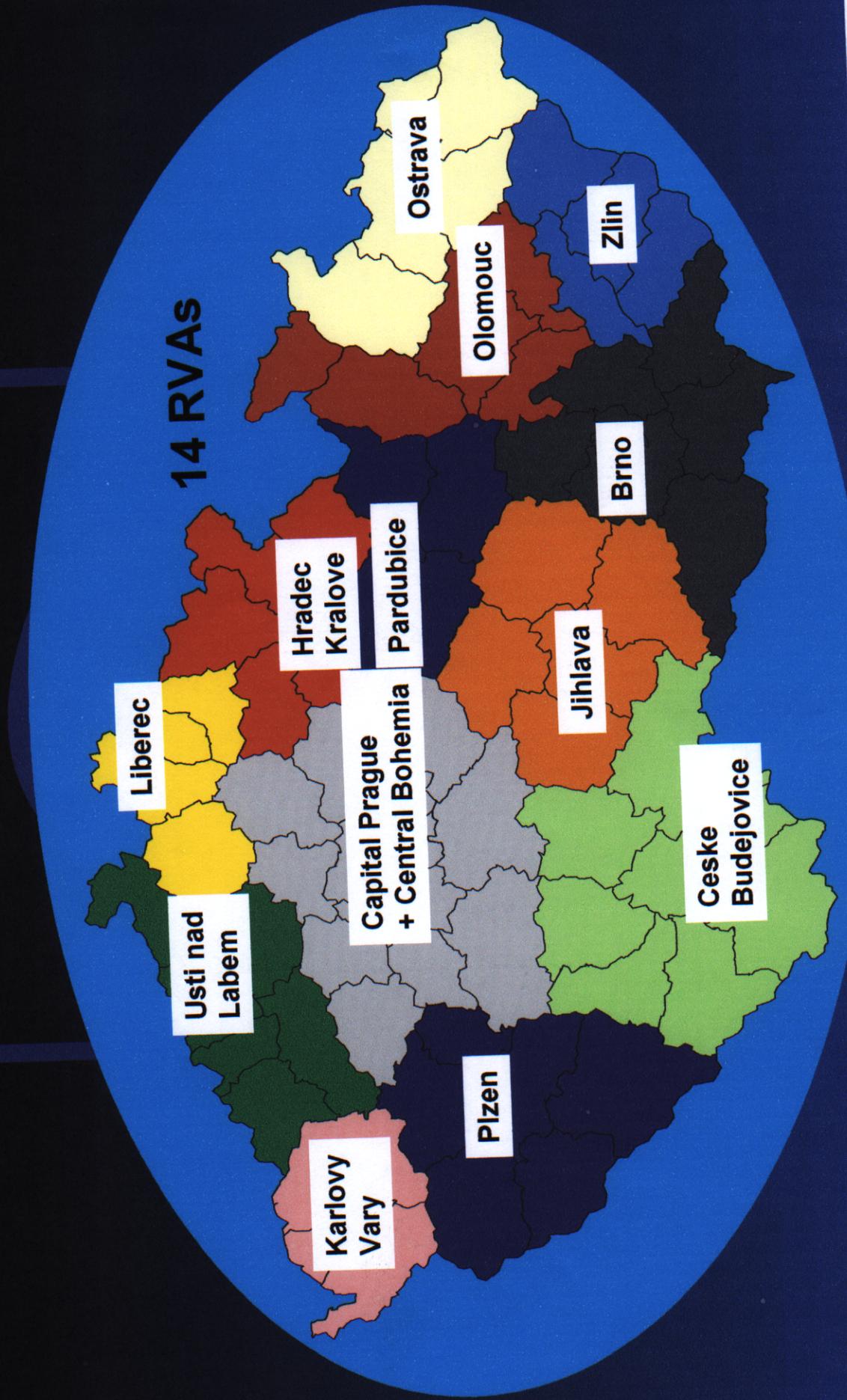
**Total number of examinations of domestic and wild boar in the Czech Republic in 2004 (I. – VIII.)**

Domestic pigs				wild boar			
CTB-ELISA		Virus isolation		CTB-ELISA		Virus isolation	
Examinations	Positive	Examinations	Positive	Examinations	Positive	Examinations	Positive
17 091	0	2	0	6 044	42	6 159	0
<b>Total in the CR</b>							

Czech Republic  
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# Regional Veterinary Administrations



## **TOPIC 5**

### **Most recent FVO inspection report – results, implemented changes**

Enclosed you will find the FVO letter of 28 September 2004 reflecting the report results of the FVO inspection mission DG(SANCO)/7092/2004 MR concerning import controls at the BIP airport Praha-Ruzyně ( see Topic 2 ).

Enclosed to this letter is as well the Action Plan describing the implemented changes carried out by the central competent authorities (CCA) in response to the findings of the FVO mission including deadlines, progress status at 01.10.2004 and FVO comments “ Action completed “.

*See the zipped material herein electronically provided to the APHIS, Unit 38*

Done in Prague on September 7, 2004