

## Free Movement of Goods

### Priorities of the 2006-2009 National Programme Chapter on Free Movement of Goods

The need for defining priorities in the area of free movement of goods stems from the impossibility of accomplishing full compliance with the EU's extensive legislation in this area in 3 years as well as the objectives and structure of relevant legislation, which may themselves serve as a basis for selection of priorities.

The key objective of the legislation on free movement of goods is to establish uniform requirements for products which serve as a basis for unimpeded import, export and marketing of these products in countries that have introduced this legislation.

The legislation on free movement of goods comprises three components: harmonised (new approach, old approach and global approach) legislation, non-harmonised legislation and public procurement legislation.

The key guiding factors in defining priorities in the area of free movement of goods are as follows:

- Production of a given product in Armenia or export of a given product from Armenia (priority is given to products with significant contribution to the exports structure of Armenia);
- The impact of qualitative characteristics of a given product on human health (impact on the environment as it relates to the cost implications and availability of devices, equipment and products in use has not been considered as a priority in the current stage of approximation with the EU legislation);
- Amount and availability of resources needed for accomplishing legislative compliance;
- Potential impact of legislative approximation on the economic development of the country.

Taking into account the volume of legislation involved, potential impact and consequences for the Armenian economy, priorities have been defined only for the harmonised framework.

Specifically, the following sections of the harmonized framework have not been included in the first National Programme:

- Motor vehicles and their trailers, two- or three-wheeled vehicles, tractors and other technical standards relating to motor vehicles (Subchapters 1.1 – 1.4), which are not produced in Armenia currently. Furthermore, immediate application of EU's strict safety and environmental standards on vehicles in use or imported vehicles may have an adverse effect on the further economic development of the country.
- Legislation on the preparation of individual food products, Subchapter 1.5.5. (mainly imported foodstuffs), Subchapter 1.5.9. on food hygiene (cost implications and potential adverse effect on the development of agriculture and food industry)
- Certain sections relating to production equipment, i.e. subchapters 1.12, 1.13, 1.15 (limited volume of exports and cost implications of ensuring compliance of devices and equipment in use as well as the potential negative impact on the development of industry)

## 1. Free Movement of Foodstuffs

### Introduction

The EU legislation on free movement of goods includes Directives of the old approach<sup>1</sup> framework and covers legislation governing the preparation, presentation and labelling of foodstuffs, food hygiene and contamination, as well as the environment.

In view of the 2006-2009 priorities provided in the Chapter on Free Movement of Goods, under the current National Programme Armenia's national legislation shall not be approximated with the EU legislation on the preparation and hygiene of individual food products.

The legal framework governing the food sector in Armenia includes the Armenian law on "Food Safety"<sup>2</sup>, Health Ministry Decree No. 181 "On Approving Hygiene Requirements, Sanitary Rules and Hygienic Norms N 2-III-4.9-01-2003 for Foodstuffs and Food Safety and Nutritional Value"<sup>3</sup>, Health Ministry Decree No. 961 "On Approving the Shelf-Life Expiry Dates and Conditions, Sanitary Rules and Hygienic Norms N2-III-4.4-1 Particularly for Perishable Food Products"<sup>4</sup> and other secondary legislation defining general requirements for food hygiene, safety and labelling during production, import, export, storage and marketing; sanitary requirements for foodstuffs and food safety as well as nutritional value; shelf-life expiry dates and conditions applying particularly to perishable foodstuffs, as well as provisions on laboratory testing of food products, which, however, are of general nature and mostly do not conform to the EU requirements.

In the area of free movement of goods, Armenia lacks legislation on certain additives used in food products to meet the standards of food purity, food labelling, presentation and advertising, quick-frozen meals, processing produce and foodstuffs through ionising radiation and other areas.

Moreover, the Armenian legislation does not provide for sanitary requirements for the ingredients used in the production of quick-frozen food products, and devices<sup>5</sup> used for their preparation, transportation, storage and handling.

### Y2006

In order to set a maximum permitted level of radioactive contamination in foodstuffs, a draft law on the maximum permitted level of radioactive contamination in foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency shall be elaborated.

### Y2007

In an effort to regulate the importation of agricultural products from third countries after the Chernobyl disaster, a draft law shall be elaborated on approving the procedure for importing of agricultural products originating in third countries following the accident at the Chernobyl nuclear power plant.

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<sup>1</sup> Measures for technical harmonisation under the old approach are based on peculiarities of the specific product and contain details peculiar to them, unlike the new approach which is based on the approaches of general nature for conformity assessment (impact on health and safety)

<sup>2</sup> Armenian Law (HO)-25, 108.12.1999

<sup>3</sup> RoA JAPLA (Journal of Agency Prudential Legal Acts) 2003 / 11.1, 12.05.2003, article 203, 2.28.2003

<sup>4</sup> RA JAPLA 2002 / 3(89), 11.02.2002, article 204, 12. 28.2001

Order of the Minister of Health No. 581-N of 1 June 2004 on Approving hygiene requirements N 2-III-4.3-04-2003 sanitary rules and hygiene norms for retail food trade organisations" as well as similar norms in the Order of the Minister of Health No. 845 of 17 December 2002 on Approving hygiene requirements N 2-III-4.4-1, sanitary norms for wholesale food trade organisations are defined in regard to frozen but not for quick-frozen food.

To ensure improved health and safety for the population, especially children, a draft law on the identification of other products hazardous to consumer health and safety shall be elaborated.

**Y2008**

To ensure improved health and safety for the population, especially children, a draft law on food products and food ingredients treated with ionising radiation shall be elaborated.

In view of the need to regulate food additives, cereal-based foods and baby foods for infants and young children, draft laws shall be elaborated on additives authorised for use in foodstuffs, processed cereal –based foods and baby foods for infants and young children.

To introduce a modern system of bovine accounting ( identification and registration) in Armenia, as well as to establish a single system of labelling of beef (cow and bull meat) and beef products, a draft Government decree on establishing a system for the identification and registration of bovine animals shall be elaborated.

**Y2009**

Although the legislation of Armenia sets forth general provisions aimed at safeguarding commercial secrets (e.g. Article 33 of the Armenian Law “On Protection of Economic Competition”), however, in order to ensure the confidentiality of product-related information of food-producers by state bodies, a draft Government decree on establishing the procedure for the disclosure of information and protection of provided information relating to production processes in food production shall be elaborated.

In view of the need to regulate and establish requirements for dietary and weight-reduction foodstuffs and their labelling, quick-frozen food products, exports of foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency, draft laws on quick-frozen food products intended for human consumption, food-products for energy-restricted diets, dietary food labelling, and on establishing special requirements for export of foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency shall be elaborated.

1.1. Legislative Approximation

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2006</b>						
1.	Elaboration of a relevant draft legal act on maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency	<p>Council Regulation (Euratom) No. 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency</p> <p>Commission Regulation (Euratom) No. 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency</p>	Relevant body authorized by the Government of Armenia	4 <sup>th</sup> quarter	15	Consultancy, provisional expertise
<b>TOTAL</b>					<b>15</b>	

2007						
2.	Elaboration of a relevant draft legal act on Approving the procedure for imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station	<p>Council Regulation (EEC) No. 737/90 of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station</p> <p>Commission Regulation (EC) No. 1609/2000 of 24 July 2000 establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station</p>	Relevant body authorized by the Government of Armenia	1 <sup>st</sup> quarter	15	Consultancy, provisional expertise
3.	Elaboration of a relevant draft legal act on Products which, appearing to be other than they are, endanger the health or	Council Directive No. 87/357/EEC of 25 June 1987 on the approximation of the	Relevant body authorized by the Government of Armenia	4 <sup>th</sup> quarter	15	Consultancy, provisional expertise

	safety of consumers	laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers				
<b>TOTAL</b>					<b>30</b>	
<b>2008</b>						
4.	Elaboration of a relevant draft legal act on Foods and food ingredients treated with ionising radiation	<p>Directive No. 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation</p> <p>Directive No. 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation</p>	Relevant body authorized by the Government of Armenia	1 <sup>st</sup> quarter	28	Consultancy, provisional expertise

5.	Elaboration of a relevant draft legal act on Processed cereal-based foods and baby foods for infants and young children	Commission Regulation No. 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children	Relevant body authorized by the Government of Armenia	3 <sup>rd</sup> quarter	24	Consultancy, provisional expertise
6.	Elaboration of a draft decree of the Government of Armenia on the Establishment of a system for the identification and registration of bovine animals	Regulation (EC) No. 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products	Ministry of Agriculture of Armenia	3 <sup>rd</sup> quarter	37	Consultancy, provisional expertise
7.	Elaboration of a relevant draft legal act on food additives authorized for use in foodstuffs intended for human consumption	Council Directive No. 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption	Relevant body authorized by the Government of Armenia	3 <sup>rd</sup> quarter	127	Consultancy, provisional expertise

	<p>First Commission Directive No. 81/712/EEC of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity</p> <p>Directive No. 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs</p> <p>Council Directive No. 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs</p> <p>Council Decision No. 88/389/EEC of 22 June 1988 on the establishment, by the Commission, of an inventory of the source materials and substances used in the</p>				
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		<p>preparation of flavourings.</p> <p>Directive No. 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners</p> <p>European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs</p> <p>Directive No. 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs</p> <p>Council Directive No. 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for</p>				
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		<p>their production</p> <p>Regulation (EC) No. 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs</p>				
<b>TOTAL</b>					<b>216</b>	
<b>2009</b>						
8.	Elaboration of a relevant draft legal act on Quick-frozen foodstuffs for human consumption	<p>Council Directive No. 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption</p> <p>Commission Directive No. 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen</p>	Relevant body authorized by the Government of Armenia	1 <sup>st</sup> quarter	15	Consultancy, provisional expertise

		foodstuffs intended for human consumption				
9.	Elaboration of a relevant draft legal act on Approving the procedure for the disclosure of information and the protection of provided information relating to production process in food production	Commission Regulation (EC) No. 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97	Relevant body authorized by the Government of Armenia	1 <sup>st</sup> quarter	15	Consultancy, provisional expertise
10.	Elaboration of a relevant draft legal act on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency	Council Regulation (EEC) No. 2219/89 of 18 July 1989 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency	Relevant body authorized by the Government of Armenia	1 <sup>st</sup> quarter	15	Consultancy, provisional expertise
11.	Elaboration of a relevant draft legal act on foods intended for	Commission Directive No. 96/8/EC of 26	Relevant body authorized by the	2 <sup>nd</sup> quarter	15	Consultancy, provisional expertise

	use in energy-restricted diets for weight reduction	February 1996 on foods intended for use in energy-restricted diets for weight reduction	Government of Armenia			
12.	Elaboration of a draft Government Decree on Nutrition labelling for foodstuffs	Council Directive No. 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs	Ministry of Health of Armenia	2 <sup>nd</sup> quarter	19	Consultancy, provisional expertise
<b>TOTAL</b>					<b>79</b>	
<b>TOTAL</b>					<b>340</b>	

**1.2. Institutional Capacities**<sup>6</sup>

0	1	2	3	4
NN	Institution	Reorganization	Training Needs	Technical Assistance Needs
1.	RoA Ministry of Healthcare RoA Ministry of Agriculture RoA Ministry of Nature Protection State Customs Committee under the Government of Armenia RoA Rescue Service	-	Course on foodstuff and feedingstuffs following a nuclear accident in the EU  (3 days/2006)	Consultancy, provisional expertise
2.	RoA Ministry of Trade and Economic Development	-	Course on the control of products which, appearing to be other than they are, endanger the health or safety of consumers (3 days/2007)	Consultancy, provisional expertise
3.	RoA Ministry of Healthcare RoA Ministry of Agriculture	-	Course on foods treated with ionising radiation (3 days/2008)	Consultancy, provisional expertise
4.	Relevant body authorized by the Government of Armenia	Establishment of a Food Safety Authority	Course on the control of foods for infants in the EU (3 days/2008)	Consultancy, provisional expertise

<sup>6</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions shall be established within the responsible ministries and state agencies mentioned in this subchapter

		(3 <sup>rd</sup> quarter, 2007)		
5.	RoA Ministry of Agriculture	Establishment of a Division for Identification and Registration of Bovine Animals (2008)	Course on the system for identification and registration of bovine animals in the EU (3 days/2008)	Consultancy, provisional expertise
6.	RoA Ministry of Healthcare RoA Ministry of Agriculture	-	Course on additives used in foodstuffs (5 days/2008)	Consultancy, provisional expertise
7.	RoA Ministry of Healthcare RoA Ministry of Agriculture	-	Course on quick-frozen foods intended for human consumption (3 days/2009)	Consultancy, provisional expertise
8.	RoA Ministry of Trade and Economic Development	-	Course on the disclosure of information related to production process in the EU (3 days/2009)	Consultancy, provisional expertise

## 2. Chemicals

### Introduction

The EU legislation on chemicals includes old approach framework<sup>7</sup> directives and regulates<sup>8</sup> issues relating to the classification, codification, packaging, labelling of hazardous substances and preparations, affixing special warning markings thereto, as well as methods and principles for the risk-assessment and oversight of hazardous materials.

The EU legislation governing this area is aimed at ensuring the free movement of chemical products within the Community and regulating matters related to the health and safety of people and animals, as well as environmental protection.

Although Armenia actively participates in the international processes related to chemical safety and has ratified a number of treaties and conventions, the relevant Armenian legislation is of general nature and is not sufficiently detailed; hence it is not complete and does not correspond to the EU legal framework.

In view of the distinctive characteristics of chemical products (closely interrelated with human health and safety and environmental impact), all EU legal acts covered by this subchapter are subject to approximation in 2006-2009.

### Y2006

In order to introduce good laboratory practices for chemical testing and control of the application of these practices<sup>9,10</sup>, a draft Government Decree “On Approving the procedure for application of universal methods of good laboratory practice for ruling out double inspections” shall be elaborated.

### Y2007

To protect the health and safety of workers from the risks related to chemical agents at work<sup>11</sup>, a draft Government Decree “On approval of the procedure for the protection of the health and safety of workers from risks related to chemical agents at work” shall be developed.

### Y2008

In order to establish requirements<sup>12,13</sup> for the classification, packaging and labelling of dangerous substances and preparations, as well as to regulate the exports and imports of

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<sup>7</sup> Measures for technical harmonization under the old approach are based on peculiarities of the specific product and contain details peculiar to them, unlike the new approach which is based on the approaches of general nature for conformity assessment (impact on health and safety)

<sup>8</sup> It should be noted that norms relating to chemical products are defined in the chapters of EU legislation on Nature Protection, on Consumers and Health Protection as well as in subchapter on foodstuff of the chapter on Free Movement of Goods, except for the chapter on Free Movement of Goods.

<sup>9</sup> Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

<sup>10</sup> Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)

<sup>11</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

<sup>12</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

dangerous chemical materials with view of protecting human and animal health and safety, as well as the environment, a draft Government Decree “On approving the procedure for classification, packaging and labelling of dangerous substances and preparations” shall be developed.

Based on the Regulation (EC) No. 304/2003<sup>14</sup> of the European Parliament and of the Council of 28 January 2003, amendments were made to the RoA Government Decree No. 171 “On Approving the Agrarian Rules of 3 February 1998. “

Armenia has signed the Rotterdam Convention on hazardous chemical substances and pesticides<sup>15</sup>, however, the national regulations for fulfilment of the commitments undertaken by this Convention have not been developed to this day<sup>16</sup>, and therefore a draft Government Decree “On the control of major-accident hazards involving dangerous substances” shall be developed.

### Y2009

The burden of proof for ensuring the safety of chemical products placed on the market in the EU currently rests with the manufacturers or importers of these products.

For regulation of the methods and principles of control and assessment of risks of dangerous materials<sup>17</sup>, application of restrictions thereto and defining of requirements for additional information and testing to be complied with by manufacturers and importers of primary materials, a draft Government Decree “On Approving the procedure for evaluation and control of the risks of certain substances and on the disclosure of information and testing” shall be developed.

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<sup>13</sup> Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

<sup>14</sup> Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals

<sup>15</sup> Council Decision No. 2003/106/EC of 19 December 2002 concerning the approval, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade

<sup>16</sup> Currently there exists a list of pesticides which are permitted to be used in Armenia approved by the Decree of the Government of Armenia

<sup>17</sup> Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances



**2.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2006</b>						
1.	Elaboration of a draft Government decree on the Approval of the procedure for applying universal methods of good laboratory practice for ruling out double inspections	<p>Directive No. 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)</p> <p>Directive No. 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances</p>	Ministry of Trade and Economic Development of Armenia	4 <sup>th</sup> quarter	32	Consultancy, provisional expertise
<b>TOTAL</b>					<b>32</b>	

<b>2007</b>						
2.	Decree of the Government of Armenia on the Approval of the procedure for the protection of the health and safety of workers from the risks related to chemical agents at work	Council Directive No. 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work	Ministry of Labour and Social Affairs of Armenia  (Ministry of Health of Armenia)	1 <sup>st</sup> quarter	41	Consultancy, provisional expertise
		<b>TOTAL</b>			41	
<b>2008</b>						
3.	Elaboration of a draft decree of the Government of Armenia on the Approval of the procedure for the classification, packaging and labelling of dangerous preparations	Directive No. 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations  Council Directive No. 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative	Ministry of Trade and Economic Development of Armenia	1 <sup>st</sup> quarter	107	Consultancy, provisional expertise

		provisions relating to the classification, packaging and labelling of dangerous substances				
4.	Elaboration of a draft decree of the Government of Armenia on Amendments to the Government Decree No. 171 of 3 February on the Approving of Agrarian Rules	Regulation (EC) No. 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals	Ministry of Agriculture of Armenia (State Customs Committee under the Government of Armenia)	1 <sup>st</sup> quarter	46	Consultancy, provisional expertise
5.	Elaboration of a draft decree of the Government of Armenia on the Control of major-accident hazards involving dangerous substances	Council Directive No. 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances  Commission Decision No. 98/433/EC of 26 June 1998 on harmonised criteria for dispensations according to Article 9 of Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (notified under document number C (1998)	Ministry of Nature Protection of Armenia  (Ministry of Trade and Economic Development of Armenia,  Rescue Service of Armenia)	2 <sup>nd</sup> quarter	60  Reorganisation of implementing body	Consultancy, provisional expertise

		1758)  Commission Decision No. 2002/605/EC of 17 July 2002 concerning the questionnaire relating to Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (notified under document number C(2002) 2656)				
<b>TOTAL</b>					<b>213</b>	
<b>2009</b>						
6.	Elaboration of a draft decree of the Government of Armenia on the Approval of the procedure for evaluation and control of the risks of existing substances and on the disclosure of information and testing	Council Regulation (EEC) No. 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances  Commission Regulation (EC) No. 2592/2001 of 28 December 2001 imposing further information and testing requirements on the manufacturers or importers of certain priority substances in	Ministry of Trade and Economic Development of Armenia  (Ministry of Nature Protection of Armenia)  (State Customs Committee of under the Government of Armenia)  (Ministry of Health of Armenia)	1 <sup>st</sup> quarter	58	Consultancy, provisional expertise

		<p>accordance with Council Regulation (EEC) No. 793/93 on the evaluation and control of the risk of existing substances</p> <p>Commission Regulation (EC) No. 2161/1999 of 12 October 1999 imposing further testing requirements on the importers or manufacturers of a certain priority substance as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances</p> <p>Commission Regulation (EC) No. 142/97 of 27 January 1997 concerning the delivery of information about certain existing substances as foreseen under Council Regulation (EEC) No.</p>				
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	793/93 Commission Regulation (EC) No. 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No. 793/93					
<b>TOTAL</b>					<b>58</b>	
<b>TOTAL</b>					<b>344</b>	

**2.2 Institutional Capacities<sup>18</sup>**

0	1	2	3	4
NN	Institution	Reorganization	Training Needs	Technical Assistance Needs
1.	RoA Ministry of Trade and Economic Development	-	Course on the universal principles for good laboratory practice in the EU (3 days/2006)	Consultancy, provisional expertise
2.	RoA Ministry of Labour and Social Affairs  RoA Ministry of Healthcare	-	Course on the protection of health and safety at work from the risks related to chemical agents in the EU (3 days/2007)	Consultancy, provisional expertise
3.	RoA Ministry of Trade and Economic Development  State Customs Committee under the Government of Armenia  RoA Ministry of Agriculture	-	Course on the classification, labelling and packaging of dangerous substances, chemicals and preparations in the EU (5 days/2008)	Consultancy, provisional expertise
4.	RoA Ministry of Nature Protection  RoA Ministry of Trade and Economic Development  RoA Rescue Service	Division for the control of major-accident hazards	Course on the control of major-accident hazards involving dangerous substances (3 days/2008)	Consultancy, provisional expertise

<sup>18</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

5.	RoA Ministry of Nature Protection RoA Ministry of Trade and Economic Development State Customs Committee of under the Government of Armenia	-	Course on evaluation and control of the risks of existing substances and on the disclosure of information and testing (3 days/2009)	Consultancy, provisional expertise
6.	RoA Ministry of Healthcare RoA Ministry of Nature Protection	Establishment of Risks Evaluation Division	Course on the methods for the assessment of risks to man and the environment of existing substances (3 days/2009)	Consultancy, provisional expertise



### **3. Pharmaceutical products**

#### **Introduction**

The EU legislation on pharmaceutical products belongs to the old approach<sup>19</sup> framework and involves harmonisation of technical requirements and improvement of the competitiveness of pharmaceuticals produced in Europe in an effort to provide people and animals with safer and less expensive pharmaceutical products.

In this area, the EU legislation<sup>20</sup> regulates certification of pharmaceuticals used in veterinary medicine and medical practices, their oversight and pricing policy, as well as multilateral trade in such commodities.

The Armenian legislation governing the circulation of pharmaceuticals, for the most part, does not conform to the requirements of the EU legal framework. By and large, the requirements for the circulation of pharmaceuticals as provided in the EU legislation are not reflected in the Armenian legislation. The procedures and requirements for state registration and review established by the Armenian Laws “On pharmaceutical products”<sup>21</sup> and “On veterinary practices”<sup>22</sup>, Armenian Government Decrees “On approving the procedure for state registration and the fee rates for state testing of pharmaceutical products”<sup>23</sup> and “On approving the procedure for state registration and the fee rates for state testing of bio-vaccines, serums and diagnostic devices used in veterinary practices in Armenia”<sup>24</sup> do not conform to the requirements and procedures for placing pharmaceutical products on the market as stipulated in EU Directives. Furthermore, there are numerous terminological discrepancies.

Specifically, the Armenian legislation does not make reference to price control mechanisms for medicinal products for human use and the transparency of such mechanisms, circulation of orphan medicinal products, application of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts “similar medicinal product” and “clinical superiority”.

Moreover, the Armenian legislation does not provide for the use of supplementary protection certificates for medicinal products, the scope of authorities of the pharmaceutical committee, etc.

In 2006-2008, it is expected to ensure full compliance with the EU legal acts on free movement of pharmaceuticals covering technical regulations, licensing of medicinal products, orphan medicinal products as well as the mandate of the pharmaceutical committee.<sup>25</sup>

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<sup>19</sup> Measures for technical harmonization under the old approach are based on peculiarities of the specific product and contain details peculiar to them, unlike the new approach which is based on the approaches of general nature for conformity assessment (impact on health and safety)

<sup>20</sup> Separate norms relating to pharmaceutical products are also defined in other sectors of the EU legislation (in chapters on Joint Stock Company (provisions related to intellectual property objects) and Agriculture)

<sup>21</sup> HO-259, 27.10.1998

<sup>22</sup> HO -16, 26.10.1999

<sup>23</sup> 347, 25.04.2001

<sup>24</sup> 1335, 09.09.1994

<sup>25</sup> Acts related to internal cooperation of EU Member States in the field of free movement of pharmaceutical products (it does not relate to Armenia in the current stage) as well as two EU Codes which accordingly refer to medical products for human and veterinary use will not be approximated in 2006-2008. As the implementation of the above-mentioned two Codes require enormous legislative and institutional preparatory activities, it is expedient to approximate them after 2008.

**Y2007**

Although the RoA Government Decree No. 347 of 25 April 2001 provides for the establishment of a Pharmaceutical Committee, however, the legal status of the Committee and its authorities do not conform to the provisions stipulated in the relevant EU Directive<sup>26</sup>, hence an Armenian Healthcare Ministry Order “On Approving the Charter of the Pharmaceutical Committee” shall be developed.

To align the national legislation with the requirements and procedures for acquiring permits for marketing of pharmaceutical products for veterinary and medical use as well as to establish control over such products as stipulated in the respective EU Regulation<sup>27</sup>, the RoA Government Decree “On Establishing Fee Rates for the State Registration and State Review of Bio-Vaccines, Serums and Diagnostic Devices Used in Veterinary Practices in Armenia” and Government Decree “On making amendments to the Armenian Government Decree on approving the procedure for state registration and fee rates for state testing of pharmaceutical products” shall be amended.

**Y2008**

In an effort to harmonise the unified standards and technical requirements for the production methods of pharmaceutical products and their composition, Armenia shall join the Convention on the Elaboration of a European Pharmacopoeia signed in Strasbourg on 22 July 1964<sup>28</sup> and shall adopt a RoA National Assembly Decree on the ratification of the European Pharmacopoeia Convention.

It is worth noting that at present the EU can significantly reduce the term of license for a given pharmaceutical product before a permit for marketing pharmaceuticals is issued and before an application is filed with the relevant bodies. Given these circumstances, in order to regulate the issuing of supplementary protection certificates for pharmaceutical products as defined by the relevant EU Regulation<sup>29</sup>, a draft Government Decree on “Approving the procedure for issuing supplementary protection certificates for medicinal products” shall be developed.

**Y2009**

The Armenian legal framework does not have laws corresponding to the EU Directives<sup>30</sup> on designation of a medicinal product as an orphan medicinal product, criteria for definition of the concepts “similar medicinal products” and “clinical superiority”. To promote the production of the referred products, as well as to regulate the conditions for government sponsorship of research in this area, a draft Government decree on approving the procedure for registration of orphan pharmaceutical products shall be developed.

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<sup>26</sup> Council Decision No. 75/320/EEC of 20 May 1975 setting up a pharmaceutical committee

<sup>27</sup> Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

<sup>28</sup> Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia

<sup>29</sup> Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products

<sup>30</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'

**3.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2007</b>						
1.	Elaboration of a draft Order of the Minister of Healthcare on the Approval of the Charter of the Pharmaceutical Committee	Council Decision No. 75/320/EEC of 20 May 1975 setting up a pharmaceutical committee	Ministry of Healthcare of Armenia	2 <sup>nd</sup> quarter	37	Consultancy
2.	Decree of the Government of Armenia on making amendments to the Government Decree on the Approval of the procedure for state registration of bio-vaccines, serums and diagnostic devices used in veterinary practices and the fee rates for their testing  Elaboration of a draft decree of the Government of Armenia on making amendments to the Government Decree on approving the procedure for state registration and fee rates for state testing of pharmaceutical products	Council Regulation (EEC) No. 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products	Ministry of Agriculture of Armenia  (Ministry of Healthcare of Armenia)	4 <sup>th</sup> quarter	110	Consultancy, provisional expertise
<b>TOTAL</b>					<b>147</b>	

<b>2008</b>						
3.	Join the Convention on the Elaboration of a European Pharmacopoeia	Council Decision No. 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia	Ministry of Health of Armenia	1 <sup>st</sup> quarter	22	Consultancy
4.	Elaboration of a draft Government Decree on the Approval of the procedure for issuing supplementary protection certificate for medicinal products	Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products	Ministry of Health of Armenia	3 <sup>rd</sup> quarter	17	Consultancy
<b>TOTAL</b>					<b>39</b>	
<b>2009</b>						
5.	Elaboration of a draft Government Decree on the Approval of the procedure for registration of orphan medicinal products	Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products  Commission Regulation (EC) No. 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation	Ministry of Health of Armenia	2 <sup>nd</sup> quarter	27	Consultancy

		of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'				
<b>TOTAL</b>					<b>27</b>	
<b>TOTAL</b>					<b>213</b>	

**3.2 Institutional Capacities**<sup>31</sup>

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	RoA Ministry of Healthcare RoA Ministry of Agriculture	-	Course on the authorization and supervision of medical products for human and veterinary use in the EU (5 days/2007)	Consultancy, provisional expertise
2.	RoA Ministry of Healthcare	-	Course on the European Pharmacopoeia (3 days/2008)	Consultancy
3.	RoA Ministry of Healthcare	-	Course on the certification of medical products, on the regulation of their prices as well as on orphan medical products in the EU (5 days/2009)	Consultancy

<sup>31</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

#### **4. Construction (Health and safety of workers)**

##### **Introduction**

The Armenian legislation on health and safety of construction workers partially conforms to the EU legal framework.

In Armenia, issues related to occupational health and safety are governed by the Armenian Labour Code (Articles 110, 160, 244, etc)<sup>32</sup>, Armenian SSR Council of Ministers and Armenian SSR Republican Board of Trade Unions Decision 634 “On Approving the By-law on the Work Schedule of Workers Engaged in Vibro-Hazardous Occupations”<sup>33</sup>, Ministry of Health Decree No. 138 “On Approving Sanitary Norms N2-III-11.3 for Noise Levels at the Workplace, Residential and Public Buildings and Residential Development Areas”<sup>34</sup>, Government Decree No 874-N “On Establishing Armenia’s List of Hazardous Wastes”<sup>35</sup> and other secondary legislation.

Key provisions on the minimum health and safety requirements regarding exposure of workers to the risks arising from vibrations in Armenia were stipulated in the above-mentioned Decision No. 634<sup>36</sup> adopted back in 1972 under the USSR, the provisions of which partially conform to the requirements of the EU legislation.

The main provisions on the minimum health and safety requirements regarding exposure of workers to the risks arising from noise are laid out in the Armenian Healthcare Ministry Decree No. 138 “On Establishing Sanitary Norms N2-III-11.3 for Noise at the Workplace, Residential and Public Building and Residential Development Areas” of 6 March 2002. The Decree sets the permitted thresholds for noise at the workplace and a methodology for defining constant noise characteristics that are at variance with the EU requirements and do not contain provisions on personal hearing protection devices, weekly estimation of impact of noise, mandatory requirement applying to employers for noise assessment and measurement, mandatory notification of employees about the harmful impact of noise and technical and health-care activities to reduce adverse impact of noise. Hence, at present there is no clearly defined framework governing legal relations arising in this area in Armenia.

In view of these considerations, the following laws shall be approximated during 2006-2009.

##### **Y2007**

To regulate the exposure of workers to mechanical vibrations and noise, the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical disturbances as laid out in the respective EU regulations<sup>37</sup>, with the aim of protecting their health and safety, draft Government decrees on establishing minimum health requirements regarding the exposure of workers to the risk arising from noise and on establishing minimum

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<sup>32</sup> 16.06.1972

<sup>33</sup> Decision No 634 of the Council of Ministers in the Soviet Union and Armenian Minister Soviet and Armenian Republican Council of the Trades Union, 31.10.1972

<sup>34</sup> RA JAPLA 2002 / 9 (95), 08.04.2002, article 38, 06.03.2002

<sup>35</sup> RA JAPLA 2004 / 34 (333), 30.06.2004, article 837, 11.12.2003

<sup>36</sup> The given decree is in force up to now in accordance with the Decree on the List of Binding decrees adopted by ASSR Council of Ministers on 23 October 1990 and still in force and Decree of the Government of Armenia No. 239 of 20 April 1999.

<sup>37</sup> Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)

Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration)

health requirements regarding the exposure of workers to the risks arising from vibration shall be elaborated.



4.1 Legislative Approximation

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2007</b>						
1.	Elaboration of a draft Government Decree on Establishing minimum health requirements regarding the exposure of workers to the risks arising from noise	Directive No. 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)	Ministry of Healthcare of Armenia	2 <sup>nd</sup> quarter	25	Consultancy, provisional expertise
2.	Elaboration of a draft Government Decree on the Approval of minimum health requirements regarding the exposure of workers to the risks arising from vibration	Directive No. 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration)	Ministry of Healthcare of Armenia	2 <sup>nd</sup> quarter	25	Consultancy, provisional expertise
<b>TOTAL</b>					<b>50</b>	
<b>TOTAL</b>					<b>50</b>	

**4.2 Institutional Capacities**<sup>38</sup>

0	1	2	3	4
NN	Institution	Reorganization	Training Needs	Technical Assistance Needs
1.	RoA Ministry of Healthcare  State Labour Inspection of Armenia  Inspectorate for security in industrial operations and mountain surveillance under the Ministry of Trade and Economic Development of Armenia	-	Course on the requirements for the protection of occupational health and safety in the EU (7 days/2007)	Consultancy

<sup>38</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

## 5. Cosmetic Products

### Introduction

The EU legislation on cosmetic products<sup>39</sup> lays down rules for the compositions and labelling of cosmetic products, regulates the provision of required information to the consumers, matters related to the oversight and control of these products, as well as the methods of testing their composition.

Armenia does not have laws regulating the circulation of cosmetic products, except for the Government Decree “On Establishing the Procedure for Communicating to the Consumer Certain Types of Information on Products (Activities, Services) and Information on Compulsory Requirements”<sup>40</sup> containing provisions on information to be provided to consumers.

None of the provisions laid down by the Armenian legislation on the required information about cosmetic products to be provided to the consumers meets the requirements of the EU legal framework.

### Y2008

To establish requirements for the regulation of cosmetic products in Armenia, to ensure application of certain restrictions on their composition, as well as communication of the required information to the consumers and the testing thereof, draft Government decrees “On Cosmetic Products” and “On Checking the Composition of Cosmetic Products” shall be developed.

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<sup>39</sup> Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

Second Commission Directive 82/434/EEC of 14 May 1982 on the approximation of the Laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

First Commission Directive 80/1335/EEC of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Third Commission Directive 83/514/EEC of 27 September 1983 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Fourth Commission Directive 85/490/EEC of 11 October 1985 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Fifth Commission Directive 93/73/EEC of 9 September 1993 on the methods of analysis necessary for checking composition of cosmetic products

Sixth Commission Directive 95/32/EC of 7 July 1995 relating to methods of analysis necessary for checking the composition of cosmetic products

Seventh Commission Directive 96/45/EC of 2 July 1996 relating to methods of analysis necessary for checking the composition of cosmetic products

<sup>40</sup> 1923-N, 07.11.2002

**5.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2008</b>						
1.	Elaboration of a draft decree of the Government of Armenia on Cosmetic products	Council Directive No. 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products	Ministry of Trade and Economic Development of Armenia	1 <sup>st</sup> quarter	35	Consultancy, provisional expertise
2.	Elaboration of a draft decree of the Government of Armenia on Checking the composition of cosmetic products	First Commission Directive No. 80/1335/EEC of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products  Second Commission No. Directive 82/434/EEC of 14 May 1982 on the approximation of the Laws of the Member States relating to	Ministry of Trade and Economic Development of Armenia	2 <sup>nd</sup> quarter	269	Consultancy, provisional expertise

		<p>methods of analysis necessary for checking the composition of cosmetic products</p> <p>Third Commission Directive No. 83/514/EEC of 27 September 1983 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products</p> <p>Fourth Commission Directive No. 85/490/EEC of 11 October 1985 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products</p> <p>Fifth Commission Directive No. 93/73/EEC of 9 September 1993 on the methods of analysis</p>				
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	<p>necessary for checking composition of cosmetic products</p> <p>Sixth Commission Directive No. 95/32/EC of 7 July 1995 relating to methods of analysis necessary for checking the composition of cosmetic products</p> <p>Seventh Commission No. Directive 96/45/EC of 2 July 1996 relating to methods of analysis necessary for checking the composition of cosmetic products</p>					
<b>TOTAL</b>						<b>304</b>
<b>TOTAL</b>						<b>304</b>

**5.2 Institutional Capacities**<sup>41</sup>

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	RoA Ministry of Trade and Economic Development  RoA Ministry of Healthcare	-	Course on the regulation of free movement of cosmetic products in the EU (7 days/2008)	Consultancy, provisional expertise

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<sup>41</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

## 6. Metrology

### Introduction

The EU legislation on metrology<sup>42</sup> is based on the new approach and regulates the free movement of measuring instruments in the EU domestic market, provides a single definition of measuring instruments and metrological requirements to ensure efficient protection of users and consumers, defines uniform physical and technical characteristics of measuring instruments subject to examination, formulae for the determination of their thresholds, schemes applicable for conformity assessment, etc.

The Armenian prudential legal acts currently in force in the sphere of metrology include the Armenian Law “On Ensuring Uniformity of Measurements”<sup>43</sup>, the Government Decree “On Establishing a Procedure for the Accreditation of Metrological Services of Measuring Instrument Calibration and/or Adjustment Provided by Legal Entities”<sup>44</sup>, the Government Decree “On Establishing Schemes of Mandatory Conformity Assessment of Goods or Services and Identification Markings”<sup>45</sup>, the Order of the RoA Ministry of Energy “On Establishing Technical Requirements for 50 Hertz Alternating Current (AC) Active Electrical Static Watt-Hour Meters Used in the Electrical Power Billing System in Armenia”<sup>46</sup>, the Order of the RoA Ministry of Urban Development “On Technical Requirements for Potable Water-meters”<sup>47</sup>, as well as other secondary legislation.

The Armenian legislation regulating the sphere of metrology is horizontal and of general procedural nature and does not include sectoral regulations on measuring instruments (vertical legislation); therefore it cannot provide for detailed regulation and appropriate level of control, hence it does not comply with the requirements of the EU legislation.

The main discrepancies in the sphere of metrology in Armenia are as follows:

#### Horizontal legislation lacks:

- Definitions of a number of concepts referring to the description of measuring instruments which are to be taken into consideration during the calibration of instruments, specifically “nominal set-point”, “malfunctioning”, “critical change value”, “climatic conditions”, “repeatability”, “discrimination and sensitivity”, “durability”, “sub-assembly” and other concepts;
- The concept of “maximum permitted deviation” and detailed definition of the affecting parameters, e.g. classification of the device installation environment into climate-based, mechanical and electromagnetic environments and their more detailed classification;
- Special rules for measuring instruments used in the utilities sector;
- Detailed rules for packaging, labelling, marking, placing on the market of measuring instruments or the required information on the conditions of their operation;
- Detailed rules for the technical documentation package for manufacturers of measuring instruments.

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<sup>42</sup> Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments, Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments

<sup>43</sup> HO-83-N, 26.05.2004

<sup>44</sup> 771, 25.11.2000

<sup>45</sup> 1170-N, 12.08.2004

<sup>46</sup> 96-DZ, 22.06.1999

<sup>47</sup> 84, 31.05.1999



No procedure for conformity verification of measuring instruments, defining additional requirements, has been established. This corresponds to the “CE” marking indicating instrument conformity to all the requirements spelled out in the respective directive (both in the designing and manufacturing phases) and a supplementary metrological marking (“M”). Measuring instruments that bear these two markings are allowed unhampered movement in the European market. The Armenian legal framework does define calibration and adjustment of measuring instruments, however not in the overall conformity verification context (it does not state that all schemes/modules of conformity verification shall apply to measuring instruments). The Armenian legislation provides a definition for “legal entities providing measuring instrument calibration and adjustment services”, rather than conformity verification entities that in a position to verify conformity based on conformity schemes and provides special metrological verification services. The Government of Armenia should grant these entities the authority for these functions and notify the European Union about their accreditation. It is worth noting that the Armenian legislation provides for the accreditation but not authorisation of certifying bodies and legal entities providing calibration and adjustment services.

The Armenian legislation does not provide for administrative cooperation among oversight bodies to ensure proper control of this market.

### **Vertical Legislation**

Only part of the requirements established for water meters, active electrical energy meters, heat meters correspond to the EU rules. Concepts describing the metrological, technical parameters for measuring instruments subject to examination, formulas for determining their ranges, a number of other requirements are missing and some other provisions that are compliant with the EU legal framework are not sufficiently detailed. No requirements are defined for instrument conformity verification schemes, which hampers proper oversight and control<sup>11</sup>.

The Armenian legislation does not contain relevant regulations on gas meters and volume conversion instruments, systems for continuous and dynamic measurement of liquid quantity, automatic weighing instruments, tariff meters, material measuring instruments, length and angle measuring instruments, gas emission analysers<sup>11</sup>, as well as non-automatic weighing instruments. Their technical and metrological descriptions are defined in the Armenian national standards: their application became non-compulsory as of 1 January 2005 and the national standards fail to define schemes applied for instrument conformity verification, which hampers efficient control of the referred instruments.

In view of the above, it is envisaged to approximate the Armenian legislation with the requirements set forth by the EU legal framework in the course of 2008.

### **Y2008**

To guarantee sound consumer protection in Armenia, to define the necessary metrological and performance requirements and to establish conformity verification, examination rules and procedures for non-automatic weighing instruments, a draft Government Decree on Non-automatic weighing instruments shall be developed.

To ensure the free movement of goods in Armenia’s domestic market, application of schemes for verification of their physical, technical conformity (use of the “CE” marking), as

well as to control their placing on the market or their use, a draft Government Decree on Measuring instruments shall be developed.

**6.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2008</b>						
1.	Elaboration of a draft Government Decree on Non-automatic weighing instruments	Council Directive No. 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments	Ministry of Trade and Economic Development of Armenia	1 <sup>st</sup> quarter	29	Consultancy, provisional expertise
2.	Elaboration of a draft Government Decree on Measuring instruments	Directive No. 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments	Ministry of Trade and Economic Development of Armenia	1 <sup>st</sup> quarter	53	Consultancy, provisional expertise
<b>TOTAL</b>					<b>82</b>	

**6.2 Institutional Capacities**<sup>48</sup>

	1	2	3	4
NN	Institution	Reorganization	Training Needs	Technical Assistance Needs
1.	RoA Ministry of Trade and Economic Development	-	Course on the EU legislation acting in the field of metrology in the EU (7 days/2008)	Consultancy, provisional expertise
2.	RoA Ministry of Trade and Economic Development  National Institute of Metrology  National Institute of Standardization	-		EU technical assistance, replenishment of relevant equipments in the field of metrology in line with the EU standards and staff training

<sup>48</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

## 7. Toys

### Introduction

The Armenian legislation governing the circulation of toys is comprised of the Law of the Republic of Armenia “On Conformity Assessment”<sup>49</sup> and the Government Decree “On Approving the Technical Regulation on Toys”<sup>50</sup>.

The Armenian legislation regulating circulation of toys mainly corresponds to the requirements laid out in the EU legal framework<sup>51</sup>, except for the definition of toys, restrictions on the entry into the market of toys without conformity marking and certain provisions on certifying bodies. The Armenian legislation does not provide for measures aimed at prohibiting entry into the market of child-care articles and toys that are intended for children under three years of age and are made of soft PVC (polyvinylchloride) containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP) and butylbenzyl phthalate (BBP).

According to the Armenian legislation, a sampling of toys is performed to verify conformity before their entry into the market, whereas the EU legislation specifies a requirement for sampling and testing of toys already placed on the market. In addition, the provisions of the Armenian legislation contain other discrepancies.

This refers to the “CE” marking designating conformity to all requirements for toys as laid out in a respective European directive. Toys bearing this mark are entitled to uninhibited movement in the European market.

Although the Armenian legislation contains an equivalent provision about conformity marking, however the image of the marking is at variance with the EU marking of conformity.

The Armenian legislation governing control of the market does not provide for a framework of administrative cooperation between control bodies.

The discrepancies noted above shall be eliminated in the course of 2007-2008.

### Y2007

To promote the free movement of toys in the Armenian market and to fully comply with the EU requirements for health and safety, amendments shall be made to the Government Decree “On Approving the Technical Regulation on Toys”.

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<sup>49</sup> HO-28, 26.05.2004

<sup>50</sup> 1551-N, 11.11.2004

<sup>51</sup> Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys

Commission Decision No. 1999/815/EC of 7 December 1999 adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP) (notified under document number C(1999) 4436) (Text with EEA relevance)

**Y2008**

A draft Government Decree shall be elaborated on the control of child-care articles and toys intended for children under three years of age and made from soft polyvinylchloride (PVC) containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP) and butylbenzyl phthalate (BBP).

**7.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2007</b>						
1.	Elaboration of a draft Government Decree on Amendments to the Government Decree No. 1551-N of 11 December 2004 on the Approval of the technical regulation on toys	Council Directive No. 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys	Ministry of Trade and Economic Development of Armenia	3 <sup>rd</sup> quarter	15	Consultancy
		<b>TOTAL</b>			15	
<b>2008</b>						
2.	Elaboration of a draft Government Decree on the Control of toys and childcare articles intended for children under three years of age made of soft PVC containing one or more of the substances di-isoo-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP)	Commission Decision No. 1999/815/EC of 7 December 1999 adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl	Ministry of Healthcare of Armenia  (Ministry of Trade and Economic Development of Armenia)	2 <sup>nd</sup> quarter	15	Consultancy

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	phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP)				
<b>TOTAL</b>				<b>15</b>	
<b>TOTAL</b>				<b>30</b>	



**7.2 Institutional Capacities**<sup>52</sup>

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	RoA Ministry of Trade and Economic Development  RoA Ministry of Healthcare	-	Course on the technical regulation of the market of the toys in the EU (5 days/2007)	Consultancy, provisional expertise

<sup>52</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter.

## 8. Medical Devices

### Introduction

The current EU legislation governing the circulation of medical devices<sup>53</sup> is guided by the new approach and regulates matters related to the placing on the market and operation of medical devices in the EU with a view to protect the health and safety of patients and operators, and also seeks to promote the free movement of these products in the EU's domestic market.

There are no Armenian legal acts regulating circulation of medical devices.

In an effort to approximate with the EU legislation covering this area, as well as to regulate the circulation of medical devices and supplementary instruments, specifically active implantation medical devices, in vitro diagnostic medical devices in the Armenian market, a draft law on medical devices shall be developed in the course of 2008.

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<sup>53</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices  
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices  
Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices  
Commission Decision No. 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices  
Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices  
Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (Text with EEA relevance)

**8.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2008</b>						
1.	Elaboration of a draft law of the Republic of Armenia on Medical devices	<p>Council Directive No. 93/42/EEC of 14 June 1993 concerning medical devices</p> <p>Commission Directive No. 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin</p> <p>Commission Directive No. 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices</p>	Ministry of Healthcare of Armenia	1 <sup>st</sup> quarter	241	Consultancy, provisional expertise

	<p>Council Directive No. 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices</p> <p>Directive No. 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices</p> <p>Commission Decision No. 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices</p>				
<b>TOTAL</b>				<b>241</b>	
<b>TOTAL</b>				<b>241</b>	

**8.2 Institutional Capacities**<sup>54</sup>

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	RoA Ministry of Healthcare	-	Course on the regulation of the circulation of medical devices in the EU market (7 days/2008)	Consultancy, provisional expertise

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<sup>54</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

## 9. Other Devices and Products

### Introduction

The current EU legislation on the circulation of other devices and products regulates safety and marking requirements for the production of recreational crafts in the EU, requirements regarding the labelling of footwear and names of textile products, as well as issues related to the placing on the market and control of explosives, classification of wood and glass.

The list of prudential legal acts governing other devices and products in Armenia includes the Armenian Law “On Conformity Assessment”<sup>55</sup>, Government decrees “On Establishing the Schemes and Associated Identification Markings Used for Mandatory Conformity Assessment of Products or Services”<sup>56</sup>, “On Approving the Procedure and License Format for Licensing of Trade in Explosive Materials or Detonation Devices”<sup>57</sup>, “On Approving the Procedure and License Format for Licensing of Detonation Activities”<sup>58</sup>, “On Approving the Procedure and License Format for Licensing of the Manufacturing of Explosive Materials and Detonation Devices in Armenia”<sup>59</sup>, as well as other Armenian laws, government decrees and secondary legislation.

The Armenian legislation regulating other devices and products is deficient, there are no regulations covering the respective vertical sectors and, the legislation in place is of general nature and is not sufficiently detailed, hence, by and large, does not conform to the EU legal framework.

The Armenian legislation lacks the following:

- A regulation on recreational crafts<sup>60</sup>,
- Provisions on the manufacturing, marking of types of glass and provisions defining conformity verification methods (laboratory testing)<sup>61</sup>,
- Provisions on the special marking of textile products based on the type of textile fibres, names and descriptions of the types of fibres<sup>62</sup>,
- Provisions on the special marking of natural and artificial leather and soles used for shoe-wear<sup>63</sup>,
- Provisions on the classification of wood<sup>64</sup>.

The Armenian legislation on explosives corresponds to the EU legal framework only in its references to the licensing of their manufacturing, trade and carrying out detonation activities. As for issues relating to the application of conformity assessment schemes to the manufacturing of explosives and products, conformity verification, control, sale and exporting, the Armenian legislation is at variance with the respective EU legislation as the referred matters are defined in laws and secondary legislation with a larger regulatory scope and do

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<sup>55</sup> HO-82, 26.05.2004

<sup>56</sup> N 1170- N, 12.08.2004

<sup>57</sup> N 1348- N, 08.08.2002

<sup>58</sup> N 1349- N, 08.08.2002

<sup>59</sup> N 2071-N, 28.11.2002

<sup>60</sup> Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft

<sup>61</sup> Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass

<sup>62</sup> Directive 96/74/EC of the European Parliament and of the Council of 16 December 1996 on textile names

<sup>63</sup> Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer

<sup>64</sup> Council Directive 68/89/EEC of 23 January 1968 on the approximation of the laws of the Member States concerning the classification of wood in the rough

not refer only to explosive materials. References are made to explosive materials in the legislation on weapons or dual purpose products, however, the referred areas fall into the non-harmonised scope of the Chapter “On Free Movement of Goods” in the EU legislation, which is subject to a different regulatory framework. Hence, explosives are not regulated in Armenia<sup>65</sup>.

**Y2007**

To provide consumers with relevant and accurate information (through special labelling) on natural and artificial leather and soles used for the production of footwear placed on the market, a draft Government Decree on the labelling of the materials used in the production of footwear shall be elaborated.

**Y2008**

To provide the consumers of the Armenian market with accurate information on the names and descriptions of textile fibres and other products through special labelling of textile products or by affixing other documents to these products, a draft Government Decree on Textile names shall be elaborated.

For the same purpose stated above, a draft Government Decree on the classification and labelling of crystal glass shall be developed.

**Y2009**

To regulate matters related to the manufacturing of explosives and application of conformity verification schemes for the these products in Armenia, conformity assessment, control, marketing, exports, as well as the transportation of these materials, a draft Government Decree on placing on the market and supervision of explosives for civil use shall be elaborated.

To regulate safety, health, environmental and consumer protection requirements for recreational crafts in Armenia, a draft Government Decree on the technical requirements to recreational crafts shall be elaborated.

To regulate the circulation of wood in the Armenian market, a draft Government Decree on the classification of wood in the rough shall also be elaborated.

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<sup>65</sup> Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses  
Commission Decision No. 2004/388/EC of 15 April 2004 on an Intra-Community transfer of explosives document (notified under document number C(2004) 1332)

**9.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2007</b>						
1.	Elaboration of a draft decree of the Government of Armenia on Labelling of the materials used in production of footwear	Directive No. 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer	Ministry of Trade and Economic Development of Armenia	2 <sup>nd</sup> quarter	15	Consultancy, provisional expertise
<b>TOTAL</b>					<b>15</b>	
<b>2008</b>						
2.	Elaboration of a draft decree of the Government of Armenia on Textile names	Directive No. 96/74/EC of the European Parliament and of the Council of 16 December 1996 on textile names	Ministry of Trade and Economic Development of Armenia	1 <sup>st</sup> quarter	25	Consultancy, provisional expertise
3.	Elaboration of a draft decree of	Council Directive No.	Ministry of Trade	2 <sup>nd</sup> quarter	15	Consultancy, provisional



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	the Government of Armenia on the Classification and labelling of crystal glass	69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass	and Economic Development of Armenia  (Ministry of Health of Armenia)			expertise
<b>TOTAL</b>					<b>40</b>	
<b>2009</b>						
5.	Elaboration of a draft decree of the Government of Armenia on the Classification of wood in the rough	Council Directive No. 68/89/EEC of 23 January 1968 on the approximation of the laws of the Member States concerning the classification of wood in the rough	Ministry of Agriculture of Armenia  (Ministry of Nature Protection of Armenia)  Ministry of Trade and Economic Development of Armenia	2 <sup>nd</sup> quarter	15	Consultancy, provisional expertise
6.	Elaboration of a draft decree of the Government of Armenia on placing on the market and supervision of explosives for civil use	Council Directive No. 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses  Commission Decision No. 2004/388/EC of 15 April 2004 on an Intra-Community transfer of	Ministry of Trade and Economic Development of Armenia  (Police under the Government of Armenia,  Rescue Service of Armenia)	2 <sup>nd</sup> quarter	74	Consultancy, provisional expertise

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		explosives document (notified under document number C(2004) 1332)				
7.	Elaboration of a draft decree of the Government of Armenia on Technical requirements to recreational crafts	Directive No. 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft	Ministry of Trade and Economic Development of Armenia	2 <sup>nd</sup> quarter	69	Consultancy, provisional expertise
<b>TOTAL</b>					<b>144</b>	
<b>TOTAL</b>					<b>215</b>	

**9.2 Institutional Capacities**<sup>66</sup>

0	1	2	3	4
NN	Institution	Reorganization	Training Needs	Technical Assistance Needs
1.	RoA Ministry of Trade and Economic Development	-	Course on the classification of footwear, textile and crystal glass (3 days/2007)	Consultancy, provisional expertise
2.	RoA Ministry of Trade and Economic Development	-	Course on the labelling of textile and crystal glass (7 days/2008)	Consultancy, provisional expertise
3.	RoA Ministry of Trade and Economic Development  RoA Ministry of Agriculture  RoA Ministry of Nature Protection	-	Course on the classification of wood in the rough (3 days/2009)	Consultancy, provisional expertise
4.	RoA Ministry of Trade and Economic Development  Police under the Government of Armenia  Rescue Service of Armenia	-	Course on the transport of explosives and on placing on the market of explosives for civil uses (3 days/ 2009)	Consultancy, provisional expertise

<sup>66</sup> For coordination of legislative approximation, activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

## 10. Horizontal and Procedural Measures

### Introduction

By designation, horizontal and procedural legislative measures apply particularly to the new and global approach legislation, which are mainly aimed at “establishing new bases for technical harmonisation”, thus harmonising only the key requirements for products and applying the “general reference to standards” formula and the principle of mutual recognition to eliminate technical barriers hampering free movement of goods.

Armenia’s current legislation governing horizontal and procedural activities includes the Armenian Law “On Standardization”<sup>67</sup>, the Government Decree “On Establishing a Procedure for the Development, Adoption and Enforcement of Technical Regulations”<sup>68</sup>, the Law “On Conformity Assessment”<sup>69</sup>, Government decrees “On Establishing the Schemes and Associated Identification Markings Used for Mandatory Conformity Assessment of Products or Services”<sup>70</sup>, “On Establishing the Image of Conformity Marking, Associated Technical Requirements and Enforcement Procedure”<sup>71</sup> and other secondary legislation.

The Armenian legislation in the sphere of horizontal and procedural measures is mainly incompliant with the requirements of the EU legislation.

The discrepancies in the horizontal and procedural measures in Armenia are as follows:

The Armenian legislation lacks:

- Definitions of concepts regarding information society services as well as a number of other concepts;
- A definition for the concept “specification”, on which the definitions “standard” and “technical regulation” are based<sup>72</sup>;
- A definition for the authorisation of conformity assessment bodies (it is worth noting that in the Armenian legislation, these bodies are referred to as “certifying bodies”, which emphasizes the dominance of the certification procedure over other types of conformity verification). The Armenian legislation envisages authorisation only for extraordinary cases, in other cases, these bodies are generally subject to accreditation, which involves recognition of the technical, rather than legal capacity of the bodies. The legislation does not provide for the exchange of information with the licensed bodies of other countries<sup>73</sup>.
- Armenia has joined the WTO and, within the framework of its WTO membership, has joined the Agreement on Technical Barriers to Trade and has established a relevant WTO Notification Centre, it uses a procedure for developing standards and technical regulations which is largely similar to the European Community requirements.

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<sup>67</sup> HO-18, 09.11.1999

<sup>68</sup> N 9, 11.01.2000

<sup>69</sup> HO -82, 26.05.2004

<sup>70</sup> 1170-N, 12.08.2004

<sup>71</sup> 1281-N, 09.09.2004

<sup>72</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services;

<sup>73</sup> Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives

However, the European Union has its own regulation<sup>74</sup> and procedures<sup>75</sup> on the publication, exchange and notification of information on barriers to trade, as well as standards, technical regulations, the equivalent provisions of which are currently not stipulated in the Armenian legislation.

- Although the schemes established for conformity assessment are approximated to the European modules and international schemes, however the procedures included in the modules are of schematic nature and cannot support detailed regulation of the legal relations arising in this sphere. There are no schemes corresponding to the European B, C, E, H modules.

- The meaning of affixing the “CE” marking on products is at variance with the purpose of applying conformity marking as provided by the Armenian legislation. When a product bears a “CE” marking, it indicates conformity of the given product to all applicable harmonised provisions of the Community and is not limited to only safety provisions and signifies that it has undergone all conformity assessment phases as established by the directive regulating the manufacturing of a given product. “CE” marking is the only sign indicating conformity of a given product to the requirements of directives based on the comprehensive (global) approach. The Armenian legislation on conformity schemes is not based on the comprehensive approach, hence does not encompass, for instance, procedures on certifying quality management systems, which, in Armenia, are defined by standards. Although the Armenian legislation provides for a procedure for the unilateral recognition of the conformity marking, however it does not contain a resolution regarding the recognition of the “CE” marking.

- There are no equivalent provisions for two-phase conformity assessment process (during product design and manufacturing phases).

In view of the above, the legislative approximation programme, which encompasses this area and is envisaged to be implemented in its entirety in 2006, includes the following:

The principles of the EU’s global approach and the detailed procedures for conformity assessment comprise a general guidance procedure, which is based on:

- the manufacturer’s internal control activities for product design and manufacturing;
- third party inspections and the manufacturer’s internal control activities for manufacturing;
- third party inspection of products or product design and establishment of third party product or production quality verification systems or third party product certification;
- third party certification of product design and production;
- establishment of comprehensive third party quality verification systems.

To establish principles, guides and detailed procedures on conformity assessment, general rules on CE marking and its use in Armenia, amendments shall be made to the Armenian Law “On Conformity Assessment”, Government decrees “On Establishing the Schemes and Associated Identification Markings Used for Mandatory Conformity Assessment of Products or Services” and “On Establishing the Image of Conformity Marking, Associated Technical Requirements and Enforcement Procedure”.

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<sup>74</sup> Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States

<sup>75</sup> Decision No. 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community

In an effort to regulate the legal framework governing publication, exchange and notification of information regarding standards, technical regulations so as to ensure the transparency of the adoption of technical regulations and standards, a draft Government Decree on Approving the procedure for provision of information in the field of technical standards and regulations shall be elaborated.

Given that at present Armenia does not have an internationally recognised conformity assessment body, which is a significant impediment to signing agreements on bilateral recognition of certificates with developed countries, a draft Government Decree on unilateral adoption of the EU's CE marking in Armenia shall be elaborated.

### **Policy Approximation**

To improve the quality assurance system, a National Programme shall be developed, which will provide a framework for signing bilateral and multilateral agreements on the recognition of certificates and inspection results. Enhancement and upgrade of testing laboratories and establishment of a reference testing laboratory shall also be considered in this framework.

As regards standardisation, it is required that the country's standards authority have a CEN (European Standards Committee) membership, however in order to become a full member of this organisation, countries must first harmonise at least 80% of their national standards with the EU standards.

To this end, an Armenian programme for joining the European Standards Authority shall be developed.

**10.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2006</b>						
1.	Elaboration of a draft decree of the Government of Armenia on Approving the procedure for the provision of information in the field of technical standards and regulations	Directive No. 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services;	Ministry of Trade and Economic Development of Armenia	4 <sup>th</sup> quarter	15	Consultancy, provisional expertise
2.	<ul style="list-style-type: none"> <li>• Elaboration of draft law on Amendments to the Law of Armenia on Conformity Assessment</li> <li>• Elaboration of draft decree of the Government of Armenia on Amendments to the Government Decree No. 1170-N of 12 August 2004 on Schemes applied for mandatory conformity assessment of products or services and</li> </ul>	Council Decision No. 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization	Ministry of Trade and Economic Development of Armenia	4 <sup>th</sup> quarter	51	Consultancy, provisional expertise

	<p>on identification marking of schemes</p> <ul style="list-style-type: none"> <li>• Elaboration of draft decree of the Government of Armenia on Amendments to the Government Decree No. 1281-N of 9 September 2004 on the Approval of the procedure of CE marking, technical requirements to it and its application</li> <li>• Elaboration of draft decree of the Government of Armenia on Unilateral adoption of the EU's CE marking in Armenia</li> </ul>	<p>directives</p>				
<b>TOTAL</b>					<b>66</b>	
<b>TOTAL</b>					<b>66</b>	



**10.2 Institutional Capacities**<sup>76</sup>

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	RoA Ministry of Trade and Economic Development	-	Training course on EU new and global approach - common approach for technical requirements to products and on labelling of products with CE mark in the EU (10 days/ 2006)	Consultancy, provisional expertise
2.	National Institute of Standardisation CJSC	Establish a “Translation Centre for of EU standards” foundation adjacent to the National Institute of Standardisation - CJSC	Training course on recognition of standards and their implementation (5 days/ 2006)	Consultancy, financial assistance
3.	Improvement of laboratory equipments in Armenia within the framework of the National Programme for the improvement of quality assurance system and establishment of a reference testing laboratory		Training of laboratory staff (10 days/2007)	Consultancy, financial assistance

<sup>76</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

**10.3 Policy Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2007</b>						
1.	“Programme to join the European Standards Organization”	-	Ministry of Trade and Economic Development of Armenia	1 <sup>st</sup> quarter	30	Consultancy, provisional expertise
2	National Programme for the improvement of the quality assurance system	-	Ministry of Trade and Economic Development of Armenia	2 <sup>nd</sup> quarter		
3.	Enhancement and upgrade of testing laboratory equipments and establishment of a reference testing laboratory	-	Ministry of Trade and Economic Development of Armenia	4 <sup>th</sup> quarter		
<b>TOTAL</b>					<b>30</b>	

## 11. Non-Harmonised Areas

### Introduction

The Community's legislation covering non-harmonised areas provides for the regulation of mechanisms for banning export of cultural values from the territory of EU Member-States, repatriation of illegally exported national property and cooperation, as well as the **mechanisms of acquisition and possession of weapons**<sup>77</sup>.

The list of Armenian prudential legal acts governing non-harmonised areas includes the Armenian Law "On Weapons"<sup>78</sup>, the Government Decree "On Regulating Circulation of Civilian and Military Weapons and their Bullets on the Territory of Armenia"<sup>79</sup>, Armenian Law "On Exporting and Importing of Cultural Values"<sup>80</sup>, the Government Decree "On Measures to Ensure Enforcement of the Armenian Law 'On Exporting and Importing Cultural Values'"<sup>81</sup>, the Government Decree "On Regulating the Export of Cultural Values and Objects of Cultural Significance"<sup>82</sup>, as well as other relevant Armenian laws, government decrees and agency legal acts.

The Armenian legislation governing the non-harmonised area is in sufficient conformity with the requirements of the European legislation; however there are several discrepancies, specifically in the legislation regulating the free movement of weapons.

The Armenian Law "On Weapons" provides a general framework for the regulation of legal relations associated with weapons and does not include a regulation equivalent to the EU directive on firearms.

The Armenian legislation on weapons lacks the following:

- definitions of "firearms", "dealer", and other terms, as well as definitions of types of firearms in accordance with the EU directive;
- classification of firearms into the following categories: banned, requiring government authorisation, subject to declaration, etc. in line with EU requirements. This is the source for other discrepancies, as the Armenian legislation is of general nature and does not contain procedures differentiated by category of firearms;
- definition of "firearm pass" in line with the requirements of the European directive. In Armenia, it corresponds to a permit, which, however, does not comply with the requirements stipulated for passes<sup>83</sup>.

In Armenia, the validity period for the firearm use permit is set for five years and applies only if the firearms are used in Armenia and, if imported, permits are provided for shorter periods, whereas the European pass is issued for 5 years.

The Armenian legislation applies differentiated approach to the right of acquisition and possession of arms by Armenian citizens and foreign citizens, which is unacceptable from

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<sup>77</sup> It is necessary to note that the comparison of the Armenian legislation in terms of dual-use items and technology with European legislation has not been involved in the current stage of the assignment, as in the framework of the first National Programme the international experts have not defined it as a priority

<sup>78</sup> HO-246, 03.07.1998

<sup>79</sup> 673, 26.10.1999

<sup>80</sup> HO -176, 06.12.2004

<sup>81</sup> 236, 26.04.1995A

<sup>82</sup> 245-N, 26.02.2004

<sup>83</sup> Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons

the viewpoint of the European approach. The bans should refer to the type of weapons rather than to nationality.

There is no established procedure for state licensing of weapons imports. Transportation of weapons by post is prohibited in Armenia, which does not comply with the European approach.

There is no procedure for the notification of weapons transportations, as well as for exchange of information on weapons.<sup>11</sup>

As regards cultural values, the Armenian legal framework does not provide for:

- a breakdown of cultural values into categories according to their antiquity and assessed value in accordance with the European approach;
- the concept “export license” and a requirement on the latter. The Armenian legislation sets forth a requirement for an export license certificate, however the procedure for export licensing is of a different nature;
- a requirement for limiting the number of customs checkpoints authorised to handle customs documentation of cultural values and notifying about these customs checkpoints to other states<sup>84</sup>.

As regards the repatriation of illegally exported cultural property, Armenia has become a signatory to a number of conventions; however no detailed procedures ensuring their enforcement have been developed<sup>85</sup>.

#### **Y2007**

To bring the legal framework regulating the circulation of weapons in conformity with the EU requirements and to define the types of firearms the acquisition and possession of which by private persons is prohibited or is subject to state licensing or declaration, amendments shall be made to the Armenian Law “On Weapons” and to the Government Decree “On Regulating Circulation of Civilian and Military Weapons and their Bullets on the Territory of Armenia”.

#### **Y2008**

To regulate repatriation of national property illegally exported from Armenia, as well as to bring the procedure for exporting cultural goods and particularly goods discovered at archaeological excavation sites, artistic, historical, religious monuments or articles removed from archaeological sites in conformity with the EU requirements, amendments shall be made to the Armenian Law “On Exporting and Importing of Cultural Goods” and the Government decrees “On Measures to Ensure Enforcement of the Armenian Law ‘On Exporting and Importing Cultural Values’” and “On Approving the By-Law and Structure of the Cultural Values Protection Agency of the Armenian Ministry of Culture and Youth Affairs”.

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<sup>84</sup> Council Regulation(EEC) No 3911/92 of 9 December 1992 on the export of cultural goods

<sup>85</sup> Council Directive 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State

**11.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2007</b>						
1.	<ul style="list-style-type: none"> <li>Elaboration of a draft law on making amendments to the Law of Armenia on Weapons</li> <li>Elaboration of a draft decree of the Government of Armenia on making amendment to the Government Decree "On Regulating Circulation of Civilian and Military Weapons and their Bullets on the Territory of Armenia"</li> </ul>	Council Directive No. 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons	Police under the Government of Armenia  (Ministry of Trade and Economic Development)	1 <sup>st</sup> quarter	26	Consultancy, provisional expertise
<b>TOTAL</b>					<b>26</b>	
<b>2008</b>						
2.	<ul style="list-style-type: none"> <li>Elaboration of a draft decree of the Government of Armenia on making amendments to the Law of Armenia on Exporting and Importing of Cultural Goods</li> <li>Elaboration of a draft</li> </ul>	Council Regulation(EEC) No. 3911/92 of 9 December 1992 on the export of cultural goods	Ministry of Culture and Youth Affairs of Armenia  (Customs Committee under the Government of Armenia)	2 <sup>nd</sup> quarter	26	Consultancy, provisional expertise

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	decree of the Government of Armenia on making amendments to the Government Decree No. 236 of 4 April 1995 on Measures to ensure the enforcement of the Armenian Law on Export and Import of Cultural Objects	Council Directive No. 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State				
<b>TOTAL</b>					<b>26</b>	
<b>TOTAL</b>					<b>52</b>	

**11.2 Institutional Capacities**<sup>86</sup>

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	Police under the Government of Armenia  (RoA Ministry of Trade and Economic Development)	-	Training course on the acquisition and on the control over the use of arms in the EU (3 days/2007)	Consultancy, provisional expertise
2.	RoA Ministry of Culture and Youth Affairs  (Customs Committee under the Government of Armenia)	-	Training course on export of cultural goods and on the return of cultural objects unlawfully removed from the territory of the EU (3 days/2008)	Consultancy, provisional expertise

<sup>86</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter

## 12. Public Procurement

### Introduction

Lack of open and efficient competition in the area of public procurement is one of the most obvious barriers to the consolidation of a common EU market and effective operation of the free trade framework; hence, in the EU legal framework, public procurement is consigned to the area of free movement of goods.

The EU directives<sup>87</sup> governing public procurement in the Community make up the core of the Community's legal framework on public procurement and are based on:

- Rules ensuring transparency through granting public contracts on a competitive basis, by giving preference to open or restricted tenders as well as clearly-defined criteria for selection of tender participants;
- Efficient and fast revision of decisions by contracting agencies in breach of the Community legislation on public procurement.

The Armenian legislation governing public procurement is comprised of the RoA Civil Code<sup>88</sup>, specifically paragraph (4) of Article 31 of the Code, the Armenian law "On Procurement"<sup>89</sup> and other laws and legal acts.

The Armenian legislation regulating public procurement for the most part does not conform to the EU legal framework. The Law "On Procurement" which is considered to be the key piece of legislation on public procurement includes many provisions that run counter to the requirements stipulated in the EU legal framework. Specifically, these provisions refer to the types of and procedures for procurement, provision of information and notification of procurement participants, review of complaints and a number of other issues.

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To regulate the procedure for concluding contracts for catering to public needs, the procedure for signing contracts for the provision of services, efficient and fast review of bids in the areas of procurement of labour, water supply, energy, transport, as well as proscribing mishandling during the process of contracting for public work or services, amendments shall be made to the Armenian Law "On Procurement".

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<sup>87</sup> Council Directive 89/665/EEC of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts

Council Directive 92/13/EEC of 25 February 1992 coordinating the laws, regulations and administrative provisions relating to the application of Community rules on the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors

Council Directive 93/36/EEC of 14 June 1993 coordinating procedures for the award of public supply contracts

Council Directive 93/37/EEC of 14 June 1993 concerning the coordination of procedures for the award of public works contracts

Council Directive 92/50/EEC of 18 June 1992 relating to the coordination of procedures for the award of public service contracts

<sup>88</sup> HO-239, 05.05.1998

<sup>89</sup> HO -160, 06.12.2004



**12.1 Legislative Approximation**

0	1	2	3	4	5	6
NN	Measure	EU Legal Source	Responsible Institutions	Submission Date	Necessary Resources (man/day)	EU Technical Assistance
<b>2008</b>						
1.	Elaboration of a draft law on making amendments to the Law of Armenia on Procurement	<p>Council Directive No. 89/665/EEC of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts</p> <p>Council Directive No. 92/13/EEC of 25 February 1992 coordinating the laws, regulations and administrative provisions relating to the application of Community rules on the procurement procedures of entities operating in the water, energy, transport and telecommunications</p>	Ministry of Finance and Economy of Armenia	3 <sup>rd</sup> quarter	242	Consultancy, provisional expertise

	sectors				
	<p>Council Directive No. 92/50/EEC of 18 June 1992 relating to the coordination of procedures for the award of public service contracts</p> <p>Council Directive No. 93/36/EEC of 14 June 1993 coordinating procedures for the award of public supply contracts</p> <p>Council Directive No. 93/37/EEC of 14 June 1993 concerning the coordination of procedures for the award of public works contracts</p>				
<b>TOTAL</b>					<b>242</b>

**12.2 Institutional Capacities<sup>90</sup>**

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>NN</b>	<b>Institution</b>	<b>Reorganization</b>	<b>Training Needs</b>	<b>Technical Assistance Needs</b>
1.	RoA Ministry of Finance and Economy	-	Training course on the public procurement in the EU (7 days/2008)	Consultancy, provisional expertise

<sup>90</sup> For coordination of legislative approximation activities, relevant EU Integration subdivisions will be established within the responsible ministries and state agencies mentioned in the present subchapter