

## CHEMICALS QUESTIONNAIRE

### Import and Export of Dangerous Chemicals

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 (Text with EEA relevance) (*OJ L 063 06.03.2003 p. 1*) **EUR-Lex** [hyperlink](#) [html](#) [pdf](#)

#### Implementation

**What has been achieved so far as regards?**

##### **1. Designating the DNA(s) (Art. 4)**

The Ministry of Environment and Forestry is the designated authority for the coordination and main authority for the implementation of this Regulation depending on ;

- Law on Environment No.2872 (Official Gazette: 11 August 1983, no 18132) as amended by the Law No.5491 (Official Gazette: 13 May 2006, no 26167)
- Law on Establishment and Duties of the Ministry of Environment and Forestry No. 4856 (Official Gazette: 08 May 2003, no 25102), including authority and responsibility related to chemicals management, Ministry of Environment and Forestry has been assigned for the determination and application of objectives and policies, and economic tools related to chemicals managements for the effective environmental management,
- Framework Law No 4703 relating to the preparation and implementation of the technical legislation on products, came into force on 11 January 2002. According to this law, only safe products will be placed on the market, and criteria /technical specifications related with product safety will be determined and applied by the competent authority according to EU product safety rules.
- Decree on The Determination of the Institutions to Prepare the Technical Legislation towards the Increase of Export No. 97/9196 (Official Gazette:29 April 1997, no 22974

##### **2.Designating authorities for controlling the import and export of Annex I chemicals (Art. 17)**

The Ministry of Environment and Forestry is responsible for controlling of industrial chemicals depending on;

- Law on Environment No.2872 (Official Gazette: 11 August 1983, no 18132) as amended by the Law No.5491 (Official Gazette: 13 May 2006, no 26167)
- By-Law on Dangerous Chemicals (Official Gazette: 11 July 1993, no 21634)
- Import Communiqué on Standardization of Foreign Trade No. 2006/6 (Official Gazette 31 December 2005, no 26040), entitled “Chemicals Taken Under the Control for the Protection of Environment” due to Standardization Regime.
- By-Law on the Ozone Depleting Substances (Official Gazette: 25 July 1999, no 23776)
- Import Communiqué for Ozone Depleting Substances (Official Gazette: 31 December 2005, no 25687)

The Ministry of Agriculture and Rural Affairs deals with controlling the pesticides and similar products depending on;

- Law on Plant Protection and Agriculture Quarantine No. 6968 (Official Gazette: 24 May 1957, no 9615)
- By –Law on the Control of the Pesticides (Official Gazette: 22 June 1995, no 22321)
- Import Communiqué on Standardization of Foreign Trade No. 2006/ 5 (Official Gazette: 31 December 2005, no 26040), entitled ‘‘Goods Taken under the Control of Ministry of Agriculture and Rural Affairs’’ due to Standardization Regime
- Phase out of Agricultural use of Ozone Depleting Methyl Bromide (Official Gazette: 23 June 2000, no 24088)

The Ministry of Health is responsible for controlling some pesticides and similar products depending on;

- Public Hygiene Law No: 1593, dated 24.4.1930, (Official Gazette: 06 May 1930, no 1489)
- By-Law on Special Qualifications of Goods and Supplies concerning General Health (Official Gazette: 18 October 1952, no 8236)
- Import Communiqué on Standardization of Foreign Trade No. 2006/4 (Official Gazette 31 December 2005, no 26040), entitled ‘‘ Goods Taken under the Control of Ministry of Health’’ due to Standardization Regime

The Ministry of Labour and Social Security is responsible for controlling import of the asbestos fibres depending on;

- Import Communiqué on Standardization of Foreign Trade No. 2006/13 (Official Gazette 31 December 2005, no 26040), entitled ‘‘ Goods Taken under the Control of Ministry of Health’’ due to Standardization Regime

### **3. Ratifying/accession to the Rotterdam Convention**

Turkey signed Rotterdam Convention in 1998, but she has not ratified it yet.

Ratification of Rotterdam Convention will be evaluated after necessary arrangements are made about establishing legal framework on Dangerous Substances Directive (67/548/EEC), Dangerous Preparations Directive (99/45/EC) and Safety Data Sheet Directive (91/155/EEC).

### **4. Implementing arrangements for explicit consent (Art. 13.6)**

In the framework of this regulation, responses to the export notifications from the EU Commission are given by the Ministry of Environment and Forestry.

### **5. Implementing an export notification system (Art. 7)**

Not applicable before membership.

## **6. Establishing a mechanism for issuing guidance to exporters**

Technical studies need to be initiated.

## **7. Implementing an effective monitoring and enforcement system (Art. 21)**

The market surveillance is carried out pursuant to the provisions of the Law on Environment No.2872 (Official Gazette: 11 August 1983, no 18132) as amended by the Law No.5491 (Official Gazette: 13 May 2006, no 26167), the By-law on Dangerous Chemicals and Communiqué on Safety Data Sheet relating to labelling, packaging and safety data sheets.

Environment Law, By-law on Dangerous Chemicals, and Communiqué on Safety Data Sheet are available for enforcing.

## **Dangerous Substances Directive**

31967L0548

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

(OJ 196 16.08.1967 p. 1) ) EUR-Lex hyperlink [html](#) including amendment proposed by [52003PC0644\(02\)](#)

### **Transposition**

#### **A. Which part of the provisions of the Directive has been transposed?**

The By-law on Dangerous Chemicals (BDC) was published at Official Gazette No: 21634, dated 11 July 1993 and came into force at the publication date. By-law on Dangerous Chemicals;

Transposes;

- Definitions (except notification and notifier and, EINECS); Article 4 of BDC
- Safety Data Sheet; Articles 12 and 22 of BDC
- Symbols and indication of danger; Annex – IV of BDC
- Nature of special risk attaching to dangerous substances; Annex – VII of BDC
- Safety advice concerning dangerous chemical substances; Annex – VII of BDC.

Partially transposes;

- Objectives and scope; Article 1 of BDC
- Packaging; Articles 23, 24, 25, 26 and 27 of BDC
- Labelling; Articles 16, 17, 18 and 20 of BDC
- Implementation of labelling requirements ; Articles 16, 17, 18 and 20 of BDC
- Exemption from labelling requirements ; Article 16, 17, 18 and 20 of BDC
- List of dangerous substances; Annex – I of BDC.

Communiqué on The Procedure for the Filling of the Safety Data Sheet (Official Gazette: 11 March 2002, no 24692) came into force on 11 March 2003 to achieve full transposition of Article 27 of the Directive related with Safety Data Sheets.

#### **B. When is the transposition foreseen for the remaining measures?**

There is a Technical Assistance project entitled “Technical Assistance for Turkey to Strengthen the Institutional and Administrative Capacity in the field of Chemicals (TeACH project - EUROPEAID/120220/D/SV/TR)” which was commenced on 16 January 2006 and will be finalized in the mid of 2007. In the framework of this project, technical studies comprising establishment of legal framework related with the four main EU Chemicals Directives (Directive on Dangerous Substances (67/548/EEC), Directive on Dangerous Preparations (99/45/EC), Directive on Risk Assessment principles of new substances (93/67/EEC) and Directive on Safety Data Sheets (91/155/EEC)) are continuing.

## **Implementation**

### **What has been achieved so far as regards:**

#### **1. Designating the Competent Authority/ies**

The Ministry of Environment and Forestry is the competent authority based on;

- Law on Environment No.2872 (Official Gazette: 11 August 1983, no 18132) as amended by the Law No.5491 (Official Gazette: 13 May 2006, no 26167).
- Law on Establishment and Duties of the Ministry of Environment and Forestry No. 4856 (Official Gazette: 08 May 2003, no 25102), including authority and responsibility related to chemicals management, the Ministry of Environment and Forestry has been assigned for the determination and application of objectives and policies, and economic tools related to chemicals managements for the effective environmental management.
- Framework Law No. 4703 related to the preparation and implementation of the technical legislation on products, came into force on 11 January 2002. According to this law, only safe products will be placed on the market, and criteria /technical specifications related with product safety will be determined and applied by the competent authority according to EU product safety rules.
- Decree on The Determination of the Institutions to Prepare the Technical Legislation towards the Increase of Export No. 97/9196 (Official Gazette:29 April 1997, no 22974).

In the framework of TeACH project regulatory cycle will be determined and competent authority/ies with their roles and responsibilities will be designated.

#### **2. Establishing a mechanism to ensure access by CA to EINECS/ELINCS databases**

In the framework of TeACH project, “National Chemicals Monitoring Database” comprising mechanism to access EINECS/ELINCS databases by CA will be established.

#### **3. Establishing a mechanism to ensure that manufactures, importers and distributors provide safety data sheets**

By-law on Dangerous Chemicals, as amended, transposes Article 27 of the Directive 67/548/EEC related with the Safety Data Sheets (SDS) and some provisions of Safety Data Sheet Directive 91/155/EEC. “Communiqué on The Procedure for the Filling of the Safety Data Sheet” was published to achieve full transposition of Safety Data Sheet Directive 91/155/EEC.

Within TeACH project Safety Data Sheet Directive 91/155/EEC will also be studied together with Directive 67/548/EEC. In the framework of this project, harmonization related with SDS will be assessed regarding established mechanism and if required, new or additional

mechanism will be established to ensure that manufactures, importers and distributors provide safety data sheets.

**4. Establishing a mechanism to provide reports to the Commission**

Not applicable before membership.

**5. Establishing a mechanism for the notification of new substances**

**6. Establishing procedures for carrying out conformity check of notifications and risk assessments of notified substances**

**7. Establishing criteria for taking temporary risk management measures on substance**

**8. Establishing measures to ensure confidentiality**

*As an answer to questions from 5 to 8:*

TeACH project comprises the Directive 93/67/EEC laying down the principles for assessment of risk to man and the environment of substances notified in accordance with the Directive 67/548/EEC besides Directive 67/548/EEC. In the framework of this project required mechanism for the notification of new substances, procedures for carrying out conformity check of notifications and risk assessments of notified substances, criteria for taking temporary risk management measures on substance and measures to ensure confidentiality will be determined and established.

**9. Carrying out an assessment of the national chemicals sector**

**10. Establishing a mechanism to ensure that all substances are packaged and labelled appropriately**

**11. Establishing an effective inspection and enforcement system**

*As an answer to questions from 9 to 11:*

In general, institutions promulgating the legislation have the main responsibility for the implementation, issuing permits, monitoring, inspection, enforcement and reporting. At provincial level, provincial directorates of related institutions are responsible for inspection.

At present the registration system for import and export established according to Custom Tariff Positions comprises only some group names of chemicals or some unique chemical names. Registrations for production were established according to chemicals name only. Currently the CAS and EINECS/ELINICS numbers are not in use at the registration system. Therefore, there is no full and clear data about the presence of chemical substances on the Turkish market and no systematic market control for the implementation of the legislation.

## **Risk Assessment Regulation**

31993R0793

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances  
(OJ L 084 05.04.1993 p. 1) ) EUR-Lex hyperlink [html](#) including amendment proposed by [52003PC0644\(01\)](#)

### **Implementation**

**What has been achieved so far as regards:**

#### **1. Designating the competent authority/ies (Art. 13)**

The Ministry of Environment and Forestry is the competent authority based on;

- Law on Environment No.2872 (Official Gazette: 11 August 1983, no 18132) as amended by the Law No.5491 (Official Gazette: 13 May 2006, no 26167)
- Law on Establishment and Duties of the Ministry of Environment and Forestry No. 4856 (Official Gazette: 08 May 2003, no 25102), including authority and responsibility related to chemicals management, the Ministry of Environment and Forestry has been assigned for the determination and application of objectives and policies, and economic tools related to chemicals managements for the effective environmental management
- Decree on The Determination of the Institutions to Prepare the Technical Legislation towards the Increase of Export No. 97/9196 (Official Gazette:29 April 1997, no 22974)

#### **2. Establishing system to designate a rapporteur (Art. 10)**

#### **3. Establishing a system for risk evaluation (Art. 10)**

#### **4. Establishing legal or administrative measures to deal with cases of non-compliance with the Regulation's requirements (Art. 17)**

#### **5. Establishing an effective inspection and enforcement system**

*As an answer to questions from 2 to 5:*

There is a Technical Assistance project entitled "Technical Assistance for Turkey to Strengthen the Institutional and Administrative Capacity in the field of Chemicals (TeACH project - EUROPEAID/120220/D/SV/TR)" which was commenced on 16 January 2006 and will be finalized in the mid of 2007. After establishment of new registration system, inventory system of chemicals and National Chemicals Monitoring Database in the framework of this project and, publication of new legislation comprising requirements of Dangerous Substances Directive (67/548/EEC) and the Directive 93/67/EEC laying down the principles for assessment of risk to man and the environment of substances notified in accordance with the Directive 67/548/EEC, Council Regulation (EEC) No 793/93 will be assessed and required system and legal or administrative measures to deal with cases of non-compliance with the Regulation's requirements will be established.

## Animal Experiments Directive

31986L0609

Council Directive 86/609/EEC of 24 November 1986 amended by Directive 2003/65/EC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 358 18.12.1986 p. 1) EUR-Lex hyperlink [html](#)

### Transposition

#### A. Which parts of the provisions of the Directive have been transposed?

Main legislation with respect to the protection of animals used for experimental and other scientific purposes are the Law on Animal Health Control No. 3285 (Official Gazette: 16 May 1986 No. 19109), the Law on Animal Protection No. 5199 (Official Gazette: 1 July 2004 No. 25509) and the By-law on the Procedures and Principles for the Protection of Animals Used for Experimental or Other Scientific Purposes, Breeding Establishments for Experimental Animals and the Establishment, Operation and Inspection of Laboratories Performing the Experiments (Official Gazette: 16 May 2004 No. 25464).

In accordance with Directives 86/609/EEC and 2003/65/EC, harmonisation has been done on the issues listed below:

- The establishment of a registration and authorization system for breeding and supplying establishments,
- The establishment of a registration and authorization system for user establishments,
- The determination of criteria for the appropriate handling of animals,
- The establishment of an authorization system for experimental animals,
- The regular keeping of archives,
- The establishment of a mechanism for collection of statistical data,
- The establishment of an effective auditing and implementation system.

#### B. When is the transposition foreseen for the remaining measures?

Technical studies are in progress.

### Implementation

#### What has been achieved so far as regards:

- **Designating authority/ies (Art. 6)**

Pursuant to the Law on Animal Health Control No. 3285, the Law on Animal Protection No. 5199 and the By-law on the Procedures and Principles for the Protection of Animals Used for Experimental or Other Scientific Purposes, Breeding Establishments for Experimental Animals and the Establishment, Operation and Inspection of Laboratories Performing the Experiments, the authorities are The Ministry of Agriculture and Rural Affairs for issuance of permissions for establishment and work permits for breeding, supplying and user



establishments of experimental animals and the execution of all related procedures, and the Ministry of Environment and Forestry for establishment of Ethics Commissions and determination of their operation principles and procedures.

- **Establishing an authorisation or registration system for breeding and supplying establishments (Arts. 15 & 16)**

Pursuant to the Articles 9 and 10 of the By-law on the Procedures and Principles for the Protection of Animals Used for Experimental or Other Scientific Purposes, Breeding Establishments for Experimental Animals and the Establishment, Operation and Inspection of Laboratories Performing the Experiments (Annex III) based on the Law on Animal Health Control No. 3285 (Annex I) and the Law on Animal Protection No. 5199 (Annex II), and according to the Implementing Instruction No. 2006/4 on the By-law; breeding and supplying establishments are registered, technical and hygienic conditions to be met by breeding and supplying establishments are determined, animal welfare criteria are determined, and breeding and supplying establishments detected to be favourable during inspections and audits are issued working permits.

- **Establishing an authorisation or registration system for user establishments (Art. 19)**

According to the Articles 9, 10, 11, 12, 13, 14 and 15 of the By-law and the Instruction No. 2006/4; user establishments are registered, technical and hygienic conditions to be met by user establishments are determined, animal welfare criteria are determined, user establishments detected to be favourable during inspections and audits are issued working permits.

- **Establishing criteria for the proper treatment of animals (Arts. 5 & 7-11)**

Pursuant to the Articles 6, 7 and 13 of the By-law and the Instruction No. 2006/4; criteria have been determined for the appropriate handling of experimental animals.

- **Establishing an authorisation system for animal experiments (Arts. 12 & 13)**

According to the Articles 5, 8 and 14 of the By-law and the Instruction No. 2006/4; an authorization system has been established for experimental animals.

- **Requiring records to be kept (Arts. 17 & 18)**

Pursuant to the Article 15 of the By-law and the Instruction No. 2006/4; criteria have been determined for the regular keeping of archives.

- **Establishing a mechanism to collect statistical information (Art. 13)**

Pursuant to the Article 15 of the By-law and the Instruction No. 2006/4; a mechanism has been established for the collection of statistical data.

- **Establishing an effective inspection and enforcement system**

Pursuant to the Articles 9, 10, 11, 16 and 17 of the By-law and the Instruction No. 2006/4; an effective auditing and implementation system has been established.

## Persistent Organic Pollutants

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158 30.04.2004 p. 7) EUR-Lex hyperlink [html pdf](#)

- **Designating the competent authority/ies (Art.15)**

There are three responsible authorities for POPs management in Turkey. According to the the Law on Environment No.2872 (Official Gazette: 11 August 1983, no 18132) as amended by the Law No.5491 (Official Gazette: 13 May 2006, no 26167) The Ministry of Environment and Forestry is responsible for direct and indirect effects of persistent organic pollutants on environment via emissions into air, releasing to water and waste to the land. Besides, pursuant to Law on Plant Protection and Quarantine No.6968, (Official Gazette: 24 May 1957, no 9615) Ministry of Agriculture and Rural Affairs deals with the use of pesticides, and according to Law on Public Hygiene No.1593 (Official Gazette: 6 May 1930, no 1489) Ministry of Health is responsible for short and long-term health impacts of persistent organic pollutants on the public health.

- **Informing and making the necessary notifications concerning possible exemptions (Art. 4)**

Turkey is not producing, importing and exporting the chemical substances listed in Annexes A and B of Stockholm Convention, and does not plan any future production and use. Therefore, Turkey does not currently have any request for the registration of any specific kind of exemptions for the chemical substances listed in Annexes A and B.

- **Establishing a system to monitor the use and management of notified stockpile (Art. 5)**

There is a project entitled “Enabling Activities to Facilitate Early Action on the Implementation of Stockholm Convention on POPs in Turkey”, which is financed by Global Environmental Facility (GEF), commenced in 2004 and will be completed in mid of 2006. Within this project, there is an ongoing activity for identifying and monitoring of stockpiles.

- **Drawing up and maintaining of release inventories for the substances listed in Annex III into air, water and land; Communicating the action plan on measures to identify, characterise and minimise total releases of POPs as part of its national implementation plan (Art. 6)**

Not available since Turkey has not established the EPER system.

- **Establishing a system to provide information to the Commission on possible authorisations under Article 7 (POP containing waste) (Art. 7)**

There is an ongoing activity in the framework of above mentioned project for managing stockpiles and taking appropriate measures for handling and disposal of articles in use.

- **Communicating the national implementation plan to the Commission and to MSs (Art. 8)**

Not applicable before membership.

- **Establishing a system of reporting to the Commission (Art. 12)**

Not applicable before membership.

- **Establishing an effective inspection and enforcement system and laying down the rules on penalties applicable to infringements of the provisions of the Regulation (Art.13)**

According to the Law on Environment No. 2872, there is an inspection system and penalties to protect environment and human health. With respect to the Law on Plant Protection and Quarantine No.6968, if some active materials are found harmful for human health and environment and for similar aspects by international organizations and the use of these materials are prohibited, the registration licences granted for all formulations containing these active materials are cancelled.

- **Full implementation**

Not applicable before membership.

## Biocidals

31998L0008

Directive 98/8/EC of The European Parliament and of The Council of 16 February 1998, concerning the placing of biocidal products on the market.  
(OJ L 123, 24.4.98, p.1) EUR-Lex hyperlink [html](#)

### Transposition

#### A. Which part of the provisions of the Directive has been transposed?

A national authorization system for regulating marketing and use of biocidal products exists, in this regard, national authorization system on biocidal product is based on:

- Law on Public Hygiene No. 1593 (Official Gazette: 06 May 1930, no 1489)
- Regulation on Special Qualifications of Food, Goods and Supplies Concerning General Health (Official Gazette: 18 October 1952, no8236)
- By-law on Medical and Pharmaceutical Products Authorization, (Official Gazette: 02 March 1995, no 22218)
- Law of Animal Health Control No. 3285 dated 16.05.1986
- By-law on Veterinary Equipment and Medical Preparations No.24915, dated 23.10.2002.
- Circular on Authorisation Requirements on Pesticides and Disinfectants (Official Gazette: 08 July 1983, no 5677).
- By-law on the Main Aspects of Applying Pesticides in Public Health Field (Official Gazette: 27 January 2005, no 25672).

#### B. When is the transposition foreseen for the remaining measures?

Technical studies are carried out under the scope of the project called Harmonisation and Implementation of the Biocidal Product Directive (TR/2004/IB/EN/03) under the Pre-accession assistance programme. A technical working group for legal drafting has been established within the Ministry of Health.

### Implementation

#### C. What has been achieved so far as regards:

- **Designation the competent authority/ies (Art 26) earliest by 30.6.05**

The Ministry of Health and the Ministry of Agriculture and Rural affairs are competent authorities in their respective fields.

- **Establishing an authorization procedure for biocidal products (Arts 3, 5-8,12-14)**

An authorization procedure for biocidal products exists in Turkey. The Ministry of Health issues the authorization for biocidal products which include insecticides, rodenticides, molluscicides, repellents and attractants, disinfectants through the circular No: 5677 dated 08 July 1983. On the basis of this circular, companies are obliged to fill an application form in order to obtain an authorization for their products. Ministry of Agriculture and Rural Affairs has an authorization procedure for authorization of veterinary disinfectants.

- **Establishing a procedure for authorizing the use of unauthorized products (Art.15-17)**

Competent authority may authorize the limited and controlled use of biocidal products if such a measure appears necessary because of unforeseen danger which cannot be contained by other means.

- **Establishing a system concerning classification, packaging and labelling of biocides (Art. 20)**

The Ministry of Environment and Forestry is the competent authority regarding classification, packaging and labeling of the chemicals and preparations. The Ministry of Health makes reference to the legislation published by the Ministry of Environment and Forestry regarding the dangerous properties of chemicals and preparations. Through the Circular No. 5677 dated 08 July 1983 published by Ministry of Health the applicant must put all necessary information on the label which is available in the application form.

- **Establishing a system for safety data sheets (Art 21)**

The Ministry of Environment and Forestry has issued the Communiqué on The Procedure for the Filling of the Safety Data Sheet (Official Gazette: 11 March 2002, no 24692) and the Ministry of Health makes reference to the legislation published by the Ministry of Environment and Forestry. The system based on this Communiqué has been evaluated within the framework of the Technical Assistance for Turkey to Strengthen the Institutional and Administrative Capacity in the Field of Chemicals (TeACH) project by the Ministry of Environment and Forestry.

- Establishing a procedure for the inclusion of inactive substances and active substances (Art. 10-11)

Not applicable before membership.

- **Establishing a procedure for placing active substances on the market (Arts. 9)**

Not applicable before membership.

- **Establishing a system to provide information to the commission**

Not applicable before membership.

- **Establishing an effective inspection and enforcement system**

Provincial Directorates of the Ministry of Health and Ministry of Agriculture and Rural Affairs conduct inspections in cases of complaints, non-compliance and accidents. The ministries have the authority to ban manufacturing and import of products, to cancel authorisations and to withdraw products from the market.

- **Full implementation**

Not applicable before membership.