

01 – FREE MOVEMENT OF GOODS

LEGISLATION CONSIDERED BENEFICIAL TO BE ENACTED (LAW)

I. LEGISLATION CONSIDERED BENEFICIAL TO BE ENACTED IN PERIOD 2007-2008 (01/10/2007 – 30/09/2007)

Reference No.	Name of the Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.0007.1.01	Law on the Amendment of the Law No. 4457 on Establishment and Tasks of Turkish Accreditation Agency	In order to implement an administrative structure in conformity with the accreditation agencies, which are members of the European Accreditation Union in Turkish Accreditation Agency that was established in the framework of EU adjustment laws, the necessity to amend certain articles of TÜRKAĞ Law No. 4457 has been borne so as to overcome the defects encountered in the 5-year implementation period	At the GNAT	EU New Approach Directives	Ministry of Industry and Trade Turkish Accreditation Agency
01.0708.1.01	Law on the Amendment of Medicinal and Pharmaceutical Products Law No. 1262	It is aimed to allow the publicity of out-of-prescription medicinal products for human use.	Technical studies are in progress	Directive 2001/83/EC	Ministry of Health
01.0708.1.02	Law on the Amendment of Law No. 5324 on Cosmetics	In order to provide cosmetic products to the society in a safe, efficient and qualified manner, it is aimed at controlling the manufacturing places of these products by means of market surveillance	Technical studies are in progress	- Directive 76/768/EEC - Directive 96/335/EC	Ministry of Health

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Reference No.	Name of the Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.0708.1.03	<p>Product Safety Law</p> <p>(Also present under the article on the Protection of Consumer and Consumer Health with reference number 28A.0708.1.02)</p>	<p>By the Law No. 4703 enforced in 2002, the obligation for all products placed on the market to comply with the technical regulations and to be safe has gained its legal basis, the obligations of manufacturers, distributors and importers have been regulated accordingly, the criteria with which conformity assessment bodies and notified bodies that perform test, inspection and certification activities shall comply have been specified, and the competency, tasks and responsibilities of public authorities that carry out market surveillance activities have been defined.</p> <p>Including the New and Old approach legislation, most of the EU technical legislation which has already been put into force after its transposition in our country is based on the Law No. 4703.</p> <p>However, the EU repealed the General Product Safety Directive No.92/59/EC. The European Commission has also been preparing a horizontal legislation on the issues of new approach, notified bodies and market surveillance since 2004.</p> <p>Aims at complying with the developments in the EU legislation.</p>	Technical studies are in progress	<p>Directive 2001/95/EC</p> <p>Draft regulations and decisions envisaged to be enacted by the EU in the next term:</p> <ul style="list-style-type: none"> - Draft Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products - Draft Regulation of the European Parliament and of the Council laying down the procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC - Draft Decision of the European Parliament and of the Council on a common framework for the marketing of products. 	Undersecretariat for Foreign Trade

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Reference No.	Name of the Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.0708.1.04	Law on the Amendment of the Law No. 132 on Establishment of the Turkish Standards Institute	Aims at meeting the administrative requirements in order to become full member of CEN and CENELEC, and satisfying the rules with which the Standardization agency should comply in respect of standardization, which is a basic requirement in the implementation of EU's New Approach Directives.	At the Prime Ministry	EU New Approach Directives	Ministry of Industry and Trade

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II. LEGISLATION CONSIDERED BENEFICIAL TO BE ENACTED IN PERIOD 2008-2009 (01/10/2008 – 30/09/2009)

NO LEGISLATIVE MEASURE IS ENVISAGED.

IV. LEGISLATION CONSIDERED BENEFICIAL TO BE ENACTED IN YEARS 2009 (01/10/2009) – 2013

Reference No.	Name of the Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.0913.1.01	Law on the Amendment of Law No. 3516 on Measurements and Adjustments	<p>The rearrangement of Law No. 3516, which will establish the legal basis to the EU legislation on legal metrology, shall be ensured. In this context, it is aimed at ensuring the manufacture, import and use of measuring instruments which are calibrated properly and in compliance with international system of units.</p> <p>The law at issue does not have a direct equivalent in the EU legislation. However, the EU legislation regarding the measurements and the measuring instruments within the scope of the law No. 3516 is listed in column five. After the legislation at issue is adapted, necessary amendments in the relevant law shall also be carried out.</p>		<p>Directives 71/316/EEC, 71/317/EEC, 71/318/EEC, 71/319/EEC, 71/347/EEC, 71/348/EEC, 71/349/EEC, 73/362/EEC, 74/148/EEC, 75/33/EEC, 75/410/EEC, 76/765/EEC, 76/766/EEC, 76/891/EEC, 77/95/EEC, 77/313/EEC, 78/1031/EEC, 79/830/EEC, 80/181/EEC, 86/217/EEC, 2004/22/EEC, 78/1031/EEC, 3821/85/EEC, 75/106/EEC, 75/107/EEC, 76/211/EEC, 80/232/EEC, 90/384/EEC</p>	Ministry of Industry and Trade

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Reference No.	Name of the Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.0913.1.02	<p>Law on the Amendment of Law No. 6136 on Firearms, Knives and Other Devices, and the Law No. 2521 on Manufacture, Purchase, Sale and Carrying of Sporting Guns, Shotguns and Hunting Knives</p> <p>(Also present under the article on Justice, Freedom and Security with reference number 24.0913.1.05)</p>	Aims at identifying the procedures of licensing, import and carrying arms for civil use between member states, and facilitating the entrance to and use of arms for hunting purposes in the country.		Directive 91/477/EEC	<p>Ministry of Interior (General Directorate of Security and General Command of Gendarmerie)</p> <p>(Institutions Concerned: Ministry of Justice, Ministry of Environment and Forestry, Undersecretariat for Foreign Trade)</p>
01.0913.1.03	<p>Law on the Prevention of Illegal Import, Export and Appropriation of Cultural and Natural Assets and Their Return to the Country of Origin</p> <p>(Also present under the article on Customs Union with reference number 29.0913.1.01.)</p> <p>Harmonization with the EU legislation will be ensured within the framework of full membership perspective.</p>	The purpose of this law is to prevent illegal circulation of cultural objects in order to circumvent such objects to be negatively affected from the free movement of goods principle that is in effect in the EU.		<ul style="list-style-type: none"> - Regulation No. 3911/92 - Regulation No. 2469/96 - Regulation No. 974/2001 - Directive 93/7/EEC - Directive 96/100/EC - Directive 2001/38/EC 	Ministry of Culture and Tourism

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SECONDARY LEGISLATION (REGULATIONS, IMPLEMENTING REGULATIONS, COMMUNIQUÉS, CIRCULARS, ETC) ENVISAGED TO BE ENACTED AND DOCUMENTS SUCH AS STRATEGIES, PLANS AND PROGRAMS ENVISAGED TO BE DRAFTED

I. SECONDARY LEGISLATION ENVISAGED TO BE ENACTED IN YEAR 2007

Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.01	Communiqués on measurements and measuring instruments implementing Law No. 3516	It covers the principles of diagnosis, adjustment, and stamping of measurements and measuring instruments that are and will be under the scope of the Law.	Technical studies are in progress.	Directives No. 71/316/EEC, 71/317/EEC, 71/318/EEC, 1/319/EEC, 71/347/EEC, 71/348/EEC, 71/349/EEC, 73/362/EEC, 74/148/EEC, 75/33/EEC, 75/410/EEC, 76/765/EEC, 76/766/EEC, 76/891/EEC, 77/95/EEC, 77/313/EEC, 78/1031/EEC, 79/830/EEC, 80/181/EEC, 86/217/EEC, 2004/22/EEC, 78/1031/EEC, 3821/85/EEC, 75/106/EEC, 75/107/EEC, 6/211/EEC, 80/232/EEC, 90/384/EEC	Ministry of Industry and Trade
01.2007.2.02	Implementing Regulation on Measuring instruments	Aims at ensuring compliance with the EU legislation.	A draft directive has already been prepared and submitted to the opinion of relevant institutions and bodies.	Directive 2004/22/EC	Ministry of Industry and Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.03	Implementing Regulation Amending Implementing Regulation on the Quantitative Analysis Methods of Binary Textile Fibres	European Commission Directive 2006/2/EC, which amends Directive 96/73/EC shall be complied with.	Technical studies are in progress.	Directive 2006/2/EC amending Directive 96/73/EC	Ministry of Industry and Trade
01.2007.2.04	Implementing Regulation Amending Implementing Regulation on the Designation of Textile Products	The amendment of the annexes of Directive 96/74/EC by Directive 2006/3/EC will be reflected in our legislation.	Technical studies are in progress.	Directive 2006/3/EC amending Directive 96/74/EC	Ministry of Industry and Trade
01.2007.2.05	Implementing Regulation Amending Implementing Regulation on Type Approvals of Liquid Fuel Tanks and Rear Protection Frame	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2006/20/EC amending Directive 70/221/EEC	Ministry of Industry and Trade
01.2007.2.06	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding Rear Rollover Protection Frame Mounted at the Back of Wheeled Farm and Forest Tractors	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2005/67/EC amending Directive 86/298/EEC	Ministry of Industry and Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.07	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding Rollover Protection Frame Mounted in front of the Driver's Seat of Narrow-Track Wheeled Tractors or Forest Tractors	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	- Directive 2003/37/EC - Directive 2005/67/EC	Ministry of Industry and Trade
01.2007.2.08	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Measures to be Taken against Gas Emissions and Particle Pollutants Originating from the Engines Designed for Exciting Farm and Forest Tractors	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2005/13/EC amending Directive 2000/25/EC	Ministry of Industry and Trade
01.2007.2.09	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Measures to be Taken against Gas Emissions and Particle Pollutants Originating from the Internal Combustion Engines of Mobile Machines Used outside of Highways	Aims at ensuring the compliance of the components and parts of heavy construction equipments used outside highways to the basic security and health requirements.	Technical studies are in progress.	- Directive 2002/88/EC - Directive 2004/26/EC	Ministry of Industry and Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.10	Implementing Regulation on Type Approvals Regarding Reusability, Transformability and Recyclability (The Regulation will be published when harmonization with ELV Directive 2000/53/EC is ensured by the Ministry of Environment and Forestry)	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2005/64/EC	Ministry of Industry and Trade
01.2007.2.11	Implementing Regulation on Type Approvals Regarding Front Protection Systems	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2005/66/EC	Ministry of Industry and Trade
01.2007.2.12	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Brake Systems of Two- or Three-Wheeled Motor Vehicles	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2006/27/EC amending Directive 93/14/EC	Ministry of Industry and Trade
01.2007.2.13	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding Necessary Markings of Two- or Three-Wheeled Motor Vehicles	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2006/27/EC amending Directive 93/34/EC	Ministry of Industry and Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.14	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Maximum Design Speed, Maximum Torque and Maximum Net Engine Power of Two- or Three-Wheeled Motor Vehicles	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2006/27/EC amending Directive 95/1/EC	Ministry of Industry and Trade
01.2007.2.15	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Certain Components and Properties of Two- or Three-Wheeled Motor Vehicles	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directives 2005/30/EC, 2006/27/EC, and 2006/72/EC amending Directive 97/24/EC	Ministry of Industry and Trade
01.2007.2.16	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Mass and Size of Two- or Three-Wheeled Motor Vehicles	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2004/86/EC amending Directive 93/93/EC	Ministry of Industry and Trade
01.2007.2.17	Implementing Regulation on Electromagnetic Compatibility	Aims at regulating the electromagnetic compatibility of equipments.	Technical studies are in progress.	Directive 2004/108/EC	Ministry of Industry and Trade
01.2007.2.18	Secondary legislation Regarding the Emissions Originating from Air Conditioning Systems	Aims at protection of health.	Technical studies are in progress.	Directive 2006/40/EC	Ministry of Industry and Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.19	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding Certain Parts and Properties of Wheeled Farm and Forest Tractors	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2006/26/EC amending Directive 74/151/EC	Ministry of Industry and Trade
01.2007.2.20	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding Electromagnetic Compatibility (Radio Interference) of Motor Vehicles	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 72/245/EEC amended by Directive 2005/83/EC and Directive 2004/104/EC	Ministry of Industry and Trade
01.2007.2.21	Implementing Regulation Amending Implementing Regulation on Type Approvals Regarding the Measures to be Taken Against Emissions of Gas and Particle Pollutants Originating from Compression Ignition Engines of Vehicles, and Gas Emissions Originating from Vehicles, which work with Liquid Petroleum Gas	Aims at ensuring the compliance of motor vehicle's components and parts to the basic security and health requirements.	Technical studies are in progress.	Directive 2005/78/EC amending Directive 2005/55/EC	Ministry of Industry and Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.22	Secondary legislation on the ecological design of energy consuming products (Also present under the article on Energy with reference number 15.2007.2.07)	Envisages to take certain criteria that will contribute to the protection of environment into account in the design stage of products (such as televisions) within the scope of relevant EU directives, and maintains these criteria regarding the protection of environment also in the design stage of the product, in order to ensure more effective applicability of the legislation on disposal conditions of such products.		Directive 2005/32/EC amending Directives 92/42/EC, 96/57/EC and 2000/55/EC	Ministry of Industry and Trade Ministry of Environment and Forestry
01.2007.2.23	Communiqué Amending Communiqué on the Reaction to Fire Classification for all Construction Materials and Fire Resistance of Construction Elements within the Scope of Construction Materials Regulation	Aims at laying down the issues set by EU Commission Decisions in the framework of needs reified by “Explanatory Document No. 2, Security in case of Fire”, which is an Explanatory Document concretizing the basic needs of the Construction Materials Regulation.	Technical studies are in progress.	Directive 89/106/EEC	Ministry of Public Works and Settlement
01.2007.2.24	Communiqué on the Attachment of the CE Sign on Construction Materials and the Preparation of Technical File	Aims at specifying the procedure of exercising the responsibility of attaching the CE sign, which is pointed out in the Construction Materials Regulation, on the material, on a label attached on the material, on the package of the material or on the commercial documents of the material while the manufacturer supplies the construction materials to the market.	Technical studies are in progress.	Directive 89/106/EEC	Ministry of Public Works and Settlement
01.2007.2.25	Communiqué on the Market Surveillance of Construction Materials at the Construction Site	Aims at ensuring and controlling the use of materials at the construction site in line with their intended use and basic requirements.	At the Prime Ministry	Directive 89/106/EEC	Ministry of Public Works and Settlement

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.26	Amendment of the Communiqué (4/5/2004 – OJ No. 25452) on Standards Referred by the Personal Protective Equipments Regulation	The Personal Protective Equipments Regulation published in the Official Journal No. 25368 dated 9/2/2004 was revised and republished according to the views communicated by the European Commission. It is aimed at ensuring the compliance of the harmonized national standards with the new revised regulation.	Technical studies are in progress	- Directive 89/686/EEC - Directive 93/68/EEC - Directive 93/95/EEC - Directive 96/58/EEC - Regulation 1882/2003	Ministry of Labour and Social Security
01.2007.2.27	Implementing Regulation of the Council of Ministries on Mutual Recognition in the Non-harmonized Area	In the interpretative communication dated 4 November 2003, the European Commission declared that, in the non-harmonized area, the Turkish products would also be subjected to the same treatment with the products of any EU Member State origin, and demanded that, in principle, products manufactured in Turkey or products put in free movement in Turkey despite they are of third country origin should not be subject to checks at the Community customs In this framework, it is aimed at laying down the procedures and principles for the incorporation of the mutual recognition clause in the national technical regulations in order to ensure free movement of goods in the non-harmonized area between Turkey and the EU, on the one hand; and for the notification of national measures, which prevent the free movement of goods between Turkey and the EU, on the other.	Technical studies are in progress	- Communication of the European Commission 2003/C 265/02 - Decision No. 3052/95/EC of the European Parliament and of the Council establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community	Undersecretariat for Foreign Trade

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.28	Regulation on Product Safety Checks in Imports from Third Countries	The aim of this regulation is to arrange the procedures and principles for product safety checks in imports from third countries, which is carried out in the framework set by obligations originating from WTO rules and Customs Union with the EU.	Technical studies are in progress	Regulation 339/93	Undersecretariat for Foreign Trade
01.2007.2.29	Amendment of the Implementing Regulation on Market Surveillance	Due to the establishment of Market Surveillance Laboratories, necessary amendments are to be made in this context.	Technical studies are in progress	Secondary regulation within the scope of Directive 1999/5/EC	Telecommunication Authority
01.2007.2.30	Amendment of the Communiqué (2004/1) on the Standards Referred in T&TTE Regulation	Aims at updating annex of the Communiqué that lists the harmonized national standards and relevant harmonized European Standards within the scope of T&TTE Regulation..	Technical studies are in progress	Secondary regulation within the scope of Directive 1999/5/EC	Telecommunication Authority
01.2007.2.31	Implementing Regulation on the Procedures and Principles of Market Surveillance that will be Carried Out by the Ministry of Health	Specifies the measures to be taken and the procedures and principles regarding the compliance to the relevant technical regulation and the safety of products during supply to or distribution in the market, or while they are in the market.	Technical studies are in progress	Directive 2001/95/EC	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2007.2.32	Implementing Regulation on the Storage and Wholesale Distribution of Medicinal products	The regulation aims at laying down the procedures and principles regarding purchase, sale, storage, shipment and distribution of social medicine products licensed/permitted to protect social health or veterinary medical products used in veterinary medicine, and the procedures and principles for the conduct of such operations under appropriate conditions in order to ensure the provision of these products safely and at the desired quality, and withdrawal of false and spoiled products from the market when necessary.	Technical studies are in progress	Directive 2001/83/EC (Title VII)	Ministry of Health
01.2007.2.33	Implementing Regulation Amending Implementing Regulation on Procedures and Principles of Market Surveillance, which will be Carried Out by the Ministry of Industry and Trade	Reviews the procedures and principles of market surveillance, which will be carried out by the Ministry, and, in addition, makes the arrangements regarding the personnel assigned to the task of market surveillance.	Technical studies are in progress	All old and new approach directives that are in the Ministry of Industry and Trade's field of responsibility.	Ministry of Industry and Trade

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II. SECONDARY LEGISLATION ENVISAGED TO BE ENACTED IN YEAR 2008

Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.01	Implementing Regulation Machinery	Satisfying the basic health and safety needs of machines and safety parts.		Directive 2006/42/EC	Ministry of Industry and Trade
01.2008.2.02	Implementing Regulation on the Classification, Labelling and Packaging of Hazardous Substances and Preparations. (Also present under the Environment article with reference number 27.2008.2.09.)	By the application of the legislation, technical obstacles in front of the international trade of chemicals can be removed, safe products can be supplied to the market, and environment and human health can be protected from the hazardous effects of chemicals. Relevant parts of Hazardous Substances Directive 67/548/EEC shall be complied with.		- Directive 67/548/EEC - Directive 99/45/EC	Ministry of Environment and Forestry
01.2008.2.03	Implementing Regulation on Procedures and Principles of Chemical Substances Inventory, its Notification and Risk Assessment. (Also present under the Environment article with reference number 27.2008.2.10.)	The inventory of chemical substances supplied to the market can be made, the risk assessment of new chemical substances, which will be newly supplied to the market can be made, safe products can be supplied to the market, international exchange of information on the risks of chemicals can be ensured, environment and human health can be protected from the hazardous effects of chemicals.		- Directive 67/548/EEC (Statement Part) - Directive 93/67/EEC - Regulation 793/93/EEC	Ministry of Environment and Forestry

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.04	Implementing Regulation on Restrictions Regarding Production, Supply to the Market and Use of Certain Hazardous Substances, Preparations and Articles	Ensuring compliance with the EU legislation and establishing legal framework. (In the Annex of Directive 76/769/EEC, the list of restricted substances in the EU countries is given. Since the situation in our country should be taken into consideration regarding these substances, all substances present in the list given by the Directive Annex are not included to the annex of the legislation to be enacted. Therefore, the legislation will be enacted partially in compliance with the Directive.)		Directive 76/769/EEC	Ministry of Environment and Forestry
01.2008.2.05	Implementing Regulation on Preparation and Dissemination of Security Information Forms			Directive 91/155/EEC	Ministry of Environment and Forestry
01.2008.2.06	Revision of the Implementing Regulation on Inspection of Good Laboratory Practices and Control of these Activities	Harmonization with the directives on GLP of EU will enable certification of public and private laboratories by GLP, which is an international quality system, so as to ensure these laboratories to supply safe products to the market in terms of environment and human health and determine the hazardous effects of these products and preparations, and a National Monitoring Authority will be established in order to ensure applicability and sustainability.		Directive 2004/10/EC	Ministry of Health Ministry of Environment and Forestry Ministry of Agriculture and Rural Affairs

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.07	Revision of the Implementing Regulation on Principles of Good Laboratory Practices and Certification of Test Laboratories	Harmonization with the directives on GLP of EU will enable certification of public and private laboratories by GLP, which is an international quality system, so as to ensure these laboratories to supply safe products to the market in terms of environment and human health and determine the hazardous effects of these products and preparations, and a National Monitoring Authority will be established in order to ensure applicability and sustainability.		Directive 2004/9/EC	Ministry of Health Ministry of Environment and Forestry Ministry of Agriculture and Rural Affairs
01.2008.2.08	Regulation Amending Regulation on Special Qualifications Food and Goods and Supplies Concerning Public Health	Aims at adopting the necessary amendment to invoke the detergent regulation that regulates the supply of detergents and surface active substances used in detergents to the market, and procedures and principles that should be applied in order to protect the environment and human health at the maximum level.		Regulation No. 648/2004	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.09	<p>Implementing Regulation on Detergents</p> <p>(In order to issue the implementing regulation, regulation on Special Qualifications Food and Goods and Supplies Concerning Public Health with reference number 01.2008.2.08 should be amended.</p> <p>Furthermore, legislation 2004/10/EC, 793/93/EEC, 1999/45/EC, 67/548/EEC, 93/67/EEC, 98/8/EEC, 86/609/EEC, 1488/94/EEC, 1992/32/EEC, 2004/9/EC, 1999/476/EC, 2003/15/EC referred in Bylaw No. 648/2004 should be harmonized by relevant ministries (Ministry of Health, Ministry of Environment and Forestry, Ministry of Agriculture and Rural Affairs))</p>	<p>Aims at adopting the necessary amendment to invoke the detergent regulation that regulates the supply of detergents and surface active substances used in detergents to the market, and procedures and principles that should be applied in order to protect the environment and human health at the maximum level.</p>		Bylaw No. 648/2004/EC	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.10	<p>Communiqué on the Prohibition of Animal Tests for Cosmetic Products</p> <p>(In order for the communiqué to be completed and take effect, the harmonization of Hazardous Substances Regulation, which will be issued by the Ministry of Environment and Forestry, with the EU legislation should be completed and this regulation should go into effect.)</p>	Harmonization with the EU legislation regarding the use of alternative methods rather than animal tests during the manufacture of cosmetic products.		Directive 2003/15/EC	Ministry of Health
01.2008.2.11	<p>Communiqué on the Procedure to be Applied in case Cosmetics Producer does not Want to Include One or More of the Ingredients in order to Protect Trade Secrets</p> <p>(In order for the communiqué to be completed and take effect, the harmonization of Hazardous Substances Regulation, which will be issued by the Ministry of Environment and Forestry, with the EU legislation should be completed and this regulation should go into effect.)</p>	Protection of the trade secrets of cosmetics producer.		Directive 1995/17/EC	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.12	<p>Implementing Regulation on Medical Implements Manufactured by Using Tissues of Animal Origin</p> <p>In order for this regulation to be issue, the Ministry of Agriculture and Rural Affairs should harmonize with the following arrangements:</p> <p>1- Bylaw No. 999/2001 on the communication of animal diseases</p> <p>2- Bylaw No. 1774/2002 on animal byproducts not intended for human consumption</p>	Aims at making necessary arrangements on medical implements manufactured by using tissues of animal origin and protecting human health.		Directive 2003/32/EC	Ministry of Health
01.2008.2.13	Implementing Regulation on the Reclassification of Hip, Knee and Shoulder Implants	Aims at making necessary arrangements for the reclassification of hip, knee and shoulder implants, protecting human health, and ensuring safety.		Directive 2005/50/EC	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.14	Secondary legislation Amending Implementing Regulation on Cosmetics	In order to ensure the society to reach cosmetic products safely, effectively and at the required quality, within the scope of new EU legislation, it is aimed at amending the current Regulation on inspection of production sites of these products by means of market surveillance before products are supplied to the market		Directive 76/768/EEC Decision 96/335/EC Decision 2006/257/EC	Ministry of Health
01.2008.2.15	Implementing Regulation on Clinical Research of Medicinal Products for Human Use	Aims at applying scientific and ethical standards in the design, implementation, recording, reporting, validation, etc. of clinical research and studies, also including bio-availability and bioequivalence studies, on licensed / permitted or unlicensed / unauthorized medicinal products for human use applied to voluntary persons within the framework of Good Clinical Practice; protecting the volunteers, and laying down the procedures and principles on the organization of approved ethical committees		- Directive 2001/20/EC - Good Clinical Practice (GCP) Manual	Ministry of Health
01.2008.2.16	Amendment of the Implementing Regulation on Packaging and Label of Medicinal Products for Human Use	Aims at correcting the defects due to implementation in the Packaging and Labelling of Medicinal Products for Human Use Regulation		Directive 2001/83/EC	Ministry of Health
01.2008.2.17	Implementing Regulation on Simplified Licensing of Traditional Herbal Medicinal Products			Directive 2004/27/EC	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.18	Implementing Regulation on Good Manufacturing Practices for Medicinal Products for Human Use and Investigational Medicinal Products for Human Use			Directive 2003/94/EC	Ministry of Health
01.2008.2.19	Implementing Regulation Veterinary Biological Products	Specifies technical and hygiene criteria for laboratories producing such products; identifies necessary measures for production and sale permit by establishment and operation permits.		Directive 2001/82/EC	Ministry of Agriculture and Rural Affairs
01.2008.2.20	Implementing Regulation Veterinary Diagnosis and Analysis Laboratories	Identifies necessary measures for giving establishment and work permits of laboratories carrying out diagnosis and analysis of animal diseases		Directive 2001/82/EC	Ministry of Agriculture and Rural Affairs
01.2008.2.21	Implementing Regulation Imported Veterinary Biological Products	Specifies necessary criteria and measures for all operations beginning from the entrance of imported veterinary biological products to the country to their provision to end-users.		Directive 2001/82/EC	Ministry of Agriculture and Rural Affairs
01.2008.2.22	Implementing Regulation Veterinary Biological Products Sampling	Specifies the criteria regarding samples taken for the purpose of performing quality control of all produced or imported veterinary biological products.		Directive 2001/82/EC	Ministry of Agriculture and Rural Affairs
01.2008.2.23	Implementing Regulation Veterinary Drugs Pharmaceutical Warehouses	Specifies procedures and principles regarding the wholesale distribution of veterinary preparations		Directive 2001/82/EC	Ministry of Agriculture and Rural Affairs

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2008.2.24	Implementing Regulation Retail Sale of Veterinary Drugs	Specifies procedures and principles regarding the retail sale of veterinary preparations		Directive 2001/82/EC	Ministry of Agriculture and Rural Affairs

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III. SECONDARY LEGISLATION ENVISAGED TO BE ENACTED IN YEAR 2009

Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.2009.2.01	Communiqués and Implementing Regulations on Measurements and Measuring instruments within the Scope of Law No. 3516 (this will be a continuation of works, which could not be concluded in 2007 and 2008)	<p>Specifies procedures and principles of determining the complaints about first, periodical or instantaneous examinations and stock examinations, and the persons, methods and means by which these will be carried out; lays down the obligations, tasks and responsibilities of the owners or users of measurements and measuring instruments subject to examinations.</p> <p>It also includes examination, adjustment and marking of measurements and measuring instruments within the scope of the law or that will be included newly in the scope of the law.</p>		<p>Directives 71/316/EEC, 71/317/EEC, 71/318/EEC, 71/319/EEC, 71/347/EEC, 71/348/EEC, 71/349/EEC, 73/362/EEC, 74/148/EEC, 75/33/EEC, 75/410/EEC, 76/765/EEC, 76/766/EEC, 76/891/EEC, 7/95/EEC, 77/313/EEC, 78/1031/EEC, 79/830/EEC, 80/181/EEC, 86/217/EEC, 2004/22/EEC, 78/1031/EEC, 3821/85/EEC, 75/106/EEC, 75/107/EEC, 76/211/EEC, 80/232/EEC, 90/384/EEC</p>	Ministry of Industry and Trade
01.2009.2.02	<p>Secondary legislation Regarding the Implementation of Product Safety Law</p> <p>(These will be issued after the Product Safety Law with reference number 01.0708.01.03 is adopted.)</p> <p>(Also present under the article on the Protection of Consumer and Consumer Health with reference number 28A.2009.2.01.)</p>	Aims at elaborating system needs by secondary legislation.		<p>Directive 2001/95</p> <p>Regulations and decisions, which the EU envisages to issue in the following period.</p>	Undersecretariat for Foreign Trade

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IV. SECONDARY LEGISLATION ENVISAGED TO BE ENACTED IN YEARS 2010 – 2013

Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.1013.2.01	Implementing Regulation on Orphan Drugs Harmonization with the EU legislation will be ensured within the framework of full membership perspective.			Bylaw No. 141/2000	Ministry of Health
01.1013.2.02	Implementing Regulation on the Specification and Application of Criteria for Identifying a Medicinal Product as Orphan Drug, and Definitions of “Similar Medicinal Product” and “Clinically Superior” Harmonization with the EU legislation will be ensured within the framework of full membership perspective.			Bylaw No. 847/2000	Ministry of Health
01.1013.2.03	Amendment of the Communiqué on Pricing of Medicinal Products for Human Use	Aims at rearranging the present legislation by fulfilling its gaps in order to ensure the pricing of medicinal products for human use to be done in terms of transparency and equity principles.		Directive 89/105/EEC	Ministry of Health

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.1013.2.04	<p>Amendment of the Implementing Regulation on Chemical Substances subject to Control</p> <p>Harmonization will be ensured in the framework of full membership perspective to the EU legislation.</p>	<p>The Regulation was prepared in parallel with the EU Legislation Specifying Detailed Rules Regarding the Production and Marketing of Certain Substances that are Used in the Illegal Production of Narcotic and Psychotropic Substances. The Regulation on Chemical Substances subject to Control needs to be amended within this scope.</p>		<ul style="list-style-type: none"> - Bylaw No. 273/2004 - Bylaw No. 111/2005 - Bylaw No. 1277/2005 	Ministry of Health
01.1013.2.05	<p>Implementing regulation on the Prevention of Illegal Import, Export and Appropriation of Cultural and Natural Assets and Their Return to the Country of Origin</p> <p>(It will be issued after the adoption of the Law on the Prevention of Illegal Import, Export and Appropriation of Cultural and Natural Assets and Their Return to the Country of Origin with reference number 01.0913.1.03)</p> <p>(Also present under the article on Customs Union with reference number 29.1013.2.9)</p>	<p>Application of the Law on the Prevention of Illegal Import, Export and Appropriation of Cultural and Natural Assets and Their Return to the Country of Origin</p>		<ul style="list-style-type: none"> - Bylaw No. 752/93/EEC - Bylaw No. 656/2004/EEC - In-Principle Decision of the Council No. 302G0205(03) 	Ministry of Culture and Tourism

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.1013.2.06	<p>Amendment of the Implementing Regulation on Import and Export of Movable Cultural and Natural Assets that needs to be Protected</p> <p>(It will be issued after the adoption of the Law on the Prevention of Illegal Import, Export and Appropriation of Cultural and Natural Assets and Their Return to the Country of Origin with reference number 01.0913.1.03)</p> <p>(Also present under the article on Customs Union with reference number 29.1013.2.9)</p>			Bylaw No. 1526/98/EC	Ministry of Culture and Tourism
01.1013.2.07	Implementing Regulation on the GMP Inspection System	Specifies procedures and principles on the establishment and operation of workshops manufacturing veterinary medicinal preparations.		<ul style="list-style-type: none"> - Directive 91/412/EEC - Directive 2003/94/EC 	Ministry of Agriculture and Rural Affairs

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Reference No.	Name of the Secondary Legislation to be Amended/Enacted	Objective/Scope	Stage	EU Legislation Envisaged to Comply with	Institution Responsible for the Preparation of the Legislation
01.1013.2.08	<p>Secondary legislation on the Functioning of the Internal Market to Ensure Free Movement of Goods between EU Countries</p> <p>Harmonization with the EU legislation will be ensured within the framework of full membership perspective.</p>			Council Regulation No. 2679/98	Undersecretariat for Foreign Trade