

## DECISION MEMORANDUM

**TO:** Dr. John C. Prucha  
Assistant Deputy Administrator  
Program Coordination and Evaluation

**FROM:** Sally Stratmoen  
Acting Director  
International Policy Staff

**SUBJECT:** Eligibility of Slovakia to Export Meat Products to the United States

PURPOSE. This is a decision memo to finalize the equivalence of Slovakia as eligible to export meat products to the United States.

SUMMARY. In September 1997, Slovakia submitted a request for initial eligibility to export meat products to the United States. A thorough review has been conducted of all meat inspection system documentation submitted by Slovakia in support of its application for equivalence. Two on-site meat inspection system audits have been conducted in that country. The International Policy Staff (IPS) has concluded that Slovakia's meat inspection system (1) meets all equivalence requirements of the Federal Meat Inspection Act (FMIA) as implemented by 9 CFR 327.2, (2) provides the same level of public health protection achieved by USDA, and (3) should therefore be eligible to export meat products to the United States.

### BACKGROUND.

Slovakia is a small country located in Central Europe. It is protected by the Carpathian Mountains on three sides and by the Danube River on the fourth. It has a common border with the Czech Republic, Poland, Ukraine, Hungary and Austria. Slovakia has a population of around 5 million people and distributed across approximately 49 000 square kilometers. The capital city is Bratislava, which has approximately 500 000 inhabitants. Slovakia's climate is temperate, with mild summers and cold winters. The terrain is rugged mountains in the central and northern parts, lowlands in the south.



In 1918, Slovaks joined the closely related Czechs to form Czechoslovakia. Following World War II, Czechoslovakia became a communist nation within Soviet-ruled Eastern Europe. When Soviet influence collapsed in 1989, Czechoslovakia once more became free. The Slovaks and the Czechs agreed to separate peacefully on 1 January 1993. Slovakia has experienced more difficulty than the Czech Republic in developing a modern market economy.

The Slovak Republic is a parliamentary democracy governed by a chief of state: (President), a head of government (Prime Minister), a Cabinet appointed by the president on the recommendation of the prime minister, a 150 member unicameral legislature (National Council of the Slovak Republic) elected on the basis of proportional representation, a Supreme Court elected by the National Council, and a Constitutional Court appointed by the president from group of nominees approved by the parliament.

Slovakian administrative territorial divisions are organized as 8 regions (or *kraje*) and 79 districts. They regions are: Banskobystricky, Bratislavsky, Kosicky, Nitriansky, Presovsky, Trenciansky, Trnavsky, Zilinsky. Local self-government is carried out by: municipalities (towns, villages, etc.), which make independent decisions on issues connected with their own administration and municipal properties. Municipal councils and municipal mayors are elected in local elections. The last local elections were held in December 1998.

The ethnic composition as of December 31, 1997 was Slovaks (85.65%), Hungarians (10.55%), Romanies-Gypsies (1.63%), Czechs (1.10%), Carpatho-Rusyns / Ruthenians / and Ukrainians (0.64%), Germans (0.10%), Poles (0.06%), Jews (the Jewish community in Slovakia has about 7,000 people). Religion according to the last census in 1991 was Roman Catholic (60.4%), Slovak Evangelic Lutheran (6.2%), Greek Catholic (3.4%), Calvinist (1.6%), Orthodox (0.7%), other 0.5%, without denomination (9.8%), not specified (17.4%). The official Language is Slovak (a member of the Slavic language group that includes Czech, Polish, Bulgarian, Serbian, Croatian, Ukrainian, Russian, etc.). Slovak is written in Roman characters.

Main National Holidays are:

- January 1 - Independence Day
- August 29 - Slovak National Uprising (1944)
- September 1 - Constitution Day

Slovakia's primary trading partners are the EU 56% (Germany 29%, Austria 7%), the Czech Republic 20%, and Poland 7% (1998).

## EQUIVALENCE EVALUATION

Slovakia requested an initial determination of eligibility to export processed meat products to the United States. The inspection system documentation submitted by Slovakia indicates that its laws, regulations, and other issuances cumulatively provide the same level of public health protection attained by the United States. Slovakia has adopted the same sanitary measures applied by FSIS in its meat inspection system. Consequently, no determinations of equivalence for different sanitary measures were made.

Two on-site audits by FSIS confirmed that Slovakia has implemented all sanitary measures described in its meat inspection system documentation. The first audit of Slovakia's meat inspection system was conducted in June of 2000 by a team of seven FSIS subject matter experts. The scope of the first audit included slaughter and processing operations. It revealed several verification and process control deficiencies. As a result of the first audit, Slovakia amended its equivalence request to delete slaughter and include processing operations only.

A second audit was conducted in December of 2000. This audit was limited to Slovakia's meat processing inspection system and the establishments that would be exporting processed meat products to the United States. The results of this audit were satisfactory.

## EQUIVALENCE CRITERIA

The central criteria for equivalence of an alternative meat inspection program are as follows:

- (1) Does the program meet all U.S. Department of Agriculture (USDA) requirements for the import of meat and meat products to the United States?
- (2) Does the program afford American consumers the same level of public health protection provided by USDA domestic meat inspection?

These criteria are addressed in the following summary of analyses conducted.

<b>Criteria 1</b>	
<b>U.S. Regulatory Requirement</b>	<b>Slovakia</b>
<i>The system shall have a program organized and administered by the national government of the foreign country.</i>	The Slovakian meat inspection system is centralized in the national government. The central competent authority is the State Veterinary Administration (SVA), which forms part of the Ministry of Agriculture. The central office of SVA is based in Bratislava under the responsibility of the Chief Veterinary Officer (CVO), who is appointed by and responds directly to the Minister of the Agriculture. The Ministry of Agriculture administers the SVA budget.
<i>Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which meat products are processed for export to the United States.</i>	Regional veterinary services are organized by <i>kraje</i> (the eight regions) each comprising several veterinary districts (7 to 15). The region and the district veterinary offices are staffed by full time employed veterinary inspectors. The Chief Veterinary Officer in the headquarters appoints the Chief Veterinary Officers of the regions and districts. The regional and district veterinary services belong to the SVA. All levels of the veterinary administration are linked in a vertical line of command. Their tasks are defined in Slovakian Veterinary Act 337/1998.
<i>Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system</i>	

<p><i>The assignment of competent, qualified inspectors.</i></p>	<p>By law, Veterinarians and veterinary auxiliaries (inspectors) must be fully qualified and trained before assuming inspection duties. Initially, Veterinarians are required to complete their DVM to perform supervisory duties, slaughter and meat inspection, processing and production controls, and related inspection decisions. To perform more specialized work, Veterinarians must complete additional training. Inspectors must be graduates of specialized secondary schools with curricula in veterinary education, food processing, or other applicable areas of specialization. Additional training is also required of inspectors through specialized graduate coursework. Other post-graduate coursework for Veterinarians and inspectors is also organized through the Institute for Postgraduate Education of Veterinarians in Kosice.</p>
<p><i>Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing meat inspection and to certify or refuse to certify meat products intended for export.</i></p>	<p>The applicable authorities and responsibilities are provided in the Collection of Laws, Act No. 272/1994, on the protection of public health and in the Collection of Laws, S.R. National Council Act No. 152/1995, on foodstuffs; as well as the regulations that are directly linked and implement these acts.</p>
<p><i>Adequate administrative and technical support.</i></p>	<p>The responsibilities of the Veterinary services is established in Article 11 of Law 87/1987. The organization of Veterinary care and local offices is established in S.R. National Council Acts No. 11/1992 and 222/1996. Support is provided through approximately 88 Veterinarians at the National (1), Regional (8), and Local-level (79) offices and 237 Veterinarians and 84 meat inspectors in the field. The national laboratories of 8 veterinary institutes and 17 public health institutes are utilized for official food and public health controls. In addition, offices are fully staffed to conduct routine administrative duties.</p>

U.S. Regulatory Requirement	Slovakia
<p><i>The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.</i></p>	<p>In addition to the Acts, laboratories and personnel noted above, Slovakia controls residues and food products through the Central Control and Testing Institute in Agriculture; the National Reference Laboratory, Faculty of Veterinary Medicine; the S.R. Food Codex; Regulation No. 981/1996-100 of the Slovak Ministry of Agriculture and Soil Management and Ministry of Health; and Acts and Regulations No. 87/1987, 239/1991, 215/1992, 11/1992, 188/1989, 72/1987, and 285/95 for veterinary, drug, chemical, and pesticide controls. Instruction No. 69/1996 as well as various ISO/AOAC sampling and analytical techniques establish guidelines for sampling and analyzing raw materials and foodstuffs.</p>
<p>The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of meat inspection organized and maintained in the United States with respect to:</p> <p><i>Ante mortem inspection of meat for slaughter, which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of veterinarians.</i></p>	<p>Not applicable. Application for eligibility does not include slaughter establishments or slaughter inspection activities.</p>
<p><i>Post mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians.</i></p>	<p>Not applicable. Application for eligibility does not include slaughter establishments or slaughter inspection activities.</p>

U.S. Regulatory Requirement	Slovakia
<p><i>Official controls by the national government over establishment construction, facilities, and equipment.</i></p>	<p>All projects for the construction of establishments is reviewed by public health and Veterinary administration authorities as established by S.R. NC Laws 272/1994, 87/1987, and 215/1992; Decree No. 981/1996-100; S.R. MH No. 17/1976; parts of the S.R. Food Codex; and Technical Standard No. 75/7111. Construction, facilities, and equipment must meet these requirements. Where applicable, nontoxic materials and appropriate surface finishes must be used. Hygienic requirements for stationary machines and the controls for securing and maintaining potable water are established (Law No. 138/1973).</p>
<p><i>Direct and continuous official supervision of slaughtering and preparation of product, by the assignment of inspectors to establishments certified for export to the United States to assure that adulterated or misbranded product is not prepared for export to this country.</i></p>	<p>With respect to the preparation of products, but not slaughter: S.R. NC Law No. 152/1995 establishes the authority of food inspection offices to ensure that the various laws and regulations are met and to prohibit the production of foodstuffs or the associated operations/facilities when warranted. S.R. MH Decree No. 981/1996-100, Act No. 87/1987, MA Decree No. 121/87, and the S.R. Food Codex ensures the safe shipment of product between establishments and the proper controls over contaminated, adulterated, or misbranded products; both shipping and handling.</p>

<b>U.S. Regulatory Requirement</b>	<b>Slovakia</b>
<i>Complete separation of establishments certified from establishments not certified, and the maintenance of a single standard of inspection and sanitation throughout all certified establishments.</i>	Where applicable, product is separated to preclude accidental (or otherwise) co-mingling of products. Species verification testing is performed. S.R. MH Decree No. 981/1996-100 and the S.R. Food Codex provide for the separation of ready-to-eat and raw products. Products ineligible for export to the U.S. are marked according to "national markings" that are different from product to be exported. Production of U.S. products will be kept completely separate from non-U.S. production and the physical presence of national veterinary officers ensures both physical and sanitary separation of products. The various Acts, Laws, and Regulations will ensure uniform inspection of all applicable products.
<i>Requirements for sanitation at certified establishments and for sanitary handling of meat products.</i>	Acts No. 272/1994 and 152/1995 and the S.R. Food Codex ensure the safe and sanitary handling of meat products and that sanitation and sanitary requirements are met.
<i>Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment.</i>	Act No. 87/1987 and Decree No. 121/87 specifically address the control of condemned and inedible products and require the designation of exclusive, special spaces and containers for storage/holding as well as (Food Codex) proper labeling, handling, and disposition.
<i>A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of USDA regulations.</i>	Slovakia has adopted the FSIS regulatory requirements for HACCP systems.

U.S. Regulatory Requirement	Slovakia
<p>The foreign inspection system must maintain a program to assure that the requirements, equivalent to those applicable to the Federal system in the United States, are being met. The program as implemented must provide for the following:</p> <p><i>Periodic supervisory visits by a representative of the foreign inspection system not less frequently than one such visit per month to each establishment certified for export to the United States to assure that U.S. import requirements are being met.</i></p> <p><i>Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting the findings.</i></p>	<p>Supervisory visits to all U.S. certified establishments are established at a frequency of not-less-than one per month by qualified supervisory personnel from the National, Regional, or District offices to review all processing and, otherwise applicable, procedures and controls.</p> <p>Written reports are prepared of the monthly visits, as performed above, and retained in the appropriate office. Non-compliances are documented and corrected.</p>
<p><i>Random sampling and testing at the point of slaughter of carcasses, including internal organs and fat, for residues identified by the exporting country's inspection authorities or USDA as potential contaminants, in accordance with sampling and analytical techniques approved by FSIS</i></p>	<p>Not applicable. Application for eligibility does not include slaughter establishments or slaughter inspection activities.</p>

**Criteria 2****FSIS Audit of June 15 – 22, 2000:**

Slovakia's meat inspection system was evaluated based on in-plant inspections as well as sanitation, animal disease, slaughter/processing, enforcement, and residue program controls of the meat inspection system by a team of 7 auditors from FSIS.

In the processing establishment (SK 15), minimal inspection system controls were found to be in place. However, the sanitation and maintenance of facilities and equipment and the HACCP program did not fully comply with U.S. requirements. The slaughter establishment (SK 26) was found to be unacceptable due to deficiencies in their HACCP, SSOP, *Salmonella* testing and generic *E. coli* testing programs. In addition, the deficiencies that were encountered during the on-site establishment reviews were not immediately corrected by the establishment management in both Establishments. However, Veterinary Services in Bratislava adequately addressed these deficiencies to the auditor's satisfaction.

**FSIS Audit of December 4 - 8, 2000:**

Effective inspection system controls were found to be in place in the one establishment that was audited (SK 15). Establishment SK 26 withdrew their request to become eligible to export to the United States.

The major concerns identified during the June 2000 audit had been satisfactorily addressed and corrected. During the current audit, deficiencies were observed in recording preventative actions to be taken in the written HACCP plan(s), on-time written rodent control findings, and the availability of monthly supervisory reports. In addition, the residue laboratory required improvement in proper page identification of record-keeping, recording expiration dates for standard solutions, and intra-laboratory check sample testing. The deficiencies encountered during this audit were adequately addressed by the establishment and the Veterinary Services to the auditor's satisfaction.

Overall, the inspection system of Slovakia was found to have effective controls in place to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments.

**RECOMMENDATION.** That Slovakia's meat inspection system be found equivalent to the FSIS system and that a rule be proposed to add Slovakia as a country eligible for export of meat products to the United States.

APPROVED:

---

John C. Prucha, D.V.M., M.S., M.P.H.  
Assistant Deputy Administrator  
Program Coordination and Evaluation  
Office of Policy, Program Development  
and Evaluation

---

(Date)