IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

A. Standard questionnaire to be filled for each sector individually:

***Sector*: Personal Protective Equipment**

1. Harmonisation of laws including technical regulations

1.1. Legal basis

- **References (and copies) of the publication of acts and decrees transposing Directive(s) on personal protective equipment (89/686/EEC) into the national legislation of your country:**

Regulation on Personal Protective Equipment (Official Gazette No. 25368 dated, 9 February 2004)

Communication on the Categorization Guide of PPE (Official Gazette No. 25452, dated 4 May 2004)

Communication on the 1st List of Harmonized National Standards (Official Gazette No. 25452, dated 4 May 2004)

Communication on the 2nd List of Harmonized National Standards (Official Gazette No. 25698, dated 12 January 2005)

Regulation on Market Surveillance and Inspection for the Ministry of Labour and Social Security (Official Gazette No. 25684, dated 28 December 2004)

Communication on the Criteria of Selection of Notified Bodies (Official Gazette No. 25684, dated 28 December 2004)

- **Date of entry into application of the national measures transposing the Directive:**

All the legislation listed above entered into force on 9 February 2005.

- **If not yet transposed, please indicate the state of play, expected timing, steps to be undertaken, difficulties encountered (if any):**

1.2. Responsible authority

- **Name and contact details of the competent authority (government, ministry, department, service) and person(s) in charge of transposing the Directive into national legislation: The main responsibility of the adoption and**

implementation of the Community acquis in the field of personal protective equipment (PPE) lies on the Ministry of Labour and Social Security (MoLSS)

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Directorate General for Occupational Health and Safety (DGOHS)

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Occupational Health and Safety Centre of the MoLLS (Local)

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1.3. Notified bodies

- **Has your country the intention to notify conformity assessment bodies for the Directive? If so, could you already identify these bodies (name, and contact details) and indicate the conformity tasks (products and modules) that they will be entitled to perform:**

The Communiqué on the Criteria of Designation of Notified Bodies was published on 28 December 2004 and is in force as from 9 February 2005. There is still no Notified Bodies designated by Turkey yet.

The potential CABs to be notified to the European Commission are as follows.

- Turkish Standardisation Institution – Ankara (all PPE – except Respiratory Protective Equipment)

- Turkish Lloyd Foundation – Istanbul (all PPE)

2. Implementation

2.1. Participation in Standing Committee and Experts' Group

- **Name, function and contact details of the representatives (and their alternates, if any) of your country's governmental authorities designated or to be designated to represent your country in the meetings of the standing committee and experts' group established under the Directive:**

Previously, two personnel from the DG for Occupational Safety and Health of the Ministry have attended the meetings of the Experts' Group on PPE. The following three personnel are going to be designated to represent Turkey in the meetings of the standing committee and experts' group established under the Directive on PPE.

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2.2. Implementing structure

- ***Responsible authority central/local:***

Name and contact details of the competent authority (government ministry, department, service) and person(s) in charge of implementing the provisions of the Directive in the territory of your country:

Ministry of Labour and Social Security (Central)
Directorate General for Occupational Health and Safety (DGOHS)

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Ministry of Labour and Social Security (Central)
Directorate General for Occupational Health and Safety (DGOHS)
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- ***Implementation:***

  - **Explain how implementation of the Directive in your country will be ensured (monitoring and control tools: market surveillance and others**

- **Explain how market surveillance is carried out and on which basis**

- **Resources available: specify the number and qualification of personnel designated for market surveillance activities (divided in office staff/field personnel)**

- **Cost: What budget will be provided for market surveillance activities? How will this be financed?**

Regulation on Market Surveillance and Inspection for the Ministry of Labour and Social Security was published on 28 December 2004 and entered into force on 9 February 2005.

Market Surveillance and Inspection Department with 10 personnel has been established under the DG for Occupational Health and Safety, which is the directly responsible unit of the Ministry for the adoption and implementation of the Community acquis in the field of PPE. At present, the department does market researches and strives for informing the relevant parties with various activities on the basis indicated in the answer to the last question.

100 technical personnel from DG for Occupational Health and Safety carry out market surveillance.

There is a regular budget line of about 60,000 Euros. In addition, DG for Occupational Health and Safety has a fund, which can be used for these purposes when it is necessary.

Methods of enforcement:

- **What means/methods will be available in your country for enforcing compliance with the Directive(s)?**

- **Which are the reactive methods available?**

- **Rights of the authority: What are the powers of the authority?**

- **Penalties: which will be the penalties applicable to violation of the national implementing measures?**

For the time being, the Ministry of Labour and Social Security makes use of the following resources for market surveillance activities:

- Findings obtained from the accident investigations

- Feedback from the labour inspections

– Consumer complaints

– Denounces

– Risky products reported through the RAPEX system

In case that there are definite indications that a product is unsafe the public authority shall temporarily prohibit the placing on the market of the product concerned, during the period required for necessary checks.

According to the Law No. 4703 (Framework Law) relating to the preparation and implementation of the technical legislation on the products;

If the product concerned is found to be unsafe after the control, the public authority shall take the measures below, on condition that the expenses be covered by the producer:

a) prohibition of the placing on the market of the product,

b) withdrawal of the marketed products,

c) whole or partial disposal of the products in case where it is impossible to render them safe,

d) Announcement of the necessary information relating to the measures laid down in the paragraphs (a), (b) and (c) to the persons at risk by publishing this information in two daily newspapers and two television channels having nationwide distribution and reach.

Penalties are laid down in Law No. 4703.

3. Calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance

Please provide information on the relevant regimes for the products in this sector:

- **short description and**

PPE placed on the market must satisfy the basic health and safety requirements laid down in the Regulation on PPE and must not endanger the safety of users, other individuals, domestic animals or goods, when used for its intended purpose.

It is presumed that the PPE of Simple Design and affixed CE Marking by the manufacturer by drawing up the EC Declaration of Conformity, satisfies the basic requirements referred to the Regulation on PPE.

It is presumed that the PPE which is not Simple Design, satisfies the basic requirements referred to the Regulation if it bears the CE marking in accordance with the declaration of conformity drawn up by the manufacturer and the certificate issued by the notified body attesting to its conformity to the harmonized national standards.

- **further evolution.**

The notified body shall conduct the EC type-Examination in accordance with the under mentioned procedures:

a) Examination of the manufacturer's technical file: It shall examine the manufacturer's technical file to establish its suitability with respect to the harmonized standards. Where a manufacturer has not applied, or has only partly applied, the harmonized standards or where there are no such standards, the body of which notification has been given must check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements before examining the manufacturer's technical file to establish its suitability with respect to these technical specifications.

b) Examination of the model: When examining the model, the notified body shall verify that it has been produced in accordance with the manufacturer's technical file and can be used in complete safety for its intended purpose. It shall conduct the necessary examinations and tests to establish the conformity of the model with the harmonized standards.

Where a manufacturer has not applied or has only partly applied the harmonized standards or where there are no such standards the body of which notification has been given shall conduct the necessary examinations and tests to establish the conformity of the model with the technical specifications used by the manufacturer, subject to their being suitable with respect to the basic requirements.