

# A Synopsis of Current Turkish Chemicals Regulations

Tuğçe Gizem Gürlerođlu  
SCHC Annual Meeting 2021

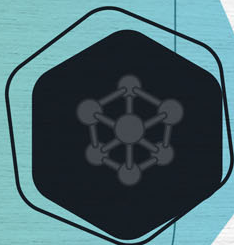




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# A SYNOPSIS OF TURKISH CHEMICALS REGULATIONS

***KKDIK, SEA, SDS***



Society for Chemical Hazard Communication



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2 November 2021

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# OUTLINE

- About REACH Global Services Group
- EU-Turkey Regulatory Approximation
- KKDİK, Transition & Key Provisions
- A Glance at KKS – Chemical Registration System & Latest News
- Tips to Consider
- Post Pre-Registrations
- SEA (Turkish CLP)
- SDS Obligations
- Foreseeable Challenges
- Choices for Compliance
- Take Home Messages



# REACH GLOBAL SERVICES GROUP

- Incorporated in 2008 in Brussels under Belgian Law (RGS S.A.) and in Istanbul under Turkish Law (RGS Danışmanlık A.Ş)
- Professional regulatory compliance consultancy ensuring worldwide chemical manufacturers and industries to comply with chemicals legislations
- Founding Member of ORO; the European Only Representative Organisation



***Each customer is a "project" deserving a tailor-made solution that best suits its needs!***



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# REACH GLOBAL SERVICES GROUP

## Our Services

### *EU Regulatory compliance services*

- EU REACH consulting
- Only Representative & Third Party Representative
- Inquiry - Registration dossier preparation/submittal to ECHA
- SIEF- Consortia Representation & Strategies on Data Sharing
- Product audit and certification
- EU Cosmetics Regulation Compliance Services
- PIF Preparation & Responsible Person
- Cosmetic Product Safety Report and Notification to CPNP

### *Turkish Regulatory compliance services*

- Turkish REACH (KKDIK) consulting
- Only Representative & Third Party Representative
- Pre-SIEF & Registration dossier preparation and submittal to MoEU
- SIEF – Consortia management & Strategies on data, cost sharing
- Defining obligations & strategic product planning
- Turkish CLP (SEA) representative
- Submission of C&L notifications in the local language with the required data
- Regulatory update monitoring
- Preparation of SDS&CSR by certified in-house authors

### *Global Chemicals Legislations*

- Global Chemicals Legislations
- Compliance with REACH-like regulations in Korea, China, Japan and Taiwan
- Submission of notifications & registrations in the local language
- Local Only Representative services
- Post-Brexit UK-REACH services
- SDS Authoring services

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# REACH GLOBAL SERVICES GROUP

## 13-Year-Long Track Record

>1035 manufacturers' compliance with **global chemicals regulations** from 53 countries

- >500 non-EU manufacturers since 2008 under EU REACH
  - >2000 substances pre/registered with ECHA
- >180 worldwide manufacturers' compliance with **Turkish CICR & CLP By-Laws**
  - >2000 substances notified under CICR&CLP (2008-2017)
- >310 global manufacturers' Compliance with **KKDIK** since entry into force
  - >12500 substances pre-registered under KKDIK for global manufacturers as OR and TPR

>55 non-EU manufacturers' compliance with **EU Cosmetics Regulation**

- > 2500 CPNP notifications as the Responsible Person for products

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## CHEMADVOCACY

- A joint venture of global leading regulatory affairs consultancy companies
  - Transposing EU REACH, K-REACH, UK REACH experience on Consortia Management, Data management, Financial Management into KKDIK
- “One-Stop-Shop” for KKDIK Compliance
  - Technical and administrative services to manage KKDIK technicalities regarding data sharing and LoA management.



## CHEMSERVICE



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# EU-TURKEY REGULATORY APPROXIMATION

Turkey-EU  
Customs Union (CU)  
providing for a single  
customs area  
(EU+TR) and free  
circulation of goods

Any chemical  
substance or article  
manufactured either  
in Turkey or in the EU  
benefits from free  
circulation

CU is applicable for  
manufactured  
industrial products  
only

Approximation of the  
regulatory  
framework  
applicable to  
chemical industry  
was necessary



**1963 - EEC-Turkey - Association  
Agreement (Ankara Treaty)**

**1995 - Turkey-EU Customs Union  
(Decision 1/95)**

**KKDIK & SEA (CLP) → regulatory  
approximation measures  
within the EU-Turkey ongoing legal  
relationship**

## KKDIK – Article 65

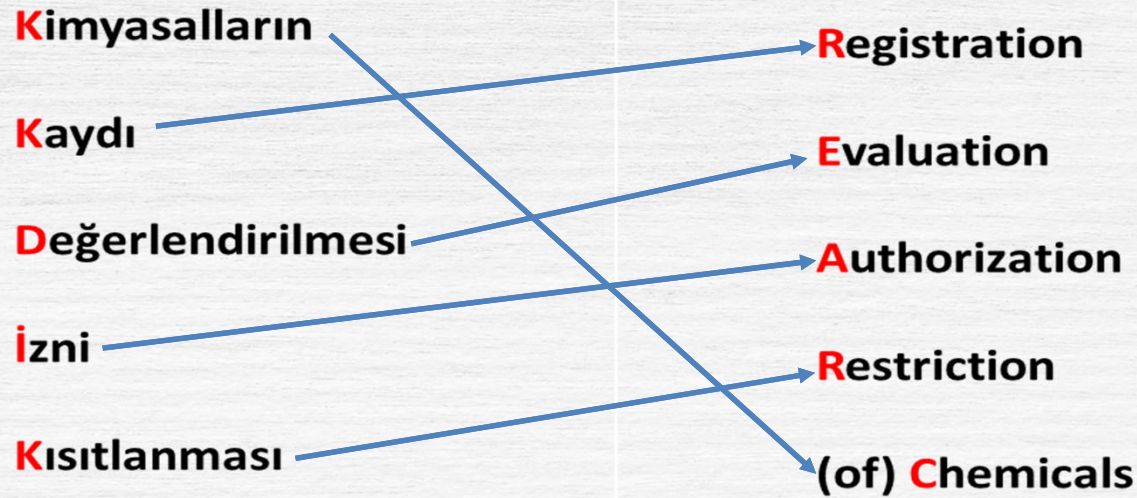
- **Art 65** - This Bylaw was prepared taking into account Regulation of European Parliament and Council numbered 1907/2006/EC on Registration, Evaluation, Authorization and Restriction of Chemicals in the framework of harmonization of European Union acquis.

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# KKDİK – Transition & Key Provisions

## KKDİK (2017)

## REACH (2007)



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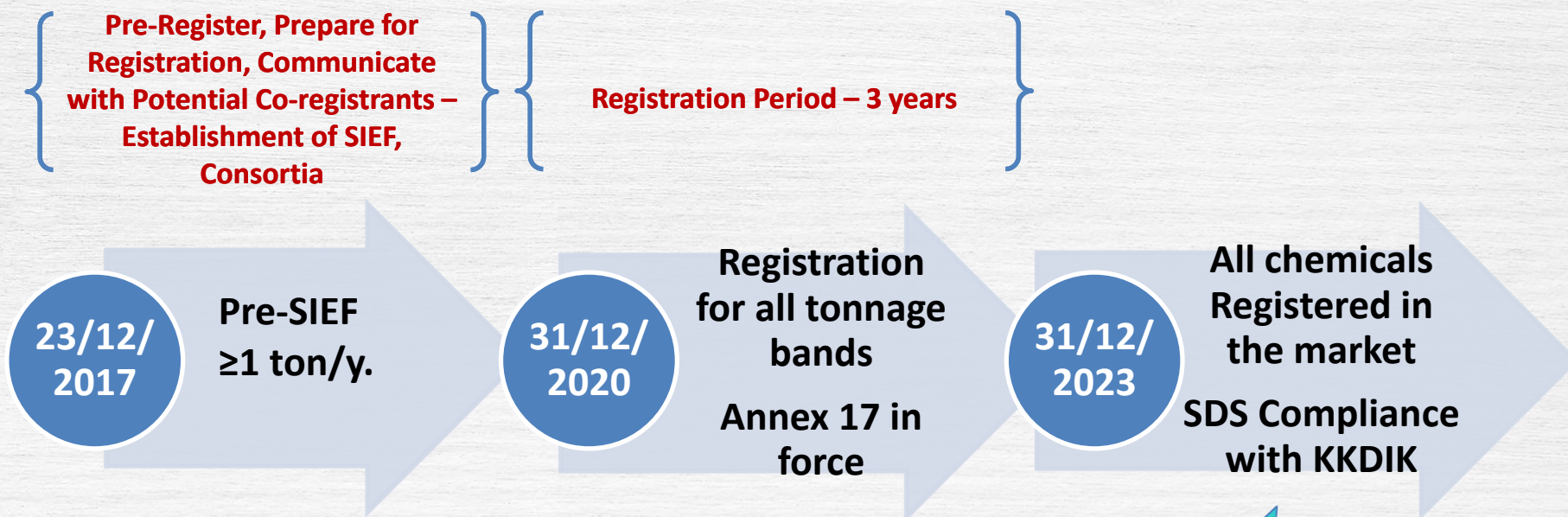
# KKDIK Annexes

<b>Annex I</b>	<b>General Provisions For Assessing Substances And Preparing Chemical Safety Reports</b>
<b>ANNEX II</b>	<b>Guide To The Compilation Of Safety Data Sheets</b>
<b>ANNEX III</b>	<b>Criteria For Substances Registered In Quantities Between 1 And 10 Tonnes</b>
<b>ANNEX IV</b>	<b>Exemptions From The Obligation To Register In Accordance With Article 2(7)(a)</b>
<b>ANNEX V</b>	<b>Exemptions From The Obligation To Register In Accordance With Article 2(7)(b)</b>
<b>ANNEX VI</b>	<b>Information Requirements Referred To In Article 10</b>
<b>ANNEX VII</b>	<b>Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 1 Tonne Or More</b>
<b>ANNEX VIII</b>	<b>Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 10 Tonnes Or More</b>
<b>ANNEX IX</b>	<b>Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 100 Tonnes Or More</b>
<b>ANNEX X</b>	<b>Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 1 000 Tonnes Or More</b>
<b>ANNEX XI</b>	<b>General Rules For Adaptation Of The Standard Testing Regime Set Out In Annexes VII To X</b>
<b>ANNEX XII</b>	<b>General Provisions For Downstream Users To Assess Substances And Prepare Chemical Safety Reports</b>
<b>ANNEX XIII</b>	<b>Criteria For The Identification Of Persistent, Bioaccumulative And Toxic Substances, And Very Persistent And Very Bioaccumulative Substances</b>
<b>ANNEX XIV</b>	<b>List Of Substances Subject To Authorisation</b>
<b>ANNEX XV</b>	<b>Dossiers</b>
<b>ANNEX XVI</b>	<b>Socio-Economic Analysis</b>
<b>ANNEX XVII</b>	<b>Restrictions On The Manufacture, Placing On The Market And Use Of Certain Dangerous Substances, Preparations And Articles</b>
<b>ANNEX XVIII</b>	<b>Conditions For Receiving Certificate Of Competency Of Chemical Assessment Expert</b>

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# KKDIK TIMELINES



SVHC List 2024

Annex 14 2024



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## KKDIK & Key Provisions

- Official Gazette No 30105 of 23/06/2017
- Applies to manufactured or imported chemicals  $\geq 1$  tonne per year (Art 7(1))
- Join pre-SIEF until **31/12/2020**
- One Registration Period **31/12/2020 – 31/12/2023** for all tonnage bands
- Web portal - Chemical Registration System (**KKS**)
- **OSOR Principle**



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## KKDIK & Key Provisions

- Typical REACH data required for registration dossier
  - KKDIK registration dossier in Turkish language
  - Registration dossier created online
  - Test reports, acceptance in English with Turkish summary (for Ecotox. – tox?, Analytical?)
- Same REACH Terms: Lead Registrant, Data sharing, SIEF, Consortium, LoA
- Chemical Safety Report
  - Prepared and signed by a certified Risk Assessor - certification principles & conditions in Annex XVIII
- Fee Regulation based on individual and member submissions are announced based on tonnage bands & company size
  - Cheaper than ECHA fees in Turkish currency (50 TL to 15000 TL ~ 5 € - 1500 €)



# A GLANCE AT KKS – CHEMICAL REGISTRATION SYSTEM

A system hybrid of REACH-IT  
and IUCLID 6.4 in Turkish  
language



Entegre Çevre Bilgi Sistemi  
v3.2.298



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# A GLANCE AT KKS – CHEMICAL REGISTRATION SYSTEM

**Madde 7** [i] [-] [+] [x]

Şablonlar Hepsi [v]

- 1 Genel Bilgi
- 2 Sınıflandırma&Etiketleme ve Kalıcı, Biyobirikimli ve Toksik özelliklerin değerlendirilmesi
- 3 İmalat, kullanım ve maruz kalma
- 4 Fiziksel ve kimyasal özellikler
- 5 Çevresel akıbet ve yolları
- 6 Ekotoksikolojik Bilgi
- 7 Toksikolojik bilgi
- 8 Analitik metodlar
- 9 Yiyecek ve besin maddelerinde kalıntılar
- 10 Hedef organizmalara karşı etki
- 11 Güvenli kullanım üzerine rehber
- 12 Literatür (yayın) araştırması
- 13 Değerlendirme Raporları
- 14 Bilgi gereklilikleri

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# A GLANCE AT KKS – New Turkish CHESAR like tool

## KGDRS- Tüketici Maruz Kalma Değerlendirmesi

The screenshot shows the KGDRS web application interface. At the top, there is a navigation bar with the logo and the text 'KGDRS Proje Adı: hhh'. Below this, there is a table with columns for 'Kategori', 'Durum', and 'Tutarlar'. The table lists several chemical substances with their respective CAS numbers and hazard information.

Kategori	Durum	Tutarlar
Tüketici	Tüketici Kalanları	1. Kullanım: 200000 g/ yıl 01/01/2011 - 01/01/2011
Tüketici	Tüketici Kalanları	2. Kullanım: 200000 g/ yıl 01/01/2011 - 01/01/2011
Tüketici	Tüketici Kalanları	3. Kullanım: 200000 g/ yıl 01/01/2011 - 01/01/2011
Tüketici	Tüketici Kalanları	4. Kullanım: 200000 g/ yıl 01/01/2011 - 01/01/2011
Tüketici	Tüketici Kalanları	5. Kullanım: 200000 g/ yıl 01/01/2011 - 01/01/2011

Below the table, there is a list of chemical substances with their CAS numbers and hazard information:

- 1. Kullanım: 200000 g/ yıl  
01/01/2011 - 01/01/2011
- 2. Kullanım: 200000 g/ yıl  
01/01/2011 - 01/01/2011
- 3. Kullanım: 200000 g/ yıl  
01/01/2011 - 01/01/2011
- 4. Kullanım: 200000 g/ yıl  
01/01/2011 - 01/01/2011
- 5. Kullanım: 200000 g/ yıl  
01/01/2011 - 01/01/2011

## KİMYASAL GÜVENLİK RAPORU

Maddelerin Adı: Etilenoksit  
 EC Numarası: 600-000-9  
 CAS Numarası: 75-21-8  
 Kayıt Etiriminin Kimliği: Kayıt Etilenoksit

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## Latest News from the MoEU

- KKS has 14 sections now, approximating IUCLID 6.4
- CSR tool (KGDRS) for Turkey is completed, ready for users as of Oct 31
- CSR tool implemented in KKS, one system for dossier and CSR preparation (in EU, Chesar is a separate tool)
- CSRs need to be in Turkish with the signature of CAE
- Direct translation of the EU CSR cannot be used - a need for modified uses and calculations



## Latest News from the MoEU

- Incorrect/misleading information can lead to penalties or imprisonment
- The penalties for manufacturers and importers are up to 4M TL. ~ 400K Euros
- Only 2 to 3 labs (in Turkey) with GLP, companies may coop with global laboratories
- Company size information will be rendered from the integrated environmental system
- Automatic fee calculation is involved in KKS
- For the time-being about 70 (LE/co-registrant) dossiers are submitted



## Latest News from the MoEU

- Completeness check will be completed by the MoEU in 3 weeks
- There is no refund if the company is unable to resubmit the corrected dossier within the given time
- Once the Lead submits their dossier, the co-registrants are informed automatically
- There is a voting in the system for substances where there is more than one LR nominee
- For registration dossiers, DU information is required



## TIPS TO CONSIDER

- Several legal entities of global companies
  - same substance might be (pre-)registered more than once
- Any Toll Manufactured chemicals
- Indirect exports
  - Substances flowing through other supply chains into Turkey
- How critical is your substance for Turkish market – data, market

**Substances placed on the TR market**



- Raw materials supplied from different manufacturers
- Suppliers with no interest in Turkish market
- If your Suppliers are compliant, no problem
  - Make sure that your volume and uses are covered under the registration
  - Seek for compliance declarations
- If non-compliant – find a new Supplier or pre-register yourself

**Mixtures & polymers placed on the TR market**



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## Your OR will guide you through compliance and...

- **Pre-register substance(s)**
  - Understand your business & substance inventory
- **Engage in pre-SIEF discussions with other pre-registrants;**
  - Determine how pre-SIEF is strategic for the company
- **Participate in SIEFs once it is formed;**
  - Engage in discussion to assess the commitment level
- **Participate in consortia once they are formed and when/if necessary;**
  - consortium agreement & level of involvement



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## POST PRE-REGISTRATION

- SIEF Activities
  - SIEF communications (Lead)
- Data gathering (Lead)
- Letter of Access (LoA) and data management
- What if there is no LR?
- Bilingual communication
- Different Platforms emphasized
- Close follow up of the Authority MOEU – Crucial – quick changes
- Tonnage band decision
  - Monitoring annual volume



# REGISTRATION

pre-SIEF

KKDIK

SEA

CICR





# SEA (Turkish CLP)



- Official Gazette No 28848 of **11/12/2013**
- Published **before** Turkish REACH Regulation (unlike in the EU)
- SEA in line with EU CLP with some differences to adapt and minor local changes
- Notifications: Same Web Portal Chemical Registration System (**KKS**) for **KKDIK & SEA**
- An amendment to SEA was applied last year, to make sure that the interfaces with KKDIK are clear



# SEA Obligations

- Applies to **hazardous substances and polymers** regardless of the volume
- Any new substances placed on the market after June 2015 must be notified within **a month**
- **SEA substances put on the Turkish market  $\geq$  1 ton/year have to be registered under KKDİK as well**
- Any classified impurity, additive or individual constituent in a mixture that may **trigger** the classification of the substance, or the mixture must be notified



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# SEA Obligations

- Update of **Labelling and Packaging** according to the **Classification**
- The information on the **labelling** must be **consistent** with the information on the SDS
- **Labelling** must be in **Turkish** and in accordance with the requirements due to packaging volume, pictogram size, substance information hazard and precautionary statements with the correct Turkish wording
- Depending on the **changes** labelling must be updated immediately or within 18 months



# SDS REGULATION AND CURRENT OBLIGATIONS

## Transitional Article 2(2) of KKDIK

*Safety Data Sheets shall be prepared according to the SDS Regulation in force until 31 December 2023.*

**(Still in Force: By-law on the Safety Data Sheets of Hazardous Substances and Mixtures No 29204, dated 2014)**

- Manufacturers, importers and distributors
  - ✓ actors placing hazardous substances or mixtures have the obligation to provide SDSs down the supply chain
  - ✓ In Turkish language, prepared by a certified authorized person
  - ✓ Hard copy, written or electronic format free of charge etc.
  - ✓ Submission to the Ministry - online

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# SDS OBLIGATION

## Certification Requirements

- SDSs can be **prepared by** certified SDS authors  
Only translation of the remaining SDS into Turkish is not sufficient
- **Exam procedure** in Turkish for SDS and CSR experts by the MoEU's accredited bodies
- CSR Expert **can also** prepare and certify an SDS; though an SDS expert **can not** prepare and sign a CSR, unless certified as a CSR expert (**KDU**) (Annex XVIII)
- Safety data sheets can also be prepared in accordance with the provisions of KKDİK from the effective date of Article 27 until 31/12/2023 (**Transitional Article 2(3)**)



## FORESEEABLE CHALLENGES

- Unqualified and inexperienced Only Representatives
- Turkish and Global Manufacturers in the same SIEF – How to communicate?
- Language burden (Turkish, English communications at the same time)
- Chemical Safety Experts newly graduated or with no REACH, or toxicology experience
- Translation will be required – cost & quality

## FORESEEABLE CHALLENGES

### MISINTERPRETATION - MISGUIDANCE

- Registration dossier must be prepared and submitted by a certified chemical safety expert – **WRONG!**
  - It is the legal entity that submits the dossier - **CORRECT**
  - CSR must be prepared by the certified expert - **CORRECT**
- Certified & Approved Only representatives – **WRONG!**
  - No accreditation or approval for ORs - **CORRECT**
- No volume tracking needed – **WRONG!**
  - Volume tracking is crucial - **CORRECT**

# FORESEEABLE CHALLENGES

## LEGAL TRUTH

Have time to pre-register – **WRONG!**

Deadline was at the end of 2020 - **CORRECT**

Late pre-registration still possible for the first-time marketed products - **CORRECT**

Have time to notify for SEA – **WRONG!**

Placing hazardous chemicals (substances/polymers) on the market – then notification within 1 month after placing on the market - **CORRECT**



# FORESEEABLE CHALLENGES

## LEAD REGISTRANT

### Management of Consortia

Data has to be exchanged between competitors  
Secretarial, fiduciary and financial activities

### Letter of Access management

Data, dossier and administrative costs  
Communication, Documentation, Calculation

### Study Management

Evaluation of studies, study monitoring  
Communication, calculation of cost shares

### Data Management

Compilation of Agreements  
Data documentation, invoicing, financial management  
Translation will be required – cost & quality

# THE RIGHT STRATEGY FOR NON-TURKISH MANUFACTURERS

**IF YOU ARE MISGUIDED , UNDESIRABLE COST!**

- Your **local importer** can register

**Risk:** You need to supply Confidential Business Information to the importer – you can not sell to any other importer or distributor

- You may appoint your **Turkish subsidiary** to register

**Problem:** Few staff to deal with the compliance burden, may need to outsource the work from a professional consultancy company

- You can appoint a professional **Only Representative company**

**FREEDOM:** CBI kept safe – Ownership of registration numbers - selling your products to any importer or distributor in Turkey



## Take Home Messages

- Identify your substance list considering your global supply chain & (Late)Pre-Register
- Plan ahead your strategy for compliance (SEA, KKDIK, SDS) !
- **JOIN PRE-SIEF NOW**
  - Communicate within SIEF and check who is the Lead Registrant
  - Make sure SIP covers your substance composition
  - Define your tonnage band for dossier information requirements
- **PREPARE FOR REGISTRATION**
  - Data Management
    - Data Sharing/Gathering
    - License to use
    - Communication with EU Consortia/lead registrant/data owner
- Closely monitor the developments in KKDIK

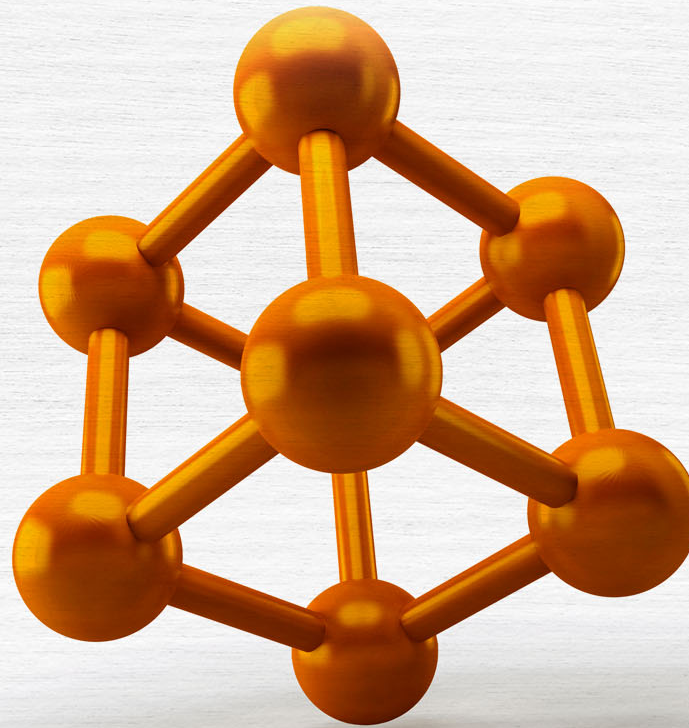
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**Thank You!**

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