CONFERENCE ON ACCESSION TO THE EUROPEAN UNION - BULGARIA -

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INTERGOVERNMENTAL CONFERENCE ON THE ACCESSION OF THE REPUBLIC OF BULGARIA TO THE EUROPEAN UNION

NEGOTIATING POSITION ON CHAPTER 1 FREE MOVEMENT OF GOODS

OVERALL POSITION

The Republic of Bulgaria accepts and is ready to implement the *acquis communautaire* in the field of free movement of goods.

As a working hypothesis, the Bulgarian Government considers that the Republic of Bulgaria will become a member of the European Union on 01.01.2007.

The Republic of Bulgaria does not request transitional periods or derogations from the *acquis* in this field.

The present position paper covers EU legislation in the field of free movement of goods, as in force on 31.12.1999.

The Republic of Bulgaria will be capable of implementing the Community *acquis* in the field of free movement of goods by the date of accession.

ACQUIS ADOPTION AND IMPLEMENTATION

The legislation of the Republic of Bulgaria in the field of free movement of goods is to a great extent compatible with the *acquis*. The Republic of Bulgaria has already adopted the framework legislation in the separate sectors of this chapter and in compliance with the National Program for the Adoption of the Acquis will gradually achieve full alignment till the end of 2005. Most of the relevant infrastructures necessary for the implementation and enforcement of the Community *acquis* are in place and operational. Their capacity to operate efficiently has been subject to strengthening. Some new structures are in process of setting up.

The Republic of Bulgaria has achieved progress in this field especially with the adoption of the Law on National Standardisation (SG 55/18.06.1999) which entered into force on 19.09.1999. Special attention has been paid on the measures necessary to achieve functional independence between technical regulation, standardisation, accreditation and certification.

The Law on Technical Requirements to Products, adopted on 17.09.1999 (SG 86/01.10.1999), has established the legal basis for the adoption of New and Global Approach principles. The Bulgarian Government has adopted a programme for the transposition of the New Approach Directives.

The transposition of the technical requirements to products and the New and Global Approach principles in the national legal system has been carried out in close cooperation with economic operators, employers' organisations and other professional organisation. Each step has been assessed in respect of the ability of the economic operators to meet the requirements of the new legislation. On the basis of the achieved so far and the expected economic growth during the years before the accession, we are in a position to say that the ability of economic operators to meet the requirements of the *acquis* in short-term will increase and this will contribute to a smoother harmonisation.

The Republic of Bulgaria is fully aware of the importance of measures to be taken to comply with the requirements of Articles 28-30 of the EC Treaty. In 1999 an ad hoc Working group was established to perform an internal screening of Bulgarian legislation, including for its conformity with Articles 28-30 of the EC Treaty. The Working group did not identify incompliance. The established interministerial mechanism for the adoption of new legislation provides the instruments necessary for ensuring compliance with the *acquis*.

Motor vehicles

The framework legislation in the field of motor vehicles is adopted. The Road Traffic Law was adopted on 18.02.1999 and entered into force on 01.09.1999 (SG 20/05.03.1999). Article 138, paragraph 3, stipulates that the Minister of Transport and Communication determines the terms and conditions for type approval of motor vehicles.

The Road Transport Law was adopted on 02.09.1999 and entered into force on 17.09.1999 (SG 82/17.09.1999). It provides for setting up of administrative structures (Automobile Administration) necessary for the implementation of the type approval system. In conformity with Article 2 of the Law, the Statute of the Automobile Administration General Directorate within the Ministry of Transport and Communication was adopted (SG 113/28.12.1999).

The Law for Ratification of the Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts, which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the bases of this prescriptions (Revision 2) was adopted on 20.10.1999. As from 21.01.2000 the Republic of Bulgaria is party to this Agreement and has declared the acceptance of 21 UN/ECE Regulations: 6, 13, 13-H, 24, 27, 28, 30, 39, 43, 48, 49, 51, 54, 55, 58, 73, 83, 84, 89, 93 and 105.

Full transposition of the acquis related to motor vehicles will be achieved with the adoption of the secondary legislation under the Road Traffic Law till the end of 2005.

Foodstuffs

The Law on foodstuffs was adopted on 30.09.1999 (SG 90/15.10.1999). It is a framework law and envisages the adoption of secondary legislation providing detailed requirements on foodstuffs in all stages of the food chain in order to ensure safe foodstuffs to the customers and to protect their rights for adequate information.

The Law on foodstuffs includes the basic provisions of Directives 79/112/EEC, 89/107/EEC, 88/388/EEC, 89/109/EEC, 89/397/EEC, 93/43/EEC and Regulation 315/93.

The ordinances based on this law will implement in Bulgarian legislation all the horizontal and vertical directives.

The control of foodstuffs is carried out by the State Sanitary Control authorities established under the Law on Public Health, the State Veterinary Control authorities established under the Veterinary Law, and by inspectors from the National Service for Plant Protection, Quarantine and Agrochemistry established under the Law on Plant Protection.

Analysis of foodstuffs for the purposes of the official control are performed in laboratories of the Hygiene Epidemiological Inspectorate, National Veterinary Service, National Service for Plant Protection, Quarantine and Agrochemistry and national institutes.

Horizontal approach

Labelling

With Council of Ministers Decree No 136/19.07.2000 Ordinance on the labelling and presentation of foodstuffs was adopted (SG 62/28.07.2000). This Ordinance transposes in the national legislation Directives 79/112/EEC, 94/54/EEC, 99/10EEC and 89/396/EEC and Regulation 1139/98 (as amended). The Ordinance enters into force on 29.07.2001.

The Ordinance on nutrition labelling for foodstuffs transposing Directive 90/496/EEC will be adopted till the end of the year 2000.

Food additives

Current legislation as regards food additives (Ordinance No 45/01.12.1995 of the Ministry of Health on the hygiene requirements to additives in foodstuffs) will be used as a basis for achieving full compliance with *acquis communautaire* in this field. The Ordinance on additives in foodstuffs implementing Directives 89/107/EEC, 94/35/EC, 94/36/EC, 95/2/EC (as amended) will be adopted till the end of the year 2000.

The Ordinance on flavourings for use in foodstuffs implementing Directive 88/388/EEC will be adopted till the end of the year 2001.

The ordinances transposing the directives laying down specific criteria of purity (78/663/EEC, 95/31/EC, 95/45/EC and 96/77/EC), as well as the methods of analysis (81/712/EEC) and Directive 67/427/EEC will be adopted till the end of the year 2001.

Extraction solvents

The Ordinance on extraction solvents used in the production of foodstuffs implementing the provisions of Directive 88/344/EEC will be adopted by the end of the year 2001.

Contamination

Ordinance No 11/11.07.2000 of the Minister of Health on the maximum levels of mycotoxines in foodstuffs (SG 58/18.07.2000) was adopted. This Ordinance transposes Regulations 315/93 and 194/97 and Directive 98/53/EC. The Ordinance enters into force on 19.07.2002.

The Ordinance on maximum levels of heavy metals in foodstuffs transposing the relevant provisions of Regulation 315/93 and Commission Decision 93/351/EEC will be adopted till the end of the year 2000.

Materials and articles in contact with food

The Ordinance on the requirements to plastic materials and articles intended to come into contact with foodstuffs implementing Directives 89/109/EEC, 78/142/EEC, 80/766/EEC, 81/432/EEC, 82/711/EEC, 85/572/EEC, 90/128/EEC, 80/590/EEC (as amended) will be adopted by the end of the year 2000.

The Ordinance on the requirements to materials and articles other than plastic intended to come into contact with foodstuffs implementing Directives 84/500/EEC, 93/10/EEC, 93/11/EEC and 80/590/EEC will be adopted in 2001.

Foodstuffs for particular nutritional uses

The Ordinance on the composition, characteristics and names of infant formulae and follow-on formulae on the basis of Directives 89/398/EEC and 91/321/EEC will be adopted by the end of the year 2001.

The ordinances transposing Directives 89/398/EEC, 96/5/EC, 96/8/EC and 99/21/EC will be elaborated in 2002.

Hygiene and control

The basic stipulations of Directives 89/397/EEC and 93/99/EEC on the official control of foodstuffs are implemented in Bulgarian legislation through Chapter IV - State control of foodstuffs of the Law on foodstuffs.

Current legislation relating to methods of sampling for foodstuffs (Ordinance No 2/21.07.1997 of the Ministry of Health on the sampling methods for foodstuffs) will be amended till mid 2001 aiming at achieving full compliance with Directive 85/591/EEC.

Directive 93/43/EEC is transposed to a great extent in the National legislation through the Law on foodstuffs, Ordinance No 19/18.09.1996 of the Ministry of Health on hygiene requirements to the manufacturers of foodstuffs and on the conditions for production of safe foods and Ordinance No 27/09.12.1996 of the Ministry of Health on the hygiene rules for the public food establishments. The above Ordinances will be amended till mid 2001 in order to bring them in full compliance with Directive 93/43/EEC. An Ordinance

on hygiene requirements to the establishments for trade with foodstuffs has been developed and the deadline for its adoption is the end of the year 2000. This Ordinance also transposes provisions of Directive 93/43/EEC.

Quick-frozen foodstuffs, novel foods and novel food ingredients

Directives 89/108/EEC, 92/1/EEC and 92/2/EEC on quick-frozen foodstuffs and Regulation 258/97 on novel food and novel food ingredients will be implemented in Bulgarian legislation in 2002.

Food irradiation

Directives 99/2/EC and 99/3/EC relating to the food ingredients treated with ionising radiation will be transposed in Bulgarian legislation by the end of the year 2001.

Vertical approach

Vertical Directives 76/621/EEC, 73/241/EEC, 73/437/EEC, 74/409/EEC, 93/77/EEC, 93/45/EEC, 79/693/EEC, 76/118/EEC, 83/417/EEC, and 99/4/EEC, setting the requirements to different types of foods, will be implemented in Bulgarian legislation on the basis of article 4 of the Law on foodstuffs in the period 2002-2003.

It is envisaged the Ordinance transposing Directive 80/777/EEC on mineral waters to be adopted by the end of the year 2001.

The transposition of Directives 80/891/EEC, 79/796/EEC, 79/1067/EEC, 87/524/EEC, 85/503/EEC, 86/424/EEC and 79/1066/EEC relating to sampling methods for certain foodstuffs is planned for a later stage due to the possibility of their modification and because certain methods currently applied are more up-to-date.

Chemicals

Dangerous substances and preparations

The operational Bulgarian legislation regarding chemical substances and preparations is only partially in line with the acquis in this field.

The Law on protection against harmful impact of chemical substances, preparations and products, adopted on 20.01.2000 (SG 10/04.02.2000), transposes basic requirements of Community legislation in this field and gives the legal framework for the implementation of acquis communautaire on chemical substances and preparations. The Law enters into force on 05.02.2002 along with a number of regulations, transposing Community legislation on chemicals relating to Free Movement of Goods, Environment and Health and Safety at Work. The provisions of Directives 67/548/EEC, 99/45/EEC and 91/155/EEC will be implemented through Ordinance on classification, packaging and labelling of dangerous substances and preparations and Directive 76/769/EEC – through Ordinance for restrictions on the marketing and use of certain dangerous substances and preparations.

Control authorities under the LPHICSPP are: Regional Inspections on Environment and Waters within the Ministry of Environment and Waters, Regional Hygiene

Epidemiological Inspections under the Ministry of Health and State Agency for Labour under the Ministry of Labour and Social Policy.

Detergents

Ordinance No 35/01.09.1995 of the Ministry of Health on the hygienic requirements to household chemical preparations (SG 83/15.09.1995) is partially in line with the provisions of Directive 73/404/EEC. This Ordinance is adopted under the Law on public health. The new legal basis for the implementation of Directives 73/404/EEC, 73/405/EEC and 82/242/EEC will be prepared by the end of the year 2000. The Ordinance on detergents will be adopted by the end of the year 2001 and the control authority will be designated.

Fertilisers

The Law amending the Law on plant protection will be adopted by the end of the year 2000. In this way a new chapter regulating fertilisers will be included. The Ordinance transposing Directives 76/116/EEC, 77/535/EEC, 80/876/EEC and 87/94/EEC will be adopted by the end of the year 2001. Control authority will be the National service for plant protection.

Drug precursors

The Law on control of narcotic substances and precursors (LCNSP) was adopted on 19.03.1999 (SG 30/02.04.1999) implementing the commitments of the Republic of Bulgaria under the United Nations Convention from 1988 for combating the illegal traffic of narcotic and psychotropic substances.

In compliance with the LCNSP with Council of Ministers Decree No 104/06.06.2000 Ordinance on the control of drug precursors was adopted (SG 48/13.06.2000) and entered into force on 17.06.2000. The Ordinance transposes the requirements of Directive 92/109/EEC, Directive 93/46/EEC and Regulation 1485/96.

The Ordinance regulates: the structure and activity of the Joint Committee for Control of Drug Precursors; the terms and conditions for issuing licenses to persons engaged in all the activities regarding precursors; the control measures concerning all the activities; the terms and conditions for issuing authorisations for import, export, re-export and transit of precursors; the documentation in operation with precursors; as well as confiscation, storage, disposal and destruction of precursors.

However, Bulgarian legislation implements some stricter requirements in comparison to those in the European legislation as follows:

- The Ordinance envisages the persons dealing with precursors from all three categories to be licensed, while Directive 92/109/EEC requires the possession of license only for category I and registration of manufacturers premises for category II;
- The exemption from the requirements for documentation of the transactions with precursors category II (Art. 2, p.2 or 92/109/EEC), when the quantity of precursors do not exceed the quantities given in Annex II, is not envisaged;

- The Ordinance stipulates a customer declaration for precursors category I and II, only for individual transactions to be submitted and does not foresee an annual declaration for precursors category II, as of Article 2 of Regulation 1485/96.

According to the LCNSP, the list of scheduled substances includes all the substances from Annex I of Directive 93/46/EEC plus three additional substances, which the control authorities have found to be illegally used on the territory of Bulgaria in amphetamines manufacture. These substances are: Phenylpropanolamine (PPA - classified under CN code 2939 49 00) and Formamide (classified under CN code 2924 10 00), included in category I, and Chloracetone (classified under CN code 2914 70 90), included in category II.

Non-compliance with the acquis will be eliminated till the year 2005.

Explosives for civil uses

The Law on technical requirements to products introduces the New Approach principles in Bulgarian legislation. According this law Ordinance on explosives for civil use will be adopted. The Ordinance transposing Directive 93/15/EEC will be elaborated till 31.01.2001 and will enter into force on 01.01.2003.

Good Laboratory Practice

In compliance with the provisions of paragraph 11(2) of the Additional Provisions of Law on medicines and pharmacies in human medicine the GLP principles were approved in 1997 by the Minister of Health and published as Guidelines.

Taking into consideration the amendments of Directive 87/18/EEC, Bulgarian legislation will be modified by the end of the year 2002 and the requirements regarding inspection and verification of GLP, set in Directive 88/320/EEC (as amended), will be implemented. The designation of the administrative infrastructure for the inspection and verification of GLP is under discussion.

Pharmaceuticals

Medicines for human use

The Law on Medicinal Substances and Pharmacies in the Human Medicine (LMSPHM) was adopted in 1995 (SG No 36/1995, amendments SG Nos. 38/1998, 30/1999, 10/2000). With the last amendment in 2000 the Law was renamed to Law on Medicines and Pharmacies in Human Medicine (LMPHM). The Law and 32 implementing regulations transpose with a high level of conformity the majority of the acquis in this field. The prevailing part of the rules relating to marketing authorisation, testing, manufacture, wholesale, advertising and storage of medicines are transposed in Bulgarian legislation aiming at ensuring the quality, safety and efficiency of the medicinal products. Ministry of Health (Medicinal policy Directorate) and the Executive Agency for Medicines (EAM is established as a result of restructuring of the National Institute for Medical Products) share the activities concerning marketing authorisation, manufacture authorisation, wholesale and retail sale licensing.

The European Pharmacopoeia was introduced as the applicable pharmacopoeia in Bulgaria with an Order of the Minister of Health (Order No RD-09-350/29.06.1995 - the second edition, Order No RD-09-118/10.03.1997 - the third edition). Three volumes of Bulgarian Pharmacopoeia were issued during the period 1994-1999 and the prevailing part of them represent an adapted translation of the European Pharmacopoeia. Bulgaria has been an observer in the European Pharmacopoeia since 22.01.1992. The necessary preparation for accession to Convention 50 of the Council of Europe was completed. The membership of Bulgaria in the European Pharmacopoeia is forthcoming.

Marketing authorisation

The requirements of the Directives 65/65/EEC and 75/319/EEC, and Directive 89/342/EEC relating to vaccines, toxins, serums and allergens, Directive 89/381/EEC relating to medicinal products derived from human blood and plasma and Directive 92/73/EEC relating to homeopathic medicinal products are implemented with high degree of compatibility in the national legislation.

After the amendments to the Law marketing authorisation is delivered in 7 months if all necessary information is presented. The authorisation is valid for 5 years and possibility for renewal is provided.

Testing

The basic provisions of Directive 75/318/EEC are included in Chapter III of LMPHM and in Ordinance on requirements for documentation for marketing authorisation. The required data from the analytical, pharmaco-toxicological and clinical testing, that must be presented for marketing authorisation are described in the annexes of the Ordinance. They are in full compliance with the requirements of Directive 75/318/EEC concerning the testing of medicinal products.

Ordinance No 14/31.07.2000 of the Ministry of Health on the conditions and the order for conducting clinical trails with medicines on human beings has been adopted in July 2000 (SG No 73/05.09.2000). This new Ordinance expands the scope of the previous one by inclusion of a new chapter “Control of the Clinical Trials”, which determines the conditions for the inspections as well as for keeping the Register of clinical trials and publishing of standard procedures. Ordinance No 14 provides also Guidelines for Good Clinical Practice.

Prices and price control

The main provisions of Directive 89/105/EEC are implemented in Bulgarian legislation According to Chapter IX of LMPHM the State regulates the prices of medicinal products on the national market. With Decree No 130/13.07.2000 the Council of Ministers adopted Ordinance on ceiling prices of medicinal products authorised for placing on the market (SG No 59/21.07.2000), which replaced the Ordinance on prices of medicinal products (adopted with Decree No 208/1995). Drug Price Commission under the Ministry of Health has been established. With Decision of Council of Ministers Transparency Commission has been set up for approving and control on the lists of medicinal products fully or partially reimbursed by the state budget or the National Health Insurance Fund. The Drug Price Commission accepts the ceiling prices and Minister of Health approves

them. After that they are registered and published in a catalogue issued by the Ministry of Health.

Manufacturing

The requirements of Directive 91/356/EEC in respect of quality management, personnel, premises and equipment, documentation, manufacturing, quality control, analysis and self-inspections, connected with the manufacture authorisation, are transposed by Chapter Two of the LMPHM and the GMP Guidelines, issued by the National Institute for Medical Products in 1999.

For the purpose of issuing certificates according to Certification scheme of WHO, EAM inspects every 12 months the manufacturers. Inspections to ascertain the conformity of manufacture conditions with the requirements of GMP precede every change in the manufacture authorisation (change of equipment, testing laboratories, introducing of new products, etc.)

Distribution

The provisions of the national legislation related to the wholesale distribution of medicines are to a great extent in compliance with the requirements of Directive 92/25/EEC.

Two types of licenses still exist: full license and partial license. Suppliers trading with medicinal products from all pharmacological groups obtain full license. Availability of a minimum 100 sq. m. storage is required for these suppliers. Availability of a minimum 35 sq. m. storage is required for obtaining partial license.

Classification

Ordinance No 12/14.07.2000 of the Ministry of Health on the conditions and order for classification of medicinal products, which are subject or not subject to medical prescription was adopted on the basis of article 27b of LMPHM. The ordinance transposes into Bulgarian legislation the Directive 92/26/EEC. It requires homeopathic products to be subject to medical prescription as there is no enough experience in their usage in Bulgaria. The Ordinance provides the criteria for the classification of medicinal products. The Minister of Health issues the list of medicines, which are not subject to medical proscription.

Labelling

According to article 4(3) of the LMPHM the Minister of Health specifies the mandatory data on the packaging and leaflets of medicinal products. In June 2000 was adopted Ordinance No 7/22.06.2000 of the Ministry of Health (SG No 54/04.07.2000) which replaced Ordinance No 24/1995. Ordinance No 7 transposes into Bulgarian legislation Directive 92/27/EEC. It requires the necessary information to be provided also in Bulgarian. Data related to the reimbursement of medicines is not required so far. The required information on the packaging and leaflets is in full compliance with the provisions of the directive.

Advertising

Chapter X of the LMPHM and Ordinance No 13/14.07.2000 of the Ministry of Health on the conditions and order for approving of advertising of the medicinal products (S.G. No 59/21.07.2000) are in full compliance with Directive 92/28/EEC. Ordinance No 13/2000 replaced Ordinance 21/1995.

Colouring matters

The use of colouring matters in the manufacture of medicinal products is not yet regulated by the Bulgarian legislation. There is only a list of permitted colouring matters, issued by EAM. This list is based on Annex IV of Directive 94/36/EEC for colouring matters used in foodstuffs.

Medicines for veterinary use

In 1999 the new Veterinary Law was adopted, which replaced the Veterinary Law from 1967. Chapter 9 of the law now in force lays down the basic principles and requirements related to registration, manufacturing, storage and distribution of veterinary medicinal products (VMP). The Law introduces the legal framework of the institutional infrastructure responsible for its implementation. The National Veterinary Service is responsible for issuing manufacture authorisation, marketing authorisation and wholesale licenses for VMP. The control on these activities is carried out by the Institute on control of VMP (a specialised body within the National Veterinary Service) and by the regional veterinary services which carry out the control on the premises, equipment and conditions for storage and distribution of VMP.

The implementing regulations under the Veterinary Law are to a great extent in compliance with the acquis.

By the end of 2000 the Draft law amending and supplementing the Veterinary Law will be elaborated aiming at achieving higher level of compliance with the acquis.

Ordinance No 13 of the Ministry of Agriculture on the registration of veterinary medicinal products transposes to a great extent the provisions of Directives 81/851/EEC and 81/852/EEC. The National Veterinary Service delivers the marketing authorisation for VMP. The required data and the procedure for granting marketing authorisation are in compliance with Directives 81/851/EEC and 81/852/EEC. The authorisation is valid for a period of 5 years and possibility for renewal is provided. The term for accomplishing the authorisation procedure is 1 year.

The changes in the Veterinary Law will bring the term for the authorisation procedure for VMP in compliance with the acquis.

By the end of 2001 amendments in the Ordinance are envisaged aiming to transpose the requirements for examination of variations to the terms of marketing authorisation in compliance with Regulation 541/95.

Ordinance No 20 of the Ministry of Agriculture on the manufacturing authorisation for veterinary medicinal products transposes into Bulgarian legislation the basic requirements of chapter 5 of the Directive 81/851/EEC and the requirements of Directive 91/412/EEC concerning the qualification of personnel, the premises and equipment, the

documentation and quality control at different stages of the production process. The National Veterinary Service grants the manufacturing authorisation within 120 days. The time limit for granting manufacturing authorisation in the case of changes in the manufacturing (premises, equipment etc.) is 2 months. These terms will be changed in compliance with the acquis after the adoption of the amendments to the Law.

Ordinance No 23 of the Ministry of Agriculture on the terms and conditions for wholesale distribution of VMP implements the basic principles and requirements of chapter VIIIa of Directive 81/851/EEC.

Ordinance No 21 of the Ministry of Agriculture on the requirements for usage of homeopathic medicines for veterinary use is in full compliance with Directive 92/74/EEC.

Cosmetics

The current Bulgarian legislation in the area of cosmetics is partially in compliance with the acquis. The major part of the requirements of Directive76/768/EEC, concerning the definition of cosmetic product, categories of cosmetic products, labelling, permitted and prohibited ingredients are implemented in Bulgarian legislation. According to the Law on Public Health, the Regulation on its implementation, Ordinance No 34/01.09.1995 of Ministry of Health concerning hygiene requirements to cosmetic products and Ordinance No 27/17.08.1995 of Ministry of Health relating to the import of goods essential for public health, cosmetic products are subject to pre-market control. That is not in compliance with the acquis.

The new Ordinance on requirements to cosmetic products transposing the provisions of Directives 76/768/EEC, 95/17/EC and 97/18/EC will be adopted by the end of the year 2000 and will enter into force eighteen mounts latter. During this period as Instructions to this Ordinance will be implemented Directives 80/1335/EEC, 82/434/EEC, 83/514/EEC, 85/490/EEC, 93/73/EEC, 95/32/EC and 96/45/EC relating to methods for analysis necessary for checking the composition of cosmetic products, as well as Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (INCI)**.** With the adoption of new Law on Public Health non-conformity with the acquis concerning pre-market control of cosmetic products will be abolished.

The Guidelines for Good Manufacturing Practice in the field of cosmetic products will be issued.

The relevant infrastructure necessary for control of cosmetic products is established and functioning - Ministry of Health and 28 regional hygiene-epidemiological inspections. In order to achieve more effective control additional equipment for laboratories and staff training are needed.

Legal metrology and pre-packaging

Legal metrology

The Law on Measurements implements the requirements of Directive 80/181/EEC. According to this Law the SI units of quantities are mandatory.

In compliance with the Law on Technical Requirements to Products an Ordinance transposing Directive 90/384/EEC will be adopted till 01.01.2001. The Draft Ordinance envisages that it shall enter into force two years after its promulgation.

A new Law on Measurements, transposing the Old Approach Directives in this field, will be adopted in the year 2001.

There are 2 competent bodies in the field of non-automatic weighing instruments and other measuring instruments that are subject to mandatory control according to the Law on Measurements: General Directorate "National Center for Metrology" - for type approval and General Directorate "Measures and Measuring Instruments" - for verification.

Pre-packaging

The harmonisation of the legislation in the field of pre-packaging will be achieved in the year 2001 after the adoption of new Law on Measurements and the implementing regulations under it.

Electrical risk and electrical equipment

Low voltage

Ordinance on the essential requirements and conformity assessment of electrical equipment designed for use within certain voltage limits, transposing Directive 73/23/EEC will be adopted according to the Law on Technical Requirements to Products till 30.11.2000. The Ordinance will enter into force on 01.01.2002. All harmonised standards related to Directive 73/23/EEC will be introduced by the end of the year 2001.

Within the scope of the Low Voltage Directive there are several testing laboratories, and three of them are preparing to obtain joint accreditation by both the Executive Agency "Bulgarian Accreditation Service" and RvA (The Netherlands).

Electromagnetic compatibility

The operating legislation is based on the Law on Telecommunications (SG 93/11.08.1998). The requirements concerning telecommunication equipment are in compliance with the requirements to such equipment provided for in Directive 89/336/EEC. By the end of the year 2000 the Law on Telecommunications will be amendment to remove duplications and contradictions with the Law on Technical Requirements to Products. As a result of this the transposition of Directive 89/336/EEC will be achieved in compliance with the Law on Technical Requirements to Products. Full compliance with the acquis concerning the scope and requirements of Directive 89/336/EEC will be achieved with the adoption of the Ordinance on EMC under the Law

on Technical Requirements to Products. The Draft Ordinance is prepared and in process of inter-service consultations. The Ordinance will enter into force in 2002.

Explosive atmospheres

An Ordinance transposing Directive 94/9/EC will be adopted in accordance with the Law on Technical Requirements to Products. The Ordinance on essential requirements and conformity assessment of equipment and protective systems intended for use in potentially explosive atmosphere has already been drafted and should be finalised till 31.12.2000. The Ordinance will enter into force on 01.07.2003.

Now operating Directives, 76/117/EEC, 79/196/EEC and 82/130/EEC concerning the equipment intended for use in potentially explosive atmosphere, are Old Approach Directives. They will be repealed as from 01.07.2003 when the transitional period of Directive 94/9/EC expires. For this reason Directives 76/117/EEC, 79/196/EEC and 82/130/EEC shall not be transposed in the Bulgarian legislation.

Telecommunications equipment

In the operating Bulgarian legislation the requirements to radio equipment and telecommunications terminal equipment are defined in Section II of the Chapter V "Activities of the State Commission on Telecommunications", Chapter VIII "Terminal equipment and electromagnetic compatibility" of the Law on Telecommunications (SG 93/11.08.1998) and Ordinance No 5/24.01.2000 of the Committee for Posts and Telecommunications on Conformity Assessment of Radio Equipment and Telecommunications Terminal Equipment and their Connection to the Public Telecommunications Network (SG 9/01.02.2000). The present Bulgarian legislation is partly in compliance with the Directive 98/13/EC on Terminal telecommunications equipment. By the end of the year 2000 the Law on Telecommunications will be amendment to remove duplications and contradictions with the Law on Technical Requirements to Products.

Under the Law on Technical Requirements to Products an Ordinance transposing Directive 99/5/EC on Radio equipment and telecommunications terminal equipment and mutual recognition of their compliance will be adopted till 31.03.2001. The Ordinance will enter into force in the year 2002.

Toys

Regarding toys two Ordinances are applied at the moment: Ordinance No3/1988 of the Ministry of Health on hygiene requirements to toys (SG 25/01.04.1988) and Ordinance No 27/17.08.1995 of the Ministry of Health relating to the import of goods essential for public health (SG 75/25.08.1995).

In accordance with the Law on Technical Requirements to Products a final Draft of Ordinance on the essential requirements and conformity assessment of toys which is in full compliance with Directive 88/378/EEC has been elaborated. The Ordinance will be adopted by the Council of Ministers and published by the end of the year 2000. The Draft Ordinance envisages that it will enter into force 1 year after the date of publication.

Mechanical devices

Machinery

The Ordinance under the Law on Technical Requirements to Products transposing Directive 98/37/EC on machinery will be elaborated till 31.01.2001 and adopted till 30.04.2001.

Lifts

In accordance with the Law on Technical Requirements to Products a Draft Ordinance on the essential requirements and conformity assessment of lifts, transposing Directive 95/16/EC has been elaborated. The Ordinance will be adopted in the year 2001.

Personal protective equipment

In accordance with the Law on Technical Requirements to Products an Ordinance on the essential requirements and conformity assessment of personal protective equipment, transposing Directive 89/686/EEC on the personal protective equipment, will be adopted till 30.04.2001. A draft of the Ordinance is developed and its final version will be ready till December 2000. The Draft Ordinance envisages that it shall come in force 1 year after its publication.

Medical devices

At present the Law on Medicines and Pharmacies in Human Medicine is in force in the Republic of Bulgaria. According this law (article 3, paragraph 5) medical devices are considered as medicinal products and are subject to marketing authorisation. For this reason Bulgarian legislation relating to medical devices is not in conformity with Directives 90/385/EEC, 93/42/EEC and 98/79/EEC. Ordinance relating to marketing authorisation of medical products under Article 3, Paragraph 3 and Paragraph 5 of the Law on Medical Products and Pharmacies in Human Medicine was adopted in September 2000. The definitions of medical devices, in vitro diagnostic medical devices, devices for self-testing and active implantable devices, and the classification are in compliance with the above-mentioned directives. Medical devices with CE marking are subject to a simplified procedure.

A detailed plan for harmonisation of the Bulgarian legislation in this field with the acquis is in process of preparation. It should be finalised till mid 2001.

The harmonisation of the Bulgarian legislation with the acquis in the field of medical devices will be accomplished till 2005.

Appliances burning gaseous fuels

In compliance with the Law on Technical Requirements to Products with Decree No 174/31.08.2000 the Council of Ministers adopted Ordinance on essential requirements and conformity assessment of gas appliances (SG 75/12.09.2000), transposing Directive 90/396/EEC. The Ordinance enters into force 9 months after its publication - on 13.06.2001.

Pressure vessels

Directive 87/404/EEC relating to simple pressure vessels and Directive 97/23/EEC concerning pressure equipment will be transposed in compliance with the Law on Technical Requirements to Products by Ordinances adopted with Council of Ministers' Decrees. The deadline for the adoption of these Ordinances is 30.04.2001. They will come into force in 2002.

Directives 75/324/EEC on aerosol dispensers, 76/767/EEC on common provisions for pressure vessels and methods for inspecting them, 84/525/EEC, 84/526/EEC and 84/527/EEC on gas cylinders will be introduced in the Bulgarian legislation till 2003.

Construction products

On the base of the Law on Technical Requirements to Products, with Decree No 230/06.11.2000 the Council of Ministers adopted Ordinance on the essential requirements and conformity assessment of construction products (SG 93/14.11.2000), transposing Directive 89/106/EEC. The Ordinance takes account also of the Commission Decisions and Guidelines connected with the implementation of Directive 89/106/EEC.

Recreational craft

Under the Law on Technical Requirements to Products Ordinance on essential requirements and conformity assessment of recreational craft, transposing Directive 94/25/EC will be adopted till 31.01.2001. The Ordinance will come into force by the end of 2002.

Glass

In accordance with the Law on Consumer Protection and Rules for Trade, an Ordinance on labelling of crystal glass articles, transposing Directive 69/493/EEC will be adopted till the end of 2000. The Ordinance will enter into force on 01.07.2001. The Commission for Trade and Consumer Protection will be responsible for market surveillance.

Textiles

In accordance with the Law on Consumer Protection and Rules for Trade, an Ordinance on labelling of textile products will be adopted. The Ordinance will transpose Directive 96/74/EC on textile names and Directives 96/73/EC and 73/44/EEC on the quantitative analysis of textile fibre mixtures. The Ordinance will be adopted till 31.03.2001. The Commission for Trade and Consumer Protection will be responsible for market surveillance.

Footwear

In accordance with the Law on Consumer Protection and Rules for Trade, an Ordinance on labelling of the materials, used in the main components of footwear, will be adopted. The Ordinance will transpose Directive 94/11/EEC. The Ordinance will be adopted till the end of 2000 and will entry into force until 01.07.2001. The Commission for Trade and Consumer Protection will be responsible for market surveillance.

Horizontal and procedural measures, including New and Global Approach

New and Global Approach

The Law on Technical Requirements to Products (SG 86/1.10.1999) is a horizontal framework for transposition of the New Approach Directives into the national legislation. The Law introduces into the national legislation the principles of the New Approach to technical regulation and the Global Approach to conformity assessment. A presumption of conformity with the essential requirements in case of conformity with the harmonised standards to the New Approach Directives is envisaged. The Law provides for conformity marking, as a proof that a product is in conformity with the essential requirements and has been subject to the relevant conformity assessment procedure.

With Decree 164/03.08.2000 the Council of Ministers adopted the Ordinance on conformity marking (SG 66/11.08.2000), which determines the graphic symbol and rules for affixing the conformity marking "Co". The rules for affixing the "Co" marking are equivalent of the rules for affixing the CE marking.

The State Agency for Standardisation and Metrology is responsible for market surveillance within the scope of the Law on technical requirements to products.

Amendments to the Law on technical requirements to products have been drafted. They aim at abolishing the contradictions between Chapter V and Chapter III of the law concerning high-risk equipment and supplementing the provisions concerning market surveillance. After the adoption of the amendments to the law Ordinance on market surveillance will be adopted.

With the adoption of several Ordinance transposing some of the new approach directives the process of establishing the necessary implementing bodies has started and Bulgaria will undertake steps to start negotiations for concluding Protocol on European Conformity Assessment (PECA).

The segregation of standardisation and certification functions managed by the State Agency for Standardisation and Metrology will be accomplished till December 2001.

Functional independence between technical regulation, standardisation, accreditation and certification (including testing and control) has been established through the Law on National Standardisation, the Law on Technical Requirements to Products and Council of Ministers' Decree 270/30.12.1999 on restructuring of the Bulgarian Accreditation Service within the Committee for Standardisation and Metrology into Executive Agency "Bulgarian Accreditation Service"(SG 13/15.02.2000).

The Executive Agency "Bulgarian Accreditation Service" to the Minister of Economy is an independent national accreditation body. Accreditation Council with 21 members has been established under the Executive Agency "Bulgarian Accreditation Service". Ministries, certification bodies, laboratories, industry and consumers' organisations are represented in the Accreditation Council. The Executive Agency "Bulgarian Accreditation Service" is a national body for accreditation of:

- testing and/or calibration laboratories;

- legal persons (bodies) for certification of products, quality systems, environment management systems and personnel;
- inspection bodies.

All accreditation procedures are in compliance with EN 45000 standards.

Executive Agency "Bulgarian Accreditation Service" applied for membership in EA on 03.10.2000. Practically the process of integration in EA started in November 1999 when the first assessment according the“30 steps approach” was carried out. The results of the second assessment (25-27 October 2000) will be available soon.

Standardisation

The Law on National Standardisation (SG 55/18.06.1999) which entered into force on 18 September 1999 has established the legal basis for transition from mandatory to voluntary standards. It regulates the activities concerning elaboration, approval, publication and distribution of Bulgarian standards and designates the State Agency for Standardisation and Metrology as a national standardisation body.

National Consultative Council on standardisation has been established. This Council is structured so as to ensure balance of interests of all parties concerned. Industry, science, consumers and administration are represented in the Council.

The SASM represents the Republic of Bulgaria in the European and international organisations for standardisation. The Republic of Bulgarian is a full member of the international organisations for standardisation ISO and IEC. Bulgaria participates in the activities of ISO technical committees and sub-committees. The SASM is an affiliated member of CEN/CENELEC.

With the adoption of amendments to the Law on National Standardisation legal status of the national standardisation body will be changed and a non-profit organisation will be established.

Notification procedure

Following the obligations of the Republic of Bulgaria as a member of the World Trade Organisation and notably the Agreement on Technical Barriers to Trade, National Enquiry Point has been set up within the State Agency for Standardisation and Metrology. The practical implementation of Directive 98/34/EC will be possible only after Bulgaria is included in the EU notification system.

Public procurement

The Law on Public Procurement was adopted in 1999 (SG 56/22.06.1999) and transposed the basic principles of Directives 92/50/EEC, 93/36/EEC, 93/37/EEC and 93/38/EEC.

As provided by article 7(4) of the Law on Public Procurement, with Council of Ministers' Decree No 59/24.04.2000 Ordinance on Public Procurement below the thresholds (SG 36/02.05.2000) was adopted. The Ordinance provides for facilitated and accelerated procedures following the principles of the Law on Public Procurement. It envisages the following procedures: open procedure, restricted procedure, design contest and negotiated procedure.

Ordinance on Public Procurement Register was adopted in October 2000. The ordinance establishes the rules for keeping, maintaining and using the Register. The Register is a unified electronic database accessible for the public including on the Internet site of the Government. The Public Procurement Directorate within the Council of Ministers' administration is responsible for keeping the Register.

The Law on Public Procurement establishes the necessary institutional mechanism by entrusting certain functions to the Minister of state administration and the Public Procurement Directorate within the Council of Ministers' administration.

Public Procurement Directorate within the Council of Ministers' administration assists the Minister of state administration in performing the following functions: provides methodological instructions on the implementation of the law; organises training of experts in the field of public procurement; informs the competent authorities (National Audit Office and State Financial Control) in respect of offences in procedures for entrustment or other provisions of the law.

Non-harmonised areas

Articles 28-30 of the Treaty

Republic of Bulgaria does not impose any quantitative restrictions or measures having equivalent effect within the meaning of Articles 28-29 of the Treaty. The existing restrictions on import and export of goods can be justified on the basis of Article 30 of the Treaty.

Information and co-operation mechanisms: Regulation 2679/98, Decision 3052/95 and Regulation 339/93

Notwithstanding that mechanisms for information exchange and co-operation could be effectively implemented only after the accession to the EU, the strengthening of the administrative capacity for the implementation of these mechanisms has already started.

Bulgarian legislation will be adjusted accordingly to transpose Decision 3052/95 and to define responsible authority.

Cooperation between customs authorities and market surveillance bodies although not formally regulated is practically operational. The national legislation will be supplemented in order to include legal obligations for the customs authorities compatible with the provisions of Regulation 339/93.

Directive 93/7/EEC on the return of cultural goods

The Law on museums (presently at second hearing in the Nation assembly) will be adopted in the first half of 2001. The law will give the legal basis for adoption of an ordinance, transposing the Directive 93/7/EEC.

Directive 91/477/EEC on control of the acquisition and possession of weapons

The existing Bulgarian legislation (the Law on explosives, arms and ammunitions control and the Regulation on its application) is to a great extant in conformity with Directive

91/477/EEC. After a detailed analysis the necessary amendments will be adopted to achieve full conformity with the acquis.

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The Government of the Republic of Bulgaria is proposing that the negotiations in this chapter should be temporary closed on the basis of the existing EU legislation.

Bulgaria is ready to open additional negotiations before the end of the Intergovernmental Conference, if a necessity for this emerges on account of the adoption of new EU legislation.