Overview of current Turkish legal framework for chemical control legislation. Including Turkey's classification and labelling regulation (SEA(CLP By-Law))

Ahu ÇEKİM Expert Ministry of Environment and Urbanization

April 2, 2014

# **INSTITUTIONAL FRAMEWORK**

INSTITUTION	TASK
Ministry of Environment and Urbanization	industrial chemicals and coordination
Ministry of Health	biocidal products
Ministry of Food, Agriculture and Livestock	plant protection products
Ministry of Labour and Social Security	health and safety in workplace
Ministry of Transport Maritime and Communication	transportation of chemicals
Ministry of Science, Industry and Technology	chemical weapons
Ministry of Economy	import and export of chemicals
Ministry of Customs and Trade	control of chemicals at customs and detergents

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# LEGISLATIVE FRAMEWORK

EU-DIR./REGULATION	TURKISH REGULATION
67/548/EC Dir. 99/45/EC .Dir.	By-law On Classification, Packaging And Labelling Of Dangerous Substances And Preparations (26.12.2008/27092) (CPL By-law)
1272/2008/EC CLP Reg.	By-law On The Classification, Labelling And Packaging Of Substances And Mixtures (11.12.2013/28848) (CLP By-law)
91/155/EC DirREACH Annex II	By-law On The Preparation And Distribution Of Safety Data Sheets (26.12.2008/27092)
76/769/EC Dir REACH Annex XVII	By-law On Restriction Of The Production, Placing On The Market And Use Of Certain Dangerous Substances, Preparations And Articles (26.12.2008/27092)
440/2008/EC Dir.	By-law On Test Methods Applied For Determining The Physicochemical Toxicological And Ecotoxicological Properties Of The Substances And Mixtures (11.12.2013/28848)

By Law on Inventory and Control of Chemicals (793/93/EEC) NATIONAL NEEDS

# LEGISLATIVE FRAMEWORK

# COMMON OBJECTIVES OF CPL AND CLP BY-LAW:

- Protect human health & the environment
- Defining rules and principles for classification labelling and packaging

# **ADDITIONAL OBJECTIVE OF CLP BY-LAW:**

- Facilitate international trade in chemicals

## MAIN DIFFERENCES:

- New Symbols
- Changes in cutt of values
- New wording and phrases
- «bridging principles»
- An Different methods for calculation

# Notification&Inventory

# LEGISLATIVE FRAMEWORK

CPL By-Law	CLP By-Law
7 Pictograms	9 Hazard Pictograms
15 Danger Category	28 Hazard Category
Risk Phrases (R)	Hazard Statement (H)
Safety Phrases (S)	Precautionary Statement (P)
	Supplemental Hazard Informations and Label Elements
	Signal Words (Danger/Warning)
Annex II	Annex VI
	Annex VII – Translation Table
preperation	mixture
danger	hazard

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Generally applies to all hazardous substances and mixtures placed on the market

Exemptions are:

- Medical products
- Veterinary medicinal products
- Cosmetic products
- Medical devices
- Food or feeding stuff

in the finished state, intended for the final user

Additional exemptions

- Radioactive substances and mixtures which are subject to customs supervision
- Non-isolated intermediates
- Substances and mixtures intended for scientific research and development,
- Waste
- Transport of hazardous substances
- Note rules on labelling of outer, inner and single packaging (Article 35 CLP)
- By-Law)

#### Ahu ÇÉKİM

Annex I	CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES
Annex II	SPECIAL RULES FOR LABELLING AND PACKAGING OF CERTAIN SUBSTANCES AND MIXTURES
Annex III	LIST OF HAZARD STATEMENTS, SUPPLEMENTAL HAZARD INFORMATION AND SUPPLEMENTAL LABEL ELEMENTS
Annex IV	LIST OF PRECAUTIONARY STATEMENTS
Annex V	HAZARD PICTOGRAMS
Annex VI	HARMONIZED CLASSIFICATION AND LABELLING FOR SOME HAZARDOUS SUBSTANCES
Annex VII	TRANSLATION TABLE FROM CLASSIFICATION UNDER BY-LAW ON CLASSIFICATION PACKING AND LABELING OF DANGEROUS SUBSTANCES TO CLASSIFICATION UNDER THIS BY-LAW
Annex VIII	CONDITIONALATIES REGARDING CLASSIFICATION AND NOTIFICATION OF SUBSTANCES
Annex IX	GENERAL PROVISIONS FOR ADAPTATION OF THE STANDARD TESTING REGIMES
Annex X	INFORMATION PRESENTED TO PUBLIC ACCESS
Annex XI	HAZARD ASSESSMENT AND FORM FOR SUBMITTING HARMONISED CLASSIFICATION
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#### MAIN RESPONSIBILITIES

- Classify substances and mixtures before placing them on the market. (Art. 6)
- Use harmonised classification, if possible (Art. 6)
- Label and package a substance or a mixture in accordance with the classification (Art. 6)
- Keep up to date with new scientific and technical information (Art. 17)
- Propose harmonised classification when appropriate (Art. 38)
- Notify to the MoEU the classification and label elements (Art.41)
- Keep all relevant information for 10 years (Art. 49)

	Classify/ Propose Harm. Classic.	Label	Package	Notify	Keep info 10 yrs
Manufacturer	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Importer	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Downstream User	✓ *	√	$\checkmark$	Х	$\checkmark$
Distributor	x***	$\checkmark$	$\checkmark$	Х	$\checkmark$

\* Change composition - classify. If not, use supplier's.\*\*\* Distributor may use classification of another actor

### CLASSIFICATION

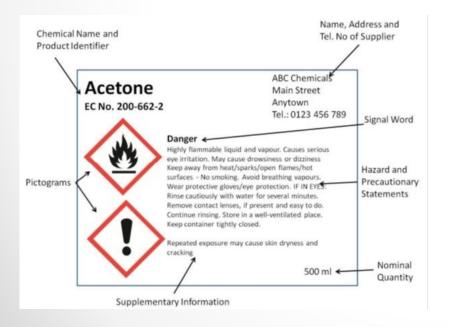
- Identify and examine available information / cross-check is the information relevant and reliable?
- Develop new information (phys. haz:performing tests; health and env. haz. : available data)
- Expert judgement & weight of evidence (If the classification criteria cannot be applied directly to available identified information)
- Bridging Principles (where no or inadequate test data on the mixture itself)

OTHER METHODS (Annex I / Part III)

### LABELLING

#### In Turkish

Suppliers may use more languages on their labels than Turkish, provided that the same details appear in all languages used.





#### BY-LAW ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES

# Content Of The Label (Article 19 ate: 11.12.2013)

- The name, address and telephone number of the supplier
- The nominal quantity of the substance or mixture
- Product identifiers
- Hazard pictograms
- Signal word
- Hazard statements
- Precautionary statements
- Supplemental information

## Updating the Label

Any change on the classification and labelling resulting a more sewere hazard or where new supplemental labelling elements are required

#### updated without undue delay

Other conditions label should be updated within 18 months

#### BY-LAW ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (Enf. Date:11.12.2013) USE OF ALTERNATIVE NAME (Article 26)

for confidentiality reasons –on the label or in the safety data sheet

- Request the relevant Institution (in the format and fee amount exists in the web page of MoEU)
- Alternative names could be used in label and in the safety data sheet for six years

when the classification of the substance in a mixture for which the alternative name is used no longer meets the 'conditions to use an alternative chemical name'

product identifier on the label and in the safety data sheet for the substance and not the alternative chemical name

PACKAGING (Article 36)

- Designed and constructed so that its contents cannot escape
- Material must not be susceptible to damage by contents or liable to form hazardous compounds with the contents
- Packaging and fastenings shall be strong and solid
- Repeated refastening of replaceable fastening must be possible without the contents escaping
- Package containing a hazardous substance / mixture supplied to the general public shall not mislead consumers.

## **PROPOSAL FOR HARMONISED CLASSIFICATION**

May be submitted to the MoEU (in accord. with Annex-11 incl.inf. Annex-6)

✓ Pay fee for the proposal

- ✓ MoEU shall adopt an opinion within 18 months

### **INFORMATION TO BE NOTIFIED (Article 41)**

- Identity and contact details
- Location of the production;
- Identity of the substance(s)
- Classification of the substance(s)
- The reason for "no classification"
- Spec. Con. Limits or M-factors and justification
- Label elements (hazard pictograms, signal words, hazard statements and any supplemental hazard statements)

\*for substances placed on the market before 1/6/2015, notify between 1/6/2014 and 1/6/2015

The obligations on notification of importers could be performed through a representative that is established in Turkey (appointed with an agreement determined by the natural or legal persons settled abroad).

### **TRANSITIONAL PROVISIONS (I)**

- From 11 December 2013 until 1 June 2015 substances shall be classified with both
- CPL By-Law and CLP By-Law
- They shall be labelled in accordance with CPL By-Law
- Declaration of classification according to CPL in the safety date sheets is obligatory
- Until 1 June 2016 mixtures shall be classified, labelled and packaged in accordance with CPL By-Law
- **Repeal** of CPL By-Law with effect from 1 June 2016



# **TRANSITIONAL PROVISIONS (II)**

Exemptions from transitional provisions:

Substances and mixtures

- Classified, labelled and packaged in accordance with CPL By-L and
- Placed on the market before 1 June 2015/1 June 2016

Not relabeled and repackaged in accordance with CLP By-Law untill

- I January 2017 for substances
- I June 2018 for mixtures

**Enforcement date**: 26 December 2008

Aim: Determine the principles and procedures related with compilation and distribution of safety data sheets

Manufacturer, importer and distributor responsible with the placing on the market of the dangerous substance or preparation has to provides the professional user of this dangerous substance or preparation a safety data sheet

- ✓ Feeless
- ✓ Turkish
- ✓ Supplied via paper or electronically
- Prepared by persons certified by institutions which are acredited about certification of persons
- ✓ A copy to relevant inst. and electronic copy to MoEU

#### BY-LAW ON TEST METHODS APPLIED FOR DETERMINING THE PHYSICOCHEMICAL TOXICOLOGICAL AND ECOTOXICOLOGICAL PROPERTIES OF THE SUBSTANCES AND MIXTURES

Enforcement date : 11 December 2013

*Aim:* For the purposes of tests on substances where such tests are required to generate information on intrinsic properties (phys. chem., tox.,ecotox.) of substances

To obtain the information listed in the Annex IX of CLP By-Law

Parallel to 440/2008/EC

# BY-LAW ON RESTRICTION OF THE PRODUCTION, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

*Enforcement date:* 26 December 2008

Asbestos Polychlorinated terphenyls (PCT) Polychlorinated biphenyls (PCB) Polybromobiphenyls (PBBs)



can not be manufactured used placed on the market

Azo colourants & Azo dyes Some Phytalates(DEHP/DBP/BBP/DINP/DIDP/DNOP) Tris (2,3 dibromopropyl) phosphate Tris (aziridinyl) phosphine oxide

RESTRICTED

Under Revision;

Additional Chemicals (11 diff. substances and compouds)

# BY LAW ON INVENTORY AND CONTROL OF CHEMICALS

<u>Aim is to constitute Turkish Chemicals Inventory in order to apply better</u> <u>chemicals management</u>

*Enforcement date* : 26 December 2008 (Amend.Nov.2009,May 2010)

Turkish manufacturers or importers of substances, on its own or in a preparation

in quantities of

- one thousand tonnes per year or more
- one tonne or more but less than one thousand tonnes

Is not applied to:

➤ substances in transit

> subtances manufactured or imported for military purposes

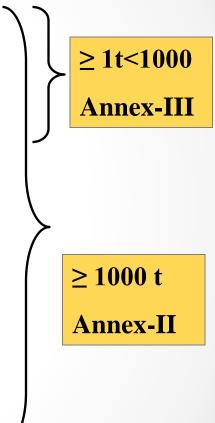
No Submission Fee

**Available Data** 



# **DATA TO BE SUBMITTED**

- Substance Name, EC number ve CAS number
- The quantity of the substance produced or imported
- Classification
- Information on the reasonably foreseeable uses
- > physico-chemical properties
- pathways and environmental fate
- ecotoxicity
- acute and subacute toxicity
- carcinogenicity, mutagenicity and/or toxicity for reproduction (CMR)
- any other information relevant to the risk evaluation





# **EXEMPTIONS LIST (ANNEX I)**

- Substances which occur in nature, if they are not chemically modified (minerals, ores, natural gas, coal, coke)
- Basic elemental substances for which hazards and risks are already well known (hydrogen, oxygen, noble gases)
- 75 substances which properties are well known and listed in the Annex 1 according their EC and CAS numbers
- Polymers



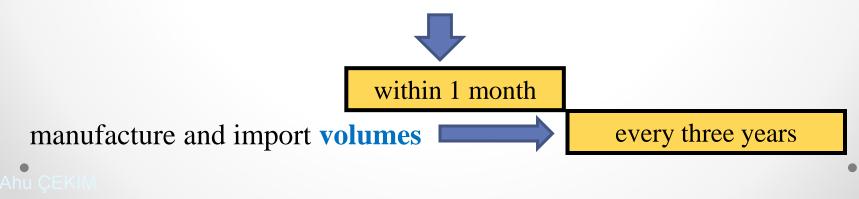
#### **UPDATING OF DATA**

New uses of the substance which substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance

# New data on the physico-chemical properties, toxicological or ecotoxicological effects

Any change in the provisional classification under By-law on Classification, Packaging and Labelling of Dangerous Substances and Preparations

New information obtained about a substance which may present a serious risk to man or the environment



# BY LAW ON INVENTORY AND CONTROL OF CHEMICALS

# **MAIN OUTPUTS**

**Appr. 10000 entries for substances manufactured or imported ≥1 t/pa** 

#### **Published Lists;**

- List of substances on its own or in a preparation, in quantities exceeding 1 tonnes per year in Turkish market (3000 substances)
- List of High Production Volume (HPV) Chemicals (600 substances)
- List of priority substances or groups of substances (131 substances)

TONNAGE RANGE	NUMBER OF SUBSTANCES	
1-10 t	750	
10-100 t	950	
100-1000 t	700	
> 1000 t	600	
Total 3000 different substances		

# **IMPLEMENTATION OF REACH**

# **REACH Chemicals Project 2011-2013**

- Awareness of major groups (manufacturers, importers, downstream users of chemicals) and decision makers has been raised.
- Chemicals Registering System & Chemicals Helpdesk has been established
- Draft legislation and guidelines on REACH has been prepared.

**REACH** Advisory Group (6 Ministries&12 Industrial Organizations)

# **CHEMICALS HELPDESK**

# https://kimyasallar.csb.gov.tr

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#### Anasayfa

BAKANLIĞI

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**REACH Neulir?** 

ÇEVRE VE ŞEHİRCİLİK

- Reach Tuzüğü
- KKDIK Nedir?
- Meyzuat
- Yardım Masası Amacı ve Kapsamı
- Reliber Dokümanlar
- Laydalı Hağlantılar
- Silica Sorulan Sorular
- Haberler
- Duyurular
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#### Soru Formu

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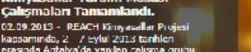
#### Kimyasallar Yardım Masası Çalışmaları Tamamlandı.

kapsaminda, 2 / Eylul 2013 tarihlen arasında Antalya'da yapılan çalışma gruhu Lupla...

**KIMYASALLAR** 

**YARDIM MASASI** 

Devamu



Go to page 7



#### Kimyasallar Yardım Masası Kapsamı

Kimyasallar Yardın Masası, 'Kimyasalların Kaydı, Değerlendirmesi, İzni ve Kısıtlanması' ve 'Maddelerin ve Kansımların Sınıflandırılması ve Etiketlenmesi' kapsamında sorularınıza kolay ve etkin bir sekilde cevap bulabileceğiniz bir bilgilendirme servisidir.



# CHEMICALS REGISTERING SYSTEM

#### http://online.cevre.gov.tr

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