IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

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

***Sector*: Cosmetics**

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:

Directive No. 76/768/EEC

The Directive, its 7 amendments and 31 technical adaptations were harmonized.

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

Law No. 5324 on Cosmetics was published in the Official Gazette No. 25771, dated 30 March 2005.

Regulation on Cosmetics was published in the Official Gazette No. 25823, dated 23 May 2005.

The Communiqués were published in the Official Gazette No.25862, dated 1 July 2005.

If not yet transposed, please indicate the state of play, expected timing, steps

Directives Nos. 2005/9/EC, 2005/42/EC, 2005/52/EC and 2005/80/EC have not been transposed yet. Technical studies are still on going.

The provisions of Directives No. 95/17/EC, 2003/15/EC and 2004/94/EC on animal testing will be transposed by the MoH after the completion of legislative works executed by the MoEF for the transposition of Directives No. 67/548/EEC, 99/45/EC, 91/155/EEC and 93/67/EEC.

- **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

Competent authority:
Cosmetics Department
General Directorate of Pharmaceuticals and Pharmacy
Ministry of Health

Contact person
Pharm. Deniz CENGİZ ÖZAY
Chief of Cosmetics Department
deniz.ozay@saglik.gov.tr
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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**

N/A

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:**

In order to harmonise Turkish cosmetics legislation to that of the EC effectively and timely, regularly attendance to the related EC technical committees is a must. Thus, an invitation for participation to these committees is expected.

The candidate representative is Pharm. Aslı Esma Bayram KARACA from Cosmetics Department of MoH.

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:

The competent authority is DG of Pharmaceuticals and Pharmacy of Ministry of Health.

Pharm. Deniz CENGİZ ÖZAY
Chief of Cosmetics Department
deniz.ozay@saglik.gov.tr

The local authorities

There are local health authorities in all of 81 provinces affiliated with the MoH. They realise market surveillance for cosmetics and also collect the required samples from the market and send to the General Directorate of Pharmaceuticals and Pharmacy for analyses.

- ***Implementation:***

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

The Cosmetics legislation provides necessary power for the competent authority for effective implementation. In this framework, a market surveillance system has been established to monitor the compliance of the products to the principles laid down in the legislation.

Market surveillance activities are carried out by the MoH and 81 local (provincial) health authorities affiliated with it.

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

The market surveillance is carried out pursuant to the provisions of the legislation on cosmetics and Law No. 4703 on Preparation and Implementation of Technical Legislation on Products.

The personnel in charge of market surveillance is authorised to make examinations on the product, review the documents, make physical examination and take samples for testing. The local health authorities perform these activities in general. In cases of complaints and suspicious situations, Cosmetics Department requires samples of these suspected products from the market by local health authorities and send them to the Refik Saydam Hygiene Institute. Their analyses are made at Drugs and Cosmetics Control Laboratory at this Institute. The Cosmetics Department of General Directorate for Pharmaceuticals and Pharmacy evaluate the results of these analyses. According to the result of the findings, the Department takes necessary legal actions, if it deemed necessary.

The first group that has been controlled by the Department among the cosmetic products is cologne products, because of its widespread use in Turkey.

For cosmetics, during the period of 30 March-31 December 2005, 115 investigations made out of which 79 products were found to be non-compliant (3 of found unsafe).

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

There are approximately 75 pharmacists, biologists, chemists are working at the Official Drug and Cosmetics Control Laboratory in Refik Saydam Hygiene Institute to conduct market controls. This Institute is the central official control laboratory.

The personnel in the local health authorities also deal with the local market surveillance activities. The MoH plans to increase the number of personnel responsible for market controls or surveillance by employing 550 more controllers. They will be employed in the market surveillance activities of cosmetics, toys, medical devices and detergents.

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

The MoH finances the expenditures of market surveillance activities from its budget.

- ***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?

The Legislation defines the necessary means for enforcing compliance with the Law.

For products having a risk to the human health or non-conforming to the provisions of the legislation, the MoH has the power to take all necessary measures (including administrative fines, withdrawal from the market and disposal of the product, etc.) by considering the level of non-conformity and the principle of proportionality.

All actions are taken and the penalties are applied according to the provisions of the legislation. In order to enforce the compliance with the Law and its implementing provisions, there are sanctions and punitive measures. There are also provisions in Law No. 5237, Turkish Criminal Code, defining the crimes against the public health and their sanctions.

For administrative enforcement, the sanctions are applied in accordance with the provisions of the Law No. 5324 on Cosmetics and Law No. 4703 on Preparation and Implementation of Technical Legislation on Products. The legal administrative sanctions are fines (up to approximately 30,000 Euros), withdrawal of the product from the market, confiscation of the product and closing of the manufacturing place.

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.**

N/A