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**Working Party on the
Accession of Ukraine**

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ACCESSION OF UKRAINE

Law Enforcement in High-Priority Areas of Trade-Related Legal Framework:
Customs Fees, Customs Valuation, Technical Barriers to Trade
and Sanitary and Phytosanitary Measures

Revision

The Governmental Commission on Ukraine's Accession to the WTO has submitted the following information with the request that it be circulated to members of the Working Party.

Laws and Regulations		The assessment of compliance with GATT/ WTO agreements, and proposed harmonization measures
Customs Fees		
Resolution of the Cabinet of Ministers of Ukraine "On Customs Fee Rates" No. 65 dated 22 January 1997	Customs fee for customs clearance of goods and other items	Compliant.
Resolution of the Cabinet of Ministers of Ukraine "On Regulation of the Customs Fees at the State Border Crossing Points" No. 1034 dated 15 June 1999	Fee for services provided in relation to ecological, veterinary, and phytosanitary control, and roads toll for vehicles and other self-propelled machinery for passing through Ukrainian roads (unified fee).	Non-compliant. <u>Proposals on law harmonization:</u> The Ministry of Economy drafted a law "On Amendment of the Law of Ukraine "On the Introduction of the Unified Fee Collected upon Crossing of the Ukrainian State Border" No. 1212-XIV dated 4 November 1999". When approved (currently, the law is under consideration at the Cabinet of Ministers of Ukraine), the law will repeal the resolution concerned, and the amount of the unified fee will be determined in accordance with the law.
Customs valuation		
Resolution of the Cabinet of Ministers of Ukraine "On Adopting the Procedure for Determining the Customs Value of Goods and other Items Crossing the Customs Border of Ukraine" No. 1598 dated 5 October 1998	Methods of customs valuation are not clearly determined. In the event the declared customs value of goods and other items is obviously non-corresponding, or its calculation is impossible, the customs authorities sequentially determine the customs value on the basis of value for identical goods and other items, or prices for similar goods.	Customs valuation methods are not compliant with the GATT 1994, Article VII, and the Agreement on Application of GATT Article VII. <u>Proposals on law harmonization:</u> The draft Customs Code of Ukraine endorsed by the Supreme Rada for the first reading on 16 December 1998, provides for methods of customs valuation that will be compliant with binding rules and requirements of the GATT/ WTO agreements.

Note: Because of the need for greater detail, the areas of import licensing and the enforcement of intellectual property rights are dealt with in separate materials.

Laws and Regulations		The assessment of compliance with GATT/ WTO agreements, and proposed harmonization measures
Technical Barriers to Trade		
Decree of the Cabinet of Ministers of Ukraine "On Standardization and Certification" No. 46-93 dated 10 May 1993	Determines the principles of the standardization and certification system in Ukraine (technical barriers to trade)	<p>Non-compliant.</p> <p><u>Proposals on laws harmonization (case-by-case):</u> Approval of the draft Law of Ukraine "On Standardization" Approval of the draft Law of Ukraine "On Conformity Assessment" Drafting and passing of the Resolution of the Cabinet of Ministers of Ukraine "On Technical Regulations" implementing requirements of the Agreement and Directives 98/34/EC, 98/48/EC providing for notification about changes in technical standards and regulations. Implementation of the Resolution of the Cabinet of Ministers of Ukraine "On Creation of the National Automated Standards Database" No. 84 dated 1 February 1995. Drafting and implementation of the National Standard "Rules of Notification to Other Members". <u>Administrative Action to be Taken</u></p> <p>Review of underlying standards of the state standardization system. Curtail list of goods subject to compulsory certification. Development and enforcement of standards as follows: -"National Standardization System. Rules and Guidelines on Adoption and Enforcement of International Standards"; -" National Standardization System. Code of Fixed Standardization Rules".</p>
Decree of the Cabinet of Ministers of Ukraine "On State Monitoring of Compliance with Standards, Rules and Regulations, and Liability for Violations"	Introduces government supervision over sustained quality of the certified products, rules of test performance.	Will be revised upon passing of the Law of Ukraine "On Conformity Assessment", "On Liability of Supplier for Manufacturing and Distribution of Hazardous and Low Quality Products"
Resolution of the Cabinet of Ministers of Ukraine "On the Approval of the Procedure for Customs Clearance of Imported Goods (Products) Subject to Compulsory Certification in Ukraine" No. 1211 dated 4 November 1997	Determines rules of customs clearance of foreign goods (products) subject to mandatory certification.	Resolution of the Cabinet of Ministers of Ukraine No. 1672 dated 8 November 2000 amends Paragraph 3 of the "Procedure of Customs Clearance of Imported Goods (Products) Subject to Compulsory Certification in Ukraine".
Rules for Compulsory Certification of Domestic Electric Appliances and Comparable Equipment and Parts	Determine rules, sequence, and processes of certification.	<p>Non-compliant.</p> <p>Will be revised upon approval of the Law of Ukraine "On Conformity Assessment", and new regulation compliant with the New Approach EC Directives 73/23EEC, 89/336EEC, 93/68EEC, 92/31EC.</p>

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Rules of Compulsory Certification of Specific Lines of Products.	Determine rules, sequence, and processes of certification.	Will be revised upon approval of the Law of Ukraine "On Conformity Assessment", and relevant regulations.
Rules for Performing Certification of Foreign Goods Manufactured as Serial Products	The Order of the State Committee for Standardization, Metrology, and Certification No. 633 dated 18 August 1998, is designed to improve rules of certification of foreign products, in particular, rules of applications assessment, creation of commission, and decision-making criteria. In terms of rules applicable to conformance assessment process, the same are applied to both domestically produced and foreign products. The rules of conformance assessment cover such issues as conformity to effective standards, sequence of tests, amount and type of fees charged, availability of information, etc.	Will be revised upon approval of the Law of Ukraine "On Conformity Assessment".
DSTU 3410-96 "UkrSEPRO Certification Systems. Guidelines"	The Standard determines underlying principles, framework and rules of the national certification system.	Will be revised upon approval of the Law of Ukraine "On Conformity Assessment".
DSTU 3411-96 "UkrSEPRO Certification Systems. Requirements for Certification Agencies and Rules of Accreditation".	Drafted in compliance with the requirements of Directive ISO/IEC39, 56, 65, Directive ISO 27 and EN45011.	Will be revised upon approval of the Laws of Ukraine "On Accreditation of the Conformance Assurance Agencies", "On Conformity Assessment".
DSTU 3412-96 "UkrSEPRO Certification Systems. Requirements for Test Labs and Rules of Accreditation"	Drafted in compliance with the requirements of the Directives ISO/IEC25, and EN45001	Will be revised upon approval of the Laws of Ukraine "On Accreditation of the Conformance Assurance Agencies", "On Conformity Assessment".
DSTU 3413-96 "UkrSEPRO Certification Systems. Certification procedures"	Drafted in compliance with the requirements of the Directives ISO/IEC7, 28, 60	Will be revised upon approval of the Laws of Ukraine "On Conformity Assessment".
Sanitary and Phytosanitary Measures		
The Law of Ukraine "On Sanitary and Epidemic Safety of the Population" No. 4004-XII dated 24 February 1994 The Law of Ukraine "On Quality and Safety of Food Products and Food Raw Materials" No. 771 dated 23 December 1997 The Law of Ukraine "On the Protection of the Population from Infectious Diseases" No. 1645-14 dated 6 April 2000	Article 16 of the Law of Ukraine "On Sanitary and Epidemic Safety of the Population" No. 4004-XII dated 24 February 1994 provides for <u>rules of import, distribution and consumption of products</u> . Businesses, organizations, and individuals have the right to <u>bring in</u> raw materials and finished products (products, equipment, technological manufacturing equipment), distribute and consume/apply in Ukraine only if <u>there is data available about safety of such products to humans</u> . The office of the Chief Sanitary Doctor of Ukraine identifies the list and content of such data. In the event safety data is not readily available, import, distribution and consumption of foreign products <u>is allowed if positive assurance of the state sanitary expert commission is obtained</u> .	Non-compliant. <u>Proposals on law harmonization:</u> To supplement Article 16 and other provisions stipulating that the security data (for products, raw materials, equipment, etc.) for the people's health and sanitary measures on prevention (elimination) of the negative influence thereof, are established by the State Chief Sanitary Officer of Ukraine, taking into account the International standards, instructions and recommendations. To adopt the draft Law of Ukraine "On State Sanitary-Hygienic Expert Examination".

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Order of the Ministry of Health Protection "On performing State Sanitary Expert Examination of Design, Manufacturing and Consumption of Potentially Harmful Products" No. 190 dated 20 October 1995	The Order determines rules of performing expert examinations, and list of food products subject to mandatory tests to be performed at the state sanitary agencies.	Compliant.
Order of the Ministry of Health Protection "On fees charged for services rendered by the state sanitary agencies to organizations, private and public businesses" Resolution of the Cabinet of Ministers of Ukraine "On the Approval of the List of Services Rendered by the State Health Protection Agencies and Higher Education Medical Institutions" No. 1138 dated 17 September 1996 Resolution of the Cabinet of Ministers of Ukraine "On Amendment of the Resolution of the Cabinet of Ministers of Ukraine No. 1138 dated 17 September 1996" No. 449 dated 12 May 1997	These regulations determine fees for performing sanitary tests and issuance of respective documents.	Compliant
The Law of Ukraine "On Veterinary Medicine" No. 567/96-BP dated 5 December 1996	The State Department for Veterinary Medicine under Ministry of Agrarian Policy of Ukraine is authorized by the Ukrainian Government to exercise veterinary control. <u>Movement across customs border of Ukraine of shipments falling under jurisdiction of state veterinary authorities, including items and materials potentially bearing pathogenic organisms harmful to animals, is subject to compulsory veterinary control.</u> Customs clearance is considered completed upon completion of veterinary control check, performed by experts of relevant regional branch veterinary agencies, and experts of customs office and customs check points. Import, export and transit through the territory of Ukraine of shipments falling under jurisdiction of state veterinary authorities, entry of vehicles subject to compulsory veterinary control, are subject to presentation of relevant documents as required by international agreements, and compliance with veterinary control requirements.	Compliant.

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<p>Resolution of the Cabinet of Ministers of Ukraine "Regulation on the Regional Service of State Veterinary Control at the State Border and on Transport of the State Department of Veterinary Medicine of the Ministry of Agriculture of Ukraine" No. 264 dated 2 March 1998</p>	<p>Regional agencies of the State Veterinary Control at the State Ukrainian Border and Transport are appointed to enforce compliance with the requirements of state veterinary control during international and national conveyance of all class of animals, products and materials of animal origin, biological, microbe, virus strands and fungus, items of collection of animal origin, veterinary medicines, and products and materials potentially bearing pathogenic organisms harmful to animals, and other shipments subject to veterinary control.</p> <p>In addition, regional agencies of the state veterinary control perform check of veterinary compliance documents, clinic examination of animals, veterinary expert examination of materials and products of animal and vegetative origin, feeding stuffs, substances designed for veterinary medicine, during their import, export, and transit through the territory of Ukraine.</p>	<p>Compliant.</p>
<p>The Law of Ukraine "On Plant Quarantine" No. 3348-XII dated 30 June 1993.</p>	<p>Plant quarantine requirements are designed to safeguard the territory of Ukraine from import and dissemination of pests, pathogenic organisms, and weed non-existent in Ukraine.</p> <p>Central State Inspection for Plant Quarantine under Ministry of Agrarian Policy of Ukraine is authorized by the Ukrainian Government to exercise veterinary control.</p> <p>All materials and items subject to plant quarantine, which are moved beyond the State Ukrainian Border and boundaries of special quarantine zones, are subject to phytosanitary control.</p> <p>Materials subject to plant quarantine can be brought into Ukraine subject to:</p> <ul style="list-style-type: none"> - Phytosanitary certificate issued by the government agencies enforcing quarantine and plants protection of the exporting country; 	<p>Compliant.</p> <p>A draft law "On amendment of the Law of Ukraine "On Plant Quarantine" is being prepared, in which the European Council Directives No. 79/93 of 1998 are taken into account.</p>

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	<p>- Quarantine import license issued by the Central State Inspection for Plant Quarantine of Ukraine.</p> <p>Customs clearance of shipments is performed upon completion of phytosanitary control.</p> <p>Specimen of the phytosanitary certificate and rules of the certificate issuance are identified by the Central State Inspection for Plant Quarantine of Ukraine, in compliance with the requirements of international conventions.</p> <p>Specimen of the quarantine import license and rules of the license issuance are identified by the Central State Inspection for Plant Quarantine of Ukraine.</p>	
<p>Resolution of the Cabinet of Ministers of Ukraine "On Fees Charged for Inspection of Materials Subject to Quarantine, and Services Provided to Businesses, Organizations, and Individuals" No. 953 dated 24 November 1993.</p>	<p>Fee for inspection of materials under quarantine.</p>	<p>Compliant.</p>
<p>Resolution "On Charter of the State Office of Plant Quarantine of Ukraine" No. 892 dated 28 October 1993</p>	<p>List of goods subject to quarantine control: seeds and sowing materials, agricultural, forestry and decorative plants and their parts (sprouts, bulbs, foetus), and other vegetative products which may potentially bear pests, plant plague and weed seeds, spores and fungus; viruses, hook-worms, ticks, insects, collections, herbariums, specimens, agricultural tools, cultivation machinery, speciality industrial products, packaging and goods manufactured from materials of vegetative origin which may potentially bear pests, plants plagues and weed seeds, monoliths and soil samples, and vehicles arriving from foreign countries and Ukrainian regions under special quarantine regime.</p>	<p>Compliant.</p> <p>Moreover, the respective amendments will be introduced after the adoption of the Law of Ukraine "On Amendment of the Law of Ukraine "On Plant Quarantine".</p>
<p>Order of the Ministry of Health No. 55 dated 17 March 2000 "Maximum Fee Rates for the Specialized Assessment and Expertise of Materials for the State Registration (Re-registration) of Medicines at the State Scientific and Expert Center of Medicines of the Ministry of Health of Ukraine".</p>	<p>The order approves fee rates without discriminating among residents and non-residents for the specialized assessment and expertise of medicines at the State Scientific and Expert Center of Medicines of the Ministry of Health of Ukraine.</p>	<p>Compliant.</p>

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Resolution of the Cabinet of Ministers of Ukraine "On the Approval of the Procedure of State Registration (Re-registration) of Medicines"	<p>The fee rates for the registration (re-registration) of medicines are uniform for residents.</p> <p>Three main GATT/WTO and EU requirements were taken into consideration:</p> <ul style="list-style-type: none"> - The registration certificate is issued to the applicant for the registration of the medicine, the applicant being a legal entity responsible for the production, quality, effectiveness and safety of the medicine. - Re-registration is only required where the registration certificate has expired. - The validity of the old registration certificate must be extended where the applicant timely submits materials for the re-registration of the medicine. 	Compliant.
Instruction "On the Procedures for Clinical Tests of Medicines and Expertise of Materials of Clinical Tests"	In the development of the instruction the 1964 Helsinki Declaration, EU directives and rules applied in international practice (ICH rules, GCP - Good Clinical Practice) were taken into consideration.	Compliant.
Sample Regulation "On the Commission on Ethics"	In the development of the regulation the 1964 Helsinki Declaration, EU directives and rules applied in international practice (ICH rules, GCP - Good Clinical Practice) were taken into consideration.	Compliant.
Instruction "On the Surveillance of Side Reactions and/or Effects of Medicines"	In the development of the instruction rules applied in the international practice (ICH rules) and EU directive on pharmacological supervision were taken into consideration.	Compliant.