IMPLEMENTATION OF ‘EU-REACH LAW’ IN **TURKEY**

TURKREACH

(abbreviated as) **KKDIK**

THE NEW TURKISH BY-LAW ON REGISTRATION, EVALUATION, AUTHORIZATION & RESTRICTION OF CHEMICALS

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Madrid

FEBRUARY 2nd, 2018

KKDIK (TURKREACH)

- This presentation, with notes, was prepared by DORUKSISTEM, the leading Chemicals Related Regulatory Compliance Consultant Co. in Turkey, to assist you about the TURKREACH - KKDIK.

- This presentation gives a short overview of the topics in the context of TURKREACH - KKDIK and gives an overview of Turkey's REACH KKDIK-2023 Roadmap.
- We welcome your comments and suggestions at info@doruksistem.com.tr

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- Evaluation
- Authorisation
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- TURKREACH KKDIK Critical Points
- SDS and labelling
- Fees

KKDIK (TURKREACH)

Overview

On June 23, 2017 the Turkish Ministry of Environment and Urbanization (MoEU) published regulations for the management of substances, very similar to the EU REACH regulation, (EC) No 1907/2006.

Regulation is known as KKDIK, it is an acronym in the Turkish language for Registration, Evaluation, Authorization and Restriction of Chemicals:

- **K**imyasalların (Chemicals)
- **K**aydı (Registration)
- **D**eğerlendirilmesi (Evaluation)
- **İ**zni (Authorisation)
- **K**ısıtlanması (Restriction)

Registration
Evaluation
Authorisation
Restriction of
CHemicals

The KKDIK regulation came into effect on December 23, 2017.

KKDIK (TURKREACH)

The Regulation - Sections

PARTS #	PART TOPICS
1	GENERAL ISSUES
2	REGISTRATION OF SUBSTANCES
3	DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING
4	INFORMATION IN THE SUPPLY CHAIN
5	DOWNSTREAM USERS
6	EVALUATION
7	AUTHORIZATION
8	RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES
9	FEES AND CHARGES
10	ACCESS TO INFORMATION
11	EXECUTION AND ENFORCEMENT
12	GENERAL AND FINAL PROVISIONS

KKDIK (TURKREACH)

The Regulation - Annexes

#	ANNEX NAME
1	GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS
2	REQUIREMENTS FOR PREPARING SAFETY DATA SHEETS (SDS)
3	CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES
4	EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(5)(a)
5	EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(5)(b)
6	INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 11
7	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 TONNE OR MORE
8	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE
9	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE

KKDIK (TURKREACH)

The Regulation - Annexes

#	ANNEX NAME
10	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE
11	GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X
12	GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS
13	CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES
14	LIST OF SUBSTANCES SUBJECT TO AUTHORISATION
15	DOSSIERS
16	SOCIO-ECONOMIC ANALYSIS (SEA)
17	RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES
18	CONDITIONS FOR RECEIVING CERTIFICATE OF COMPETENCY OF CHEMICAL ASSESSMENT EXPERT

KKDIK (TURKREACH)
Repealing & Replacing

KKDIK - TURKREACH replaces three existing regulations:

- The Inventory and Control of Chemicals (CICR was immediately replaced by KKDIK regulation on June 23, 2017)
- The Restrictions Relating to the Production, Supply to the Market and Use of Certain Hazardous Materials, Products and Goods; (repealed on December 23, 2017)
- The Preparation and Distribution of Safety Data Sheets for Hazardous Materials and Products; (will be replaced from December 31, 2023)

KKDIK (TURKREACH)

Aim

The purpose of KKDIK is

to regulate the administrative and technical procedures and principles regarding the registration, evaluation, authorization and restriction of chemicals,

to ensure a high level of protection of human health and the environment,

including the promotion of alternative methods for assessment of hazards of substances while enhancing competitiveness and innovation.

KKDIK (TURKREACH)

Scope

KKDIK covers

manufacturing, placing on the market or use of the substances on their own, in a mixture or in an article and placing the mixtures on the market.

>1 ton per year

KKDIK (TURKREACH)

Out of Scope

KKDIK shall not apply ;

- Radioactive substances and mixtures
- Substances, on their own, in a mixture or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re- exportation, or in transit;
- Non-isolated intermediates;
- The carriage of hazardous substances and hazardous mixtures by rail, road, inland waterway, sea or air;
- Wastes
- Substances and mixtures which are manufactured or imported for the purpose of defense

KKDIK (TURKREACH)
Out of Scope

- Medicinal products for human or veterinary use
- Foods
- Feeding stuffs

The provisions of Second Part (**Registration**), Fifth Part (**Downstream Users**), Sixth Part (**Evaluation**) and Seventh Part (**Authorisation**) shall not apply to these substances manufactured or imported in order to use in the products

KKDIK (TURKREACH)

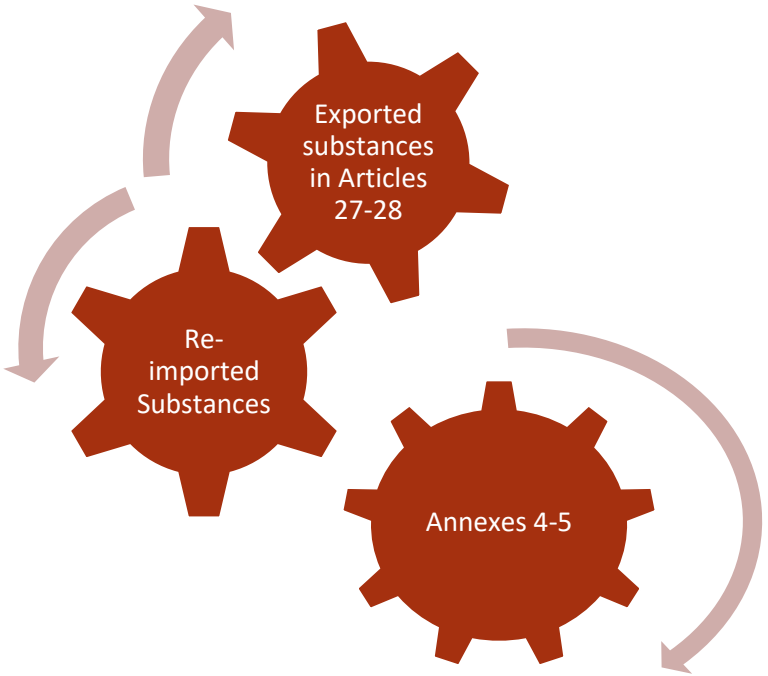
Out of Scope

- Medicinal products for human or veterinary use
- Cosmetic Products
- Invasive medical devices or medical devices which can be used in direct physical contact with the human body
- Foods
- Feeding stuffs

The provisions of Fourth Part (**Information in the Supply Chain**) shall not apply to the extent these mixtures in the finished state, intended for the final user

KKDIK (TURKREACH)
Out of Scope

- Substances in Annexes 4-5
- substances on their own or in mixtures, registered in accordance with Second Part, exported from Turkey by an actor in the supply chain and re-imported into Turkey by the same or another actor in the same supply chain who proofs that:
- the substance being re-imported is the same as the exported substance;
- he has been provided with the information in accordance with Articles 27 or 28 relating to the exported substance.



These substances shall be exempted from Second Part (**Registration**), Fifth Part (**Downstream Users**), Sixth Part (**Evaluation**)

KKDIK (TURKREACH)

Out of Scope

- Substances, on their own, in mixtures or in articles, which have been registered in accordance with Second Part and which are recovered in Turkey if:

1) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Second Part; and
2) the information required by Articles 27 or 28 relating to the substance that has been registered in accordance with Second Part is available to the establishment undertaking the recovery.

- Section 1 of Second Part (**Registration**) , with the exception of Articles 9 and 10; and Seventh Part (**Authorisation**) shall not be applied to the on-site isolated intermediates and transported isolated intermediates.

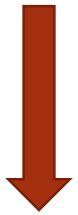
- The provisions of the Second (**Registration**) and Sixth Part (**Evaluation**) shall not apply to the **polymers**.

KKDIK (TURKREACH)
Out of Scope

- Active substances for use in **Biocidal Products** are regarded as already **registered**, as biocidal products and their active ingredients are covered by Biocidal Products Regulation (BPR) . However, several conditions have to be fulfilled to benefit from the exemption.
- Active substances for use in **Plant Protection Products** (PPPs) are regarded as **registered** as the plant protection products and their active ingredients are covered by Directive on Procedures and Principles of Plant Protection Products.

KKDIK (TURKREACH)
Out of Scope

- PPORD (Product and Process Oriented Research and Development)



- PPORD can be exempted from the duty to register for a period of 5 years
- To be exempted a company needs to submit a PPORD notification to the MoEU
- PPORD can be exempted from Authorisation. (Check Annex XIV for the conditions)

KKDIK (TURKREACH)
Key Elements

Registration	• Substances manufactured and imported into Turkey are registered with MoEU • Information for safe use is communicated in the supply chain
Evaluation	• Examination of registrant testing proposals • Compliance check of registration dossiers • Evaluation of substances
Regulatory Risk Management	• Authorisation • Restriction • Harmonised classification

KKDIK (TURKREACH)
Responsible Authorities

AREA OF RESPONSIBILITY (REGULATION)	RESPONSIBLE AUTHORITY
BIOCIDAL PRODUCTS (BP)	MINISTRY OF HEALTH (MOH)
DETERGENTS AND SURFACTANTS USED IN DETERGENTS AIR AROMATIZING PRODUCTS CLEANING PRODUCTS CONTAINING STRONG ACID AND BASE AUXILIARY CHEMICALS USED IN POOL WATER	MINISTRY OF CUSTOMS AND TRADE (MoCT)
PLANT PROTECTION PRODUCTS (PPP)	MINISTRY OF FOOD, AGRICULTURE AND LIVESTOCK (MoFGL)
REGULATIONS REGARDING EXPLOSIVE AND PYROTECHNICAL MATERIALS	MINISTRY OF SCINCE, INDUSTRY AND TECHNOLOGY (MoSIT)
KKDIK – TURKREACH / CLP – SEA / SDS – GBF / (CICR – KEK) COORDINATION FOR OTHER SUBSTANCES AND MIXTURES	**MINISTRY OF ENVIRONMENTAL AND URBANISATION (MoEU)**
INSPECTION AND MANAGEMENT OF RESTRICTED AND PROHIBITED SUBSTANCES UNDER KKDIK ANNEX-17	MoH, MoCT, MoFGL, MoEU, MoEU. MINISTRY OF ECONOMY (MoE), MINISTRY OF ENERGY & NATURAL SOURCES (MoENS), MINISTER OF LABOUR AND SOCIAL SECURITY (MOLSS)

KKDIK (TURKREACH)

Duties of the Ministry (MoEU)

- After submission registration dossier, the Ministry shall assign
- submission number - until the registration is completed
- submission date - date of receipt of the registration dossier at the Ministry

- Once the registration is complete, the Ministry shall assign
- registration number
- registration date - shall be the same as the submission date

- The Ministry shall communicate the registration number and registration date to the registrant concerned.

KKDIK (TURKREACH)

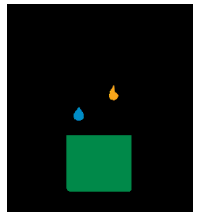
Roles Defined By the Regulation

Importer

Manufacturer

Distributor

Article producer



Formulator

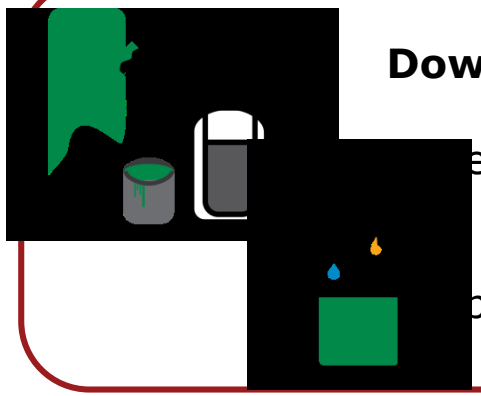
End user industry

End user professionals

KKDIK (TURKREACH)
Roles Defined By the Regulation

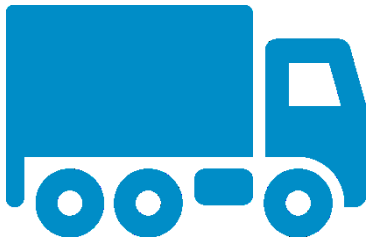
Manufacturer: manufactures a substance

Importer: imports chemicals from outside Turkey



Downstream user: uses chemicals, e.g.: formulates, transfers or uses mixtures, produces articles

Distributor: stores or distributes chemicals



A company may have multiple roles – the role depends on the activity being undertaken with a given substance

KKDIK (TURKREACH)
Roles & Obligations

ROLES	RESPONSIBILITIES
MANUFACTURER	• Pre-SIEF • Registration • SDS Preparation and Distribution • communication throughout the supply chain
IMPORTER (= Manufacturer)	• Pre-SIEF • Registration • SDS Preparation and Distribution • communication throughout the supply chain
ARTICLE PRODUCER/IMPORTER	• Registration for substances intended to be released from articles • The total quantity of the SVHC substance present in articles is over 1 tonne per year and above a concentration of 0.1% weight by weight (w/w) notify the substance

KKDIK (TURKREACH)
Roles & Obligations

ROLES	RESPONSIBILITIES
DOWNSTREAM USER	• Identify and apply appropriate measures in the safety data sheet and exposure scenario • Report after receipt of the safety data sheet (SDS) for a registered substance if their use is not supported and they prepare a DU CSR or claim exemptions. • Inform suppliers if they have new information on the hazards or risks • Prepare and distribute new SDSs for the new mixtures they formulate
DISTRIBUTOR	• Give information to the Supply Chain • Prepare Exposure Scenerio

KKDIK (TURKREACH)
Registration

- KKDIK - TURKREACH regulation requires companies to register all substances manufactured or imported into Turkey in volumes greater than or equal to 1 tonne per year (1t/y).

- Who can register?
  - Manufacturer
  - Importer
  - “Only Representative (OR)” for non-Turkey manufacturers

KKDIK (TURKREACH)
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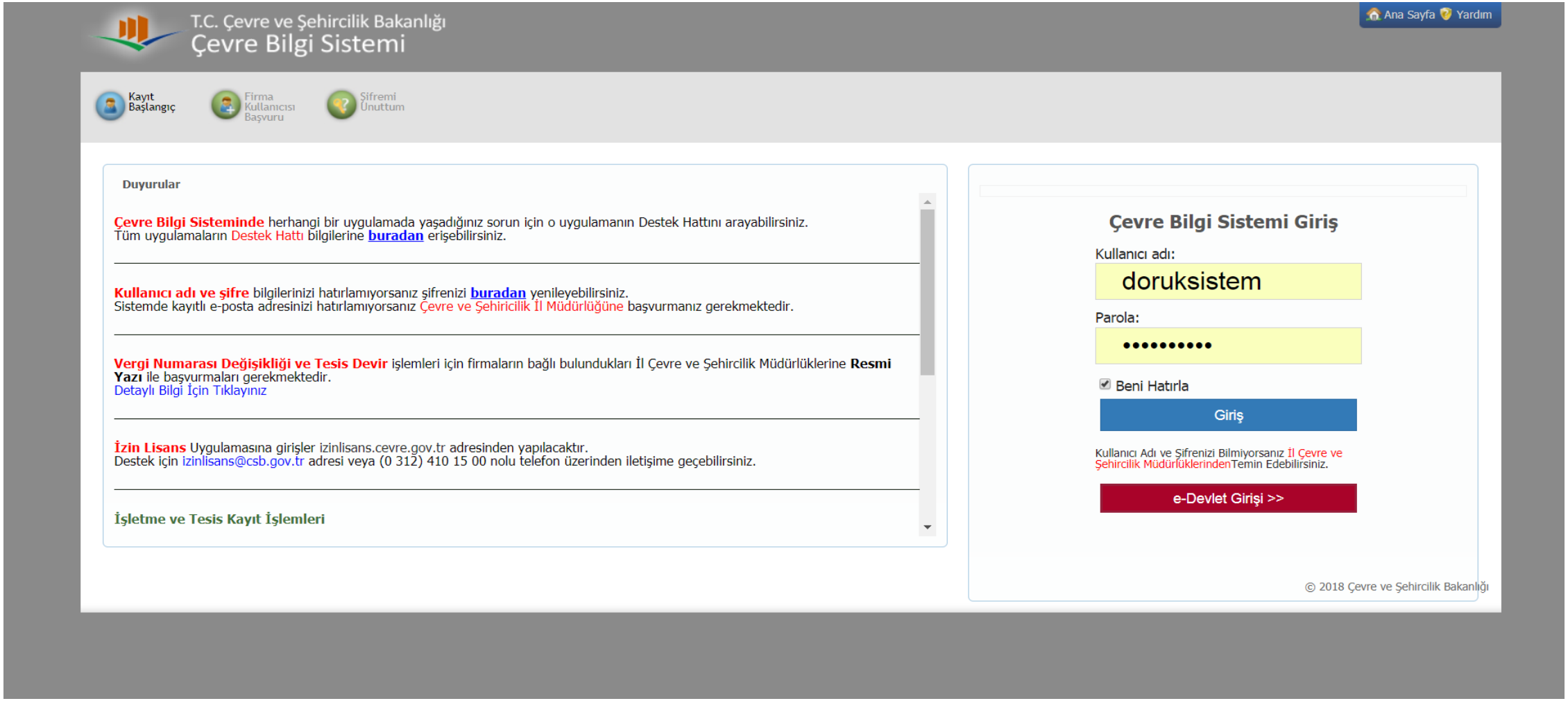
KKDIK (TURKREACH)

Registration

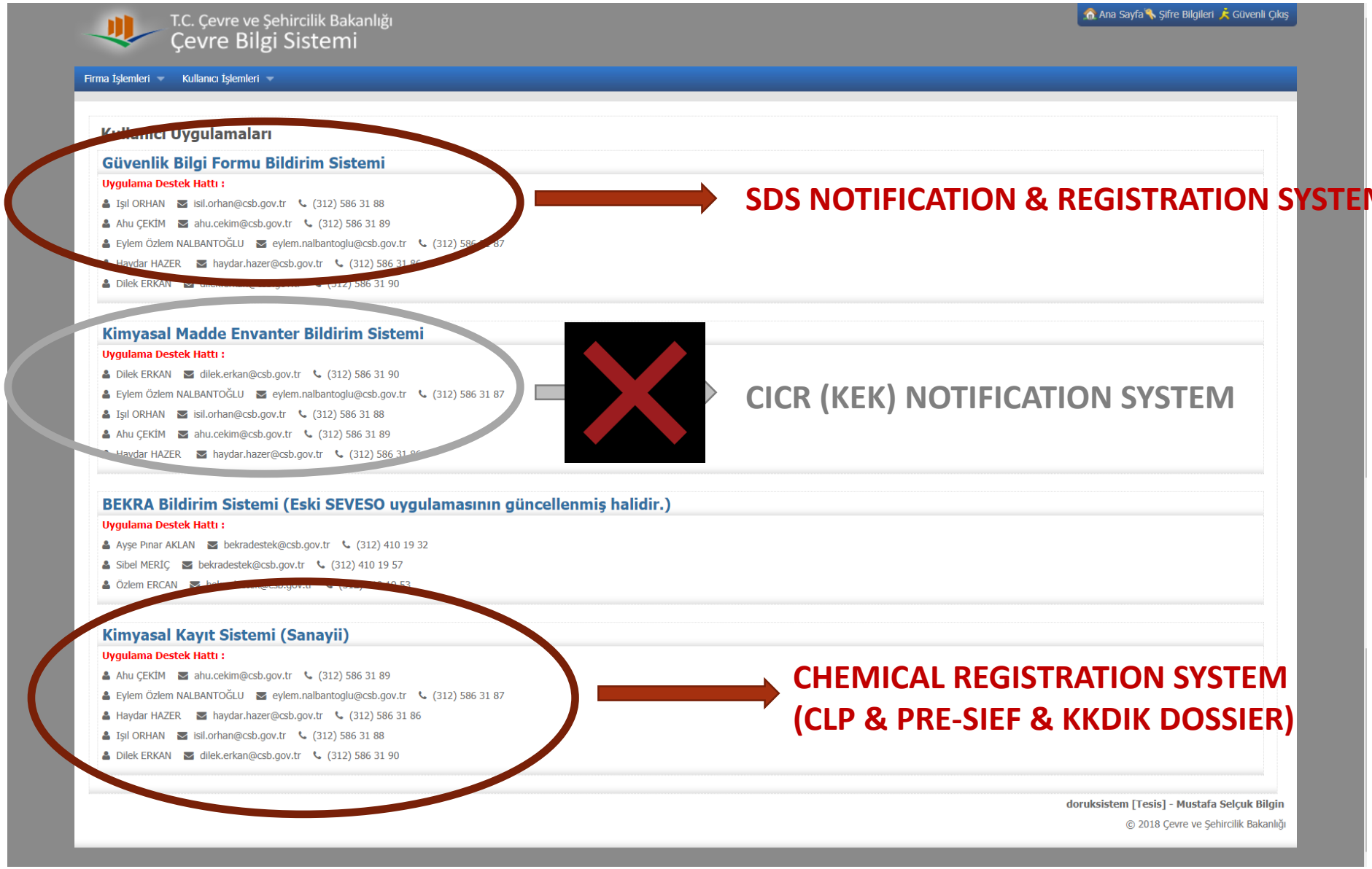
- Registration starting date : 31/December/2020
- Chemicals Registration System - (CRS/KKS)
- Technical Dossier - Annex 6
- Safety Data Sheets - Annex 2
- Chemical Safety Report – Annex 1
- Information requirements (According to annual tonnage band) – Ek 7-10

- Substances registered to EU-REACH will be register again to CRS
- All information registering to CRS/KKS system should be in TURKISH

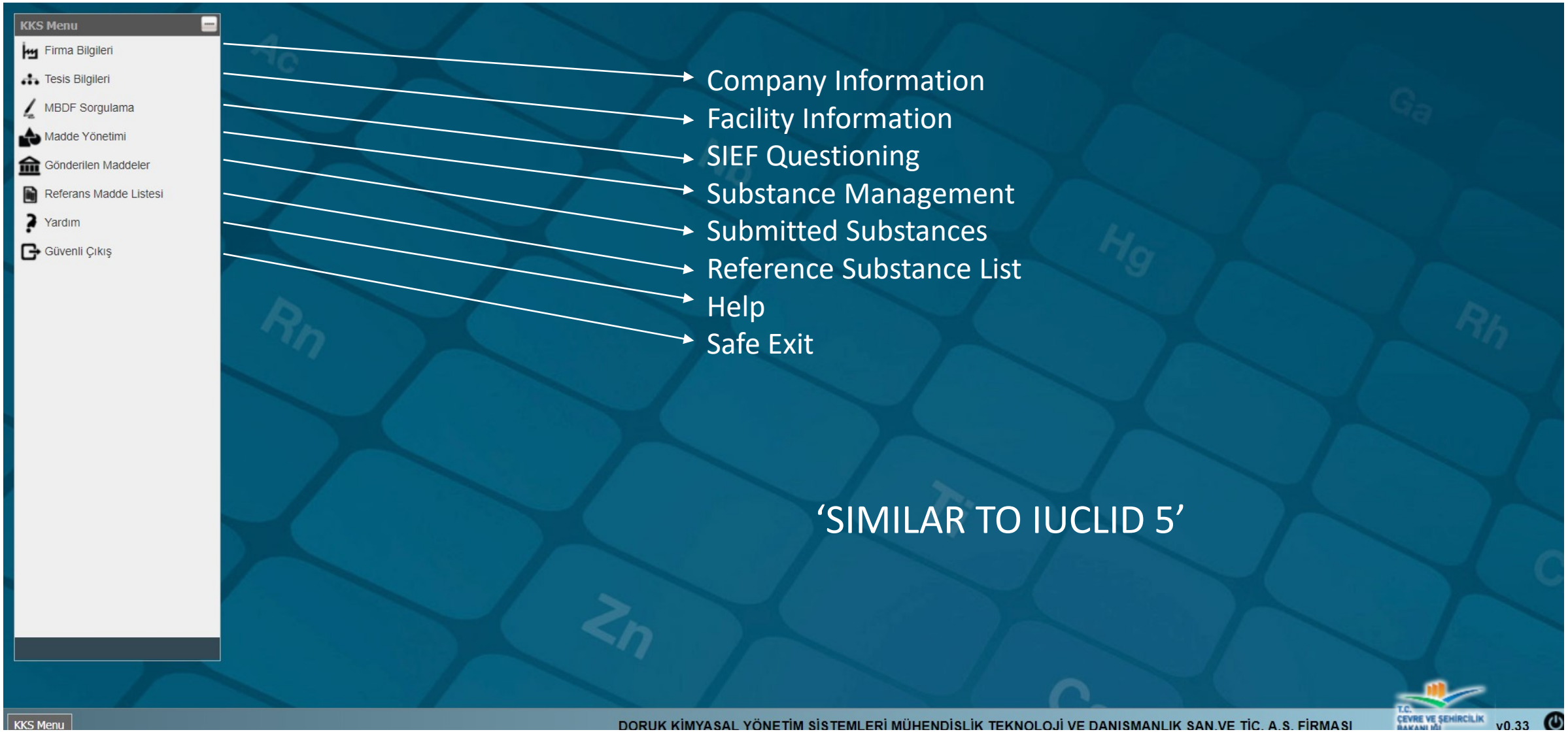
KKDIK (TURKREACH)
Registration



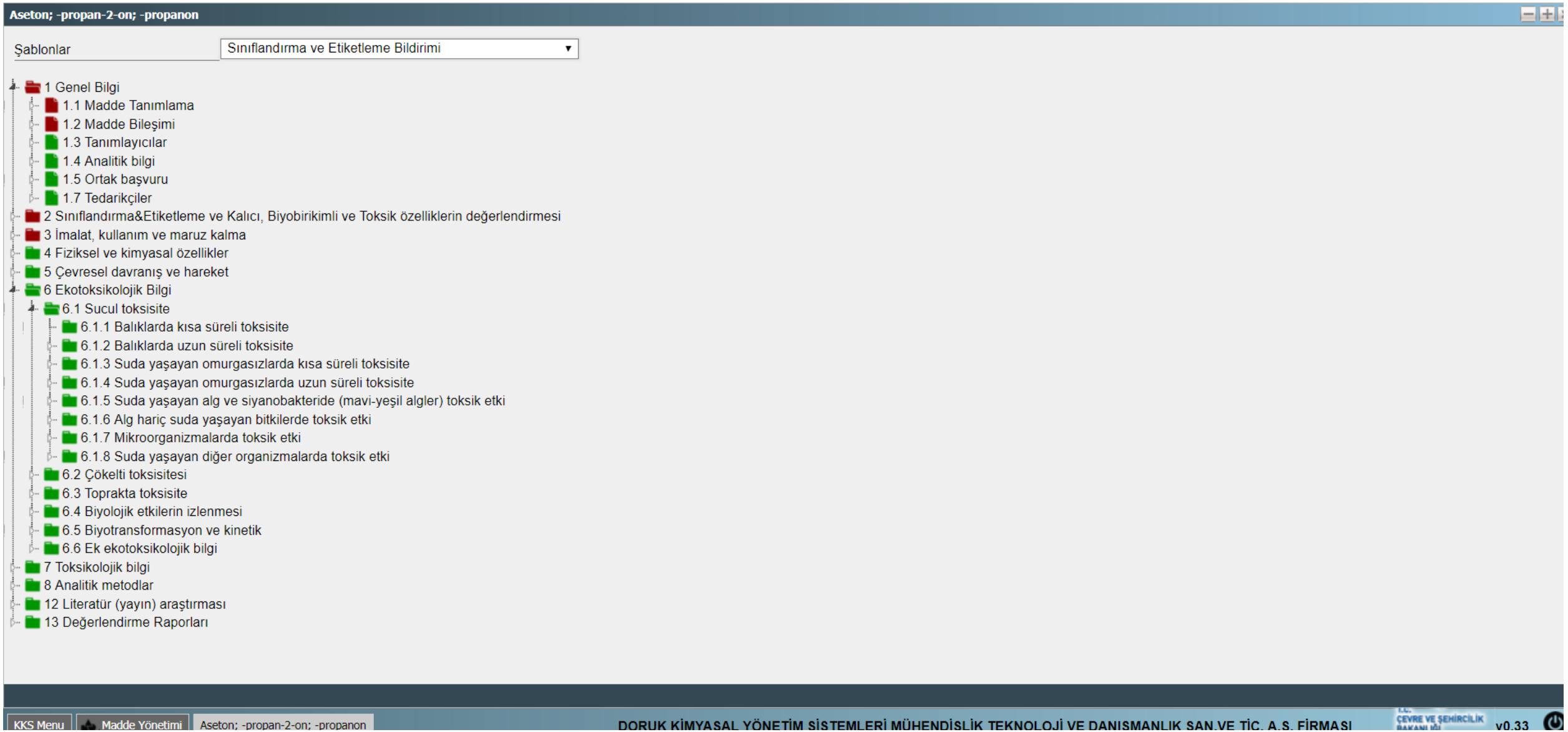
KKDIK (TURKREACH)



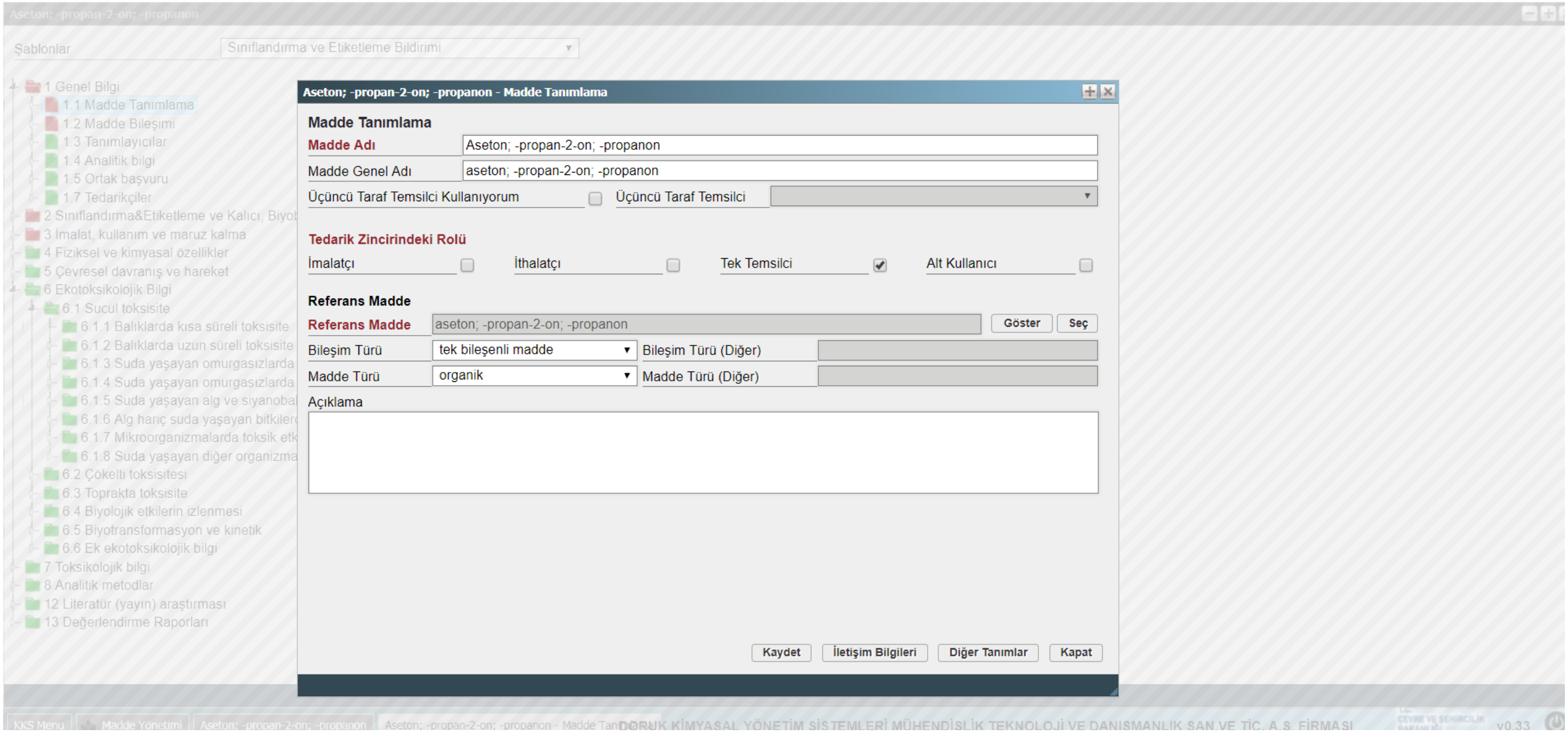
KKDIK (TURKREACH)



KKDIK (TURKREACH)



KKDIK (TURKREACH)



KKDIK (TURKREACH)
CSA & CSR

CSA

- Chemical Safety Assessment. This is carried out for all registered substances manufactured or imported at 10 tonnes per year or greater. It should address all the identified uses of a substance on its own (including any major impurities and additives), in a preparation and in an article. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.

CSR

- Chemical Safety Report. A CSR should be completed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant and is a documentation of the chemical safety assessment

KKDIK (TURKREACH)
CSA & CSR & ES

Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR)

- Data requirement and risk assessment report similar to EU REACH
- CSRs are required to be prepared and signed by a Certified Chemical Safety Assessor.
- A certified Chemical Safety Assessor is needed to compile the dossier and to prepare the Chemical Safety Assessment Report.

Exposure Scenario (ES)

- The set of conditions, including operational conditions and risk management measures, that describe how a substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

ES shall address all identified uses of the registrant. Exposure/use scenarios is an annex of the Safety Data Sheet (SDS).

KKDIK (TURKREACH)

SIEF

SIEF = Substance Identification Exchange Forum

‘SIEF participants should include all relevant actors submitting information to the Agency on the same substance.’

- cost sharing and data sharing
- prevent unnecessary animal testing and reduce costs
- joint submission of the same substance

Each SIEF shall be operational until 21/12/2025

KKDIK (TURKREACH)
Pre-SIEF, Consortium

Pre-SIEF: Potential registrants who pre-registered the same Substance to form SIEFs.

Pre-SIEF Registration can be assumed as Pre-Registration in EU-REACH

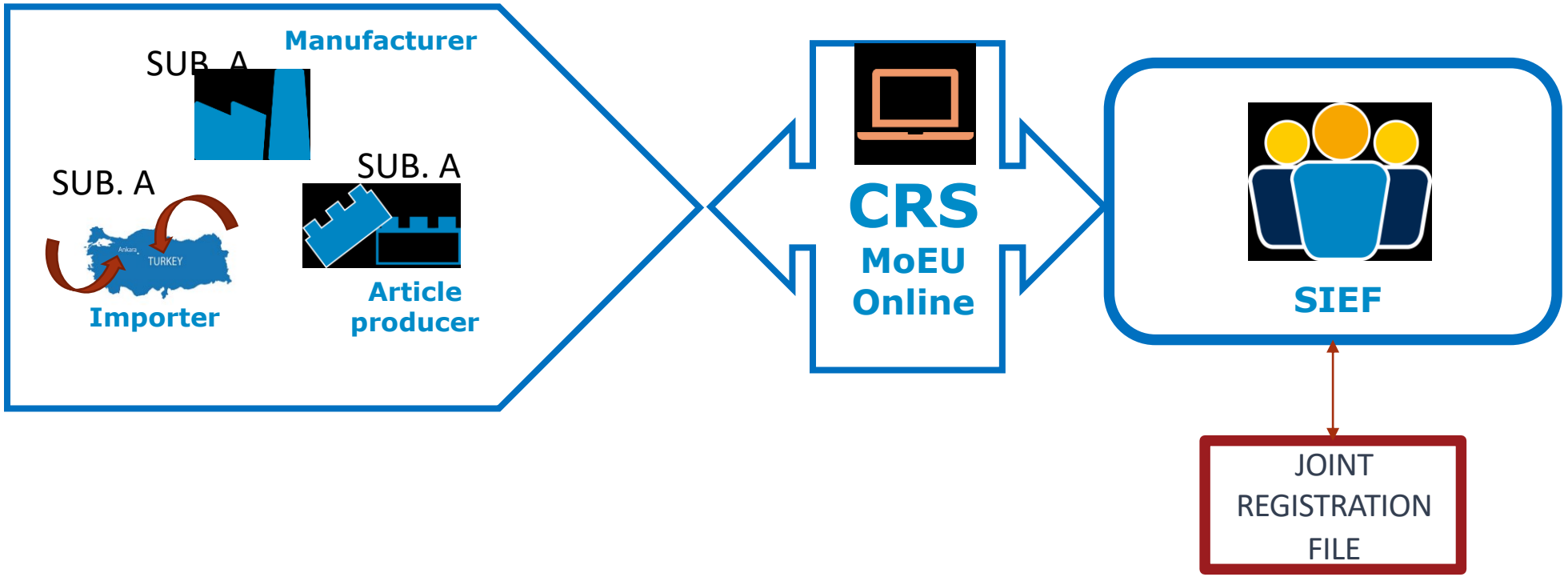
Consortium: association of companies (manufacturer/importers) who want to register the same substances.

All registrants shall send a pre-SIEF application to the Ministry by 2020/12/31 including information:

- substance identity according to Annex 6
- role in the supply chain

KKDIK (TURKREACH)
Joint Registration

- Different companies who want to register the same substance can create a joint registration file inside the SIEF and submit registration dossier jointly.



KKDIK (TURKREACH)
Joint Registration

Roles inside of a SIEF: Lead registrant (LR) or member registrants

- **Lead registrant** should submit registration dossier first
- **Member registrants** always submit after the lead registrant

- Information to be submitted depends on tonnage:

  information specified in Annexes 7-10.

KKDIK (TURKREACH)

Only Representative in KKDIK - TURKREACH

- ARTICLE 9 – (1) A natural or legal person established outside Turkey who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the Turkey may by mutual agreement appoint a natural or legal person established in the Turkey to fulfil, as his only representative, the obligations on importers under the scope of this Bylaw. Only representative shall also comply with all obligations of importers under this Regulation.
- The representative shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 32, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 27.
- If a representative is appointed in accordance with paragraphs 1 and 2, the non-resident manufacturer in Turkey shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Bylaw.
- Exemption from the general obligation to register for product and process orientated research and development (PPORD)

KKDIK (TURKREACH)

Only Representative in KKDIK - TURKREACH

Only representatives have to be:

- A natural person or legal entity established physically in TURKEY
- Equipped with sufficient knowledge in the practical handling of the substances and information related to them (CICR/KEK, CLP/SEA, SDS/GBF, TURKREACH/KKDIK, BPR, PPPR, related TR Reg.)
- Appointed by a mutual agreement with a manufacturer, formulator or article producer, established outside Turkey
- Responsible for complying with the legal requirements for importers under TURKREACH (KKDIK)
- Only representatives can represent more than one non-TR supplier, but must keep the information related to each of them separate.
- The non-TR company has to inform the importer(s) within the same supply chain of your appointment as an only representative. These importers are then regarded as downstream users for TURKREACH.

KKDIK (TURKREACH)

Only Representative in KKDIK - TURKREACH

The Right OR in Turkey:

- OR Should have minimum 5 years experiences in Turkish Chemical Regulations published after 2008 (CICR/KEK, SDS/GBF, DSD-DPD/SAE, CLP/SEA, BPR, PPPR, etc)
- Sufficient Knowledge related to KKDIK
- Regulatory Compliance in Control
- Easy to crossbridge the questions between EU-REACH & KKDIK (TURKREACH) in Turkish & English
- Having Valid Certificates (SDS,CSAE)
- Well experienced technical staff having capability to use IUCLID 5 (at least),6 and MoEU/CRS easily
- International References
- Trusted in CBI Concerns
- Well prepared OR Agreement
- Well experienced certificated experts in SDS Compliance and Management
- Good communications with Industry, Associations, Authorities, International Network, Global Organisations, etc.

Certificate

MUSTAFA SELÇUK BİLGİN

has obtained the certification as

Material Safety Data Sheet Preparing Personnel

after satisfying the evaluation and the examination on 14.12.2017 in İSTANBUL organized by

TURKISH STANDARDS INSTITUTION
PERSONNEL CERTIFICATION CENTER

in accordance with

TSE Material Safety Data Sheet Preparing Personnel Certification Scheme (*)

The certification is in the line with the requirements of ISO 17024:2012 "General Requirements for bodies operating certifications of persons"

Belge Tarihi : 21.12.2017 — Sertifika No: GBF-A-0-2707
Geçerlilik Tarihi : 21.12.2020

E-Signed

Muzaffer ÖZEN
Turkish Standards Institution
Director of Personnel Certification Center

(*)Certification Scheme has been issued to be predicated on "Regulation on the Material Safety Data Sheets regarding hazardous materials and mixtures– Official Gazette 13 December 2014- 29204.

Personnel Certification Center of Turkish Standards Institution is accredited by Turkish Accreditation Agency in the field of "Certification of Material Safety Data Sheet Preparing Personnel" according to TS EN ISO/IEC 17024 with accreditation number of AB-0001-P.

Necatibey Caddesi 112 Bakanlıklar ANKARA Tel: (312) 416 60 20 Faks: (312) 4166598 e-posta: ptm@tse.org.tr

https://basvuru.tse.org.tr/uye/QRKodDogrulama?code=08C0F9 adresinden belgenin doğruluğunu ve geçerliliğini sorgulayabilirsiniz

KKDIK (TURKREACH) - certificates

doruksistem

Sertifika

MUSTAFA SELÇUK BİLGİN

TSE Güvenlik Bilgi Formu Hazırlayıcısı Belgelendirme Programı'na (*) göre

TÜRK STANDARDLARI ENSTİTÜSÜ
PERSONEL BELGELENDİRME MÜDÜRLÜĞÜ

tarafından yapılan değerlendirme ve 14.12.2017 tarihinde İSTANBUL'da düzenlenen sınavlar sonucunda gerekli şartları sağlayarak

Güvenlik Bilgi Formu Hazırlayıcısı

belgesi almaya hak kazanmıştır.

Verilen Bu Belge TS EN ISO/IEC 17024:2012 "Personel Belgelendiren Kuruluşlar İçin Genel Şartlar"ın Gerekliliklerini Sağlamaktadır.

Belge Tarihi : 21.12.2017
Geçerlilik Tarihi : 21.12.2020

Sertifika No:
GBF-A-0-2707

E-İmzalı

Muzaffer ÖZEN
Türk Standardları Enstitüsü
Personel Belgelendirme Müdürü

(*) Belgelendirme Programı, "Zararlı Maddeler ve Karışımlara İlişkin Güvenlik Bilgi Formları Hakkında Yönetmelik"–R.G. 13 Aralık 2014-29204 dikkate alınarak hazırlanmıştır.

Türk Standardları Enstitüsü Personel Belgelendirme Müdürlüğü "Güvenlik Bilgi Formu Hazırlayıcısı" belgelendirmesi konusunda Türk Akreditasyon Kurumu (TÜRKAK) tarafından TS EN ISO/IEC 17024 standardına göre AB-0001-P akreditasyon numarası ile akredite edilmiştir.

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E-Signed

Muzaffer ÖZEN
Turkish Standards Institution
Director of Personnel Certification Center

(*)Certification Scheme has been issued to be predicated on "Regulation on the Material Safety Data Sheets regarding hazardous materials and mixtures– Official Gazette 13 December 2014- 29204.

Personnel Certification Center of Turkish Standards Institution is accredited by Turkish Accreditation Agency in the field of "Certification of Material Safety Data Sheet Preparing Personnel" according to TS EN ISO/IEC 17024 with accreditation number of AB-0001-P.

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https://basvuru.tse.org.tr/uye/QRKodDogrulama?code=08C0F9 adresinden belgenin doğruluğunu ve geçerliliğini sorgulayabilirsiniz

Katılım Sertifikası

MUSTAFA SELÇUK BİLGİN

11.12.2017 – 13.12.2017

tarihleri arasında, TÜRK STANDARDLARI ENSTİTÜSÜ Eğitim Dairesi Başkanlığı tarafından düzenlenen

Güvenlik Bilgi Formu Hazırlayıcısı Eğitimi

konulu eğitim programını tamamlamıştır.

GBF-A0-0155
Sertifika No

E-İmzalı

Muzaffer ÖZEN
TSE Personel Belgelendirme Müdürü

Necatibey Caddesi No. 112 Bakanlıklar 06100 ANKARA
Tel. (312) 416 63 28

Belge Tarihi : 11.12.2017

https://basvuru.tse.org.tr/uye/QRKodDogrulama?code=2AC033 adresinden belgenin doğruluğunu ve geçerliliğini sorgulayabilirsiniz.

KKDIK (TURKREACH)

Importer's exemption

Importers will be exempted from KKDIK/TURKREACH registration if their non-TR suppliers have registered the substances through an OR

Before placing the substances on Turkish market, importers should ask the supplier’s OR for a TURKREACH Certificate of Compliance.

Importer

- Should be included in the OR’s inventory – List of Turkish importers in the same supply chain
- Tonnage and uses should be covered by non-Turkey suppliers OR

KKDIK (TURKREACH)

Registration requirements differs from EU REACH

EU REACH

- Published 2006/6/1
- Pre-registration deadline 2008/12/1
- Registration deadlines:

>1000 t/y, CMR, R50/53 2010/12/1
100-1000 t/y 2013/5/31
1-100 t/y **2018/5/31**

KKDIK

- Published 2017/6/23
- Pre-registration deadline 2020/12/31

- Registration deadline **2023/12/31**

tonnage does not affect deadlines
4 bands for information requirements:
1-10t/y, 10-100t/y, 100-1000t/y, 1000t/y+

KKDIK (TURKREACH)

Registration differs from EU REACH

EU REACH

- **Phase-in and non-phase in** substances
- Phase-in (EINECS inventory) had delayed registration deadlines

KKDIK

- Turkey has an inventory, but inventory status of substances does not affect deadlines

KKDIK (TURKREACH)

Registration differs from EU REACH

EU REACH

- Any person at the company and often different specialists in different branches of companies, had input on the registration dossier

KKDIK

- **Only** certified **Chemical Safety Assessors** can file registration and notification in Turkey (or write SDSs!)

KKDIK (TURKREACH)

Registration dossier submission

EU REACH

Dossier submission to **ECHA**

- IUCLID 6 application for registration REACH – IT for communication
- Registration language = English

KKDIK

Dossier submission to **MoEU**

- Ministry's **Chemical Registration System (CRS)** online system
- Registration language = Turkish

KKDIK (TURKREACH)

Registration dossier submission

- Information to be submitted for **general registration purposes**:

- **Technical dossier** (including registrants identification, Substance ID, tonnage, C&L, uses, Guidance on safe use, Study summaries, Robust study summaries…) *(Article 11(a)).*

    - some information submitted (C&L, uses, study summaries) **has been reviewed** by an Chemical Safety Assessor chosen by the manufacturer or importer

- **Chemical Safety Report (CSR)** when required *(Article 15).*

KKDIK (TURKREACH)

Evaluation

- Dossier Evaluation
  - Examination of Test Proposals
  - Registration Dossiers Compliance Check

- Substance Evaluation
  - Prioritization will be made by the Ministry using a risk-based approach:

    1. hazard information
    2. exposure information
    3. tonnage

  - Evaluation process is to occur within 12 months.

KKDIK (TURKREACH)
Authorisation

- A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex 14, unless the conditions writen in the regulation (46) - Annex 14 is similar to EU REACH Annex XIV Authorisation List
- Applications for authorisation:
  - shall be made to the Ministry through Chemicals Registration System (CRS)
  - summaries of the Ministry decisions, including the authorisation number shall be published in the web-site of the Ministry
- Downstream users using a substance in accordance with Article 46(2) shall notify the Ministry within 90 days of the first supply of the substance.
- Before applying for authorisation, registrants must investigate substituting substances with safer alternatives or technologies.

KKDIK (TURKREACH)
Authorisation

SVHCs may have the following hazard properties:

- carcinogenic, mutagenic or toxic for reproduction category 1A or 1B (CMR)
- persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB)
- substances with serious effect such as those having endocrine disrupting
- properties

Candidate substances for inclusion in Annex 14 is similar to EU

Authorisation is required for substances of very high concern (SVHC), listed in Annex 14

KKDIK (TURKREACH)
Restrictions (Annex 17)

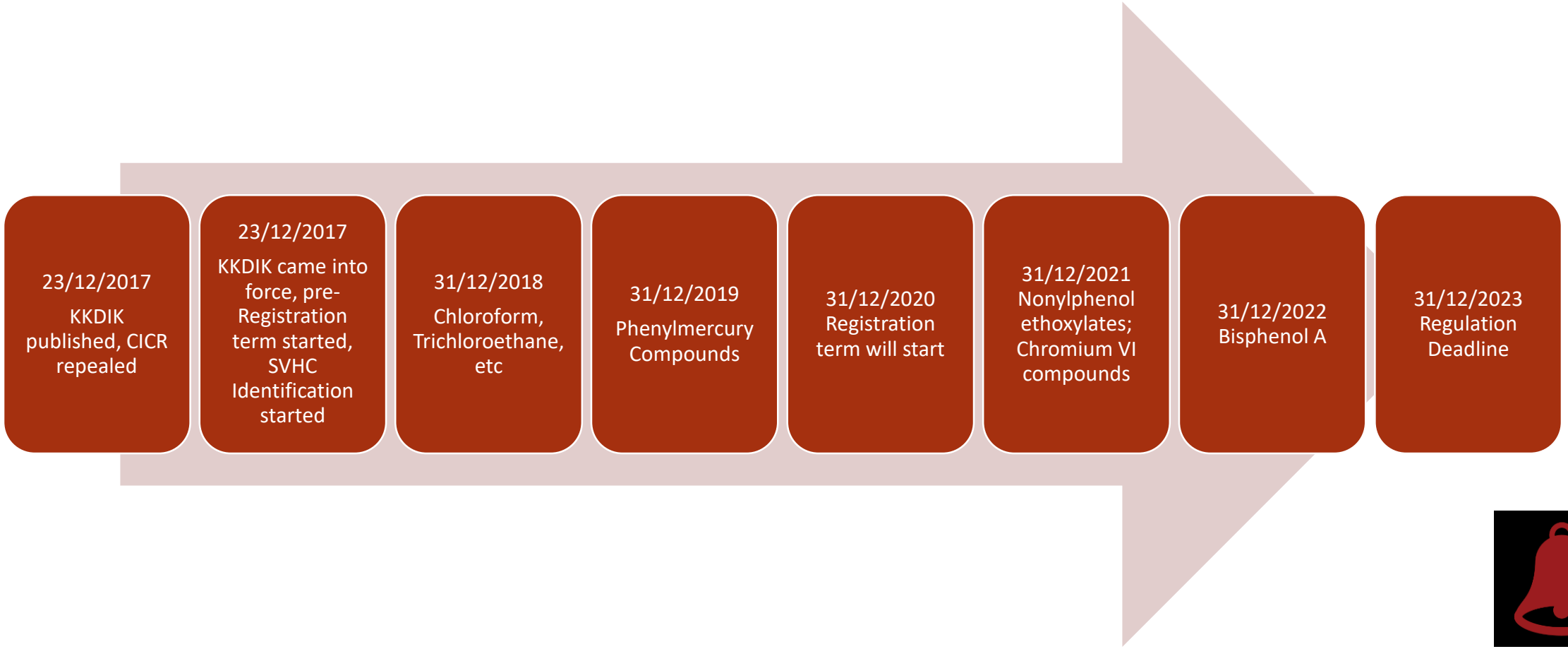
Turkish MoEU can impose restrictions and prohibit or set conditions for

- ✓ manufacturing
- ✓ placing on the market or
- ✓ using of certain dangerous substances or substances group

Annex 17 is similar to EU REACH Annex XVII Restricted Substances List
This list is not as complete as Annex XVII of EU REACH but the numbering system for the 66 entries is consistent.

Must comply with restriction conditions set out in Annex 17

KKDIK (TURKREACH)
Restrictions (Annex 17)



KKDIK (TURKREACH)
Critical Points

There is no separation of deadlines depending on the tonnage bands or the classification of the substances.

Approximately 3 years pre-registration period (23.12.2017-31.12.2020)

All the registrations for substances ≥1 mta have to be submitted in 3 years period (31.12.2020 – 31.12.2023)

KKDIK (TURKREACH)

Critical Points

Companies that are exporting chemicals (and articles that are containing some certain chemicals) can appoint an OR and submit the registrations through the OR by which & then their importers will become downstream users. (Article 9)

NONS (Notification of New Substances) were deemed as registered under REACH but they need to be registered under the scope of KKDIK.

A certified Chemical Safety Assessor is needed to compile the dossier and to prepare the Chemical Safety Assessment Report.

Competent Authority will provide trainings for Chemical Safety Assessors and certify them after an exam

KKDIK (TURKREACH)

Critical Points

SDS Compilers who are certified in accordance with 29204 (existing SDS Regulation) can compile SDS till 31.12.2023 in accordance with 29204

After 31.12.2023 certified Chemical Safety Assessor’s will be eligible to compile the SDS and e-SDS where required.

KKDIK (TURKREACH)
SDS & Labelling

Key Requirements of Turkish SDS Regulation

- standard 16-section SDSs
- must be prepared in Turkish
- should be prepared and signed by a certified expert in Turkey
- shall contain the classification according to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures
- shall be provided free of charge, on paper or electronically
- copy of SDSs have to be submitted to the Ministry of Environment and Urbanization (MoEU)

KKDIK (TURKREACH)

SDS & Labelling

Transition period

SDS shall be prepared according to the Regulation on Safety Data Sheets Concerning Hazardous Substances and Mixtures until 2023/12/31

The transition period is intended to provide sufficient time for the Chemical Safety Assessors to acquire the training and certification required for authoring SDSs (KKDIK, Annex 18)

KKDIK (TURKREACH)
SDS & Labelling

Suppliers shall update the SDS without delay on the following occasions:

- As soon as new information which may affect the risk management measures, or new information on hazards becomes available
- Once an authorization has been granted or refused
- Once a restriction has been imposed

The SDS need not be supplied where substances that are hazardous are offered or sold to the general public, unless requested by a downstream user or distributor.

KKDIK (TURKREACH)

SDS & Labelling

Labelling requirements in Turkey

- standard GHS label elements must be included
- nominal quantity needs to be shown on labels
- "non-toxic” or “not harmful" are not allowed
- must be prepared in Turkish language - other languages in addition to Turkish are acceptable, as long as the same information appears in all languages used

KKDIK (TURKREACH)
SDS & Labelling

Information disclosure on the labels and in SDSs:

- If a hazardous substance needs to be hidden on labels or in SDSs for confidentiality reasons, companies shall submit a request to MoEU to obtain an approval of using an alternative name

- Such an alternative name can only be used for 6 years

KKDIK (TURKREACH)
SDS & Labelling

Information disclosure on the labels and in SDSs:

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KKDIK (TURKREACH)

SDS Regulation Timetable

23.12.2017 – 31.12.2023

SDS Regulation 29204 will be in force

Also for the same term
Annex II of the KKDIK will be in force

In theory ; SDS can be compiled in accordance with either of the regulations

KKDIK (TURKREACH)

SDS Regulation Timetable

23.12.2017 to (sometime between 31.12.2020 &31.12.2023)

- SDS Regulation 29204 will be used because
- No CSA will be availble to compile SDS in accordance with KKDİK
- There will not be available data from the Registration dossier to use for KKDIK Compliant SDS such as
  - ❑ Registration number
  - ❑ Chemical Safety assessment (Sec 15.2)
  - ❑ Exposure scenarios
- From sometime between 31.12.2020 & 31.12.2023
  - ❑ KKDIK Annex II will be used for compilation of SDS

KKDIK (TURKREACH)

Fees

Fees will be determined annually and published at the website of the Ministry of Environment and Urbanization (MoEU)

No fee shall be taken for the substances in the 1-10 tonnage band which have all of the information according to Annex 7 in their registration dossier

KKDIK (TURKREACH)

Fees

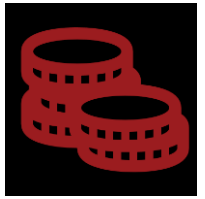
Standard KKDIK Official fees (as of today)		
Standard fees	Individual submission	Joint submission
Fee for substances in the range 10 to 100 mta	3.680 TL	2.588 TL
Fee for substances in the range 100 to 1 000 mta	9.840 TL	6.900 TL
Fee for substances above 1 000 mta	26.560 TL	18.675 TL

Standard KKDIK Official fees (as of today) (Med Ent)		
Standard fees	Individual submission	Joint submission
Fee for substances in the range 10 to 100 mta	2.030 TL	1.540 TL
Fee for substances in the range 100 to 1 000 mta	5.600 TL	4.200 TL
Fee for substances above 1 000 mta	15.085 TL	11.305 TL

KKDIK (TURKREACH)

Fees

Standard KKDIK Official fees (as of today) (Small Ent)		
Standard fees	Individual submission	Joint submission
Fee for substances in the range 10 to 100 mta	1.120 TL	840 TL
Fee for substances in the range 100 to 1 000 mta	3.010 TL	2.240 TL
Fee for substances above 1 000 mta	8.120 TL	6.090 TL



KKDIK (TURKREACH)
Sources of Information

KKDIK HELPDESK (http://kimyasallar.csb.gov.tr/)

TURKREACH (www.turkreach.com.tr)

DORUKSISTEM (www.Doruksistem.com.tr)

Thank You

Please contact for further information you need or
Questions you have

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www.Doruksistem.com.tr
www.turkreach.com.tr