IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

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

***Sector*: Toys**

1. Harmonisation of laws including technical regulations

1.1. Legal basis

- **References (and copies) of the publication of acts and decrees transposing Directive(s) …….. into the national legislation of your country:**

A. EU Legislation

"Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys" and "Council Directive 93/68/EEC of 22 July 1993 amending Directive 88/378/EEC" were transposed by the "Regulation on Toys", published in Official Gazette No. 24758, dated 17 April 2002 and the "Regulation amending the Regulation on Toys", published in Official Gazette No. 25293, dated 18 November 2003.

B. Date of entry into force of the national legislation transposing the Directive:
- "Regulation on Toys" –entered in force on 17.11.2003
- "Regulation amending the Regulation on Toys" – published in Official Gazette No. 25293, dated 18 November 2003 and entered in force on the date of its publication.

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

N/A

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**

Ministry of Health, General Directorate of Curative Health Care, Biomedical Engineering Services Department, Market Surveillance & Vigilance Division.

Address: Sağlık Bakanlığı
Mithatpaşa Caddesi
Sıhhiye Ankara Turkey

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**

No application has been received yet.

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:**

So far, there has been limited participation to the technical committees. Yet, Turkey would like to regularly participate in Toys Safety Expert Group.

Selma Beyzadeoğlu - Head of Market Surveillance & Vigilance Division of General Directorate of Curative Health Care of Ministry of Health.

Serpil Şenelt - Poison Research Directorate, Refik Saydam National Hygiene Centre.

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:

Selma Beyzadeoğlu
Ministry of Health
Head of Market Surveillance and Vigilance Division of DG for Curative Health Care

- ***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?**

The implementation of the Regulation on Toys is ensured in accordance with the provisions of the Law No. 4703, the "Principal Law on Health Services No. 3359", the "Law No. 181 on the Organisation and Missions of the Ministry of Health".

Market surveillance is performed by the inspectors, who are trained on the market surveillance and working in the Provincial Health Directorates through a centralized system (1 Head of Unit - 3 technical staff). There are also inspectors of the Ministry in 81 provinces. These staffs consist of biologists, chemists, medical doctors, engineers, medical technologist, environmental health technicians and health officers.

The budget for market surveillance of toys is as follows:

- 625 Euro's for training of the inspectors in Provincial Health Directorates
- 312,500 Euro's for performing market surveillance.

- ***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?

All actions are taken and penalties are applied according to the provisions of the Law No.4703 and the “Regulation No. 2001/3529 on Market Surveillance of Products”.

During market surveillance activities on toys, inspectors check the warnings and signs, which should be on the labels of the toys for the children less than 36 months. Complaints are also taken under consideration for market surveillance purposes.

Manufacturers and importers and other related parties are informed on the procedures of the CE marking and other necessary information about the Regulation through the Ministry’s web site. “Consumer’s Guide”, including recommendations concerning toys, accident risks of toys and other necessary information for consumers, is also available on the web site.

The inspectors in İstanbul, Ankara, İzmir, Urfa and Adana provinces in which imports of toys is intense, are trained on market surveillance. It is also planned to train the inspectors in the provinces of Interior Anatolian region in the first quarter of 2006. Other trainings will continue on a regional base.

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**
- **further evolution.**

The analysis of the samples, which are collected through market surveillance, will be performed by Turkish Standards Institute (TSE), in line with the Protocol made between TSE and Curative Health Care DG of Ministry of Health. Refik Saydam National Hygiene Centre, following strengthening its infrastrucure, will perform this analysis.