

REACHLaw Webinar
October 26th, 2017



KKDIK Entering Into Force

Status update on Turkish chemicals regulations

AGENDA

1. Latest updates from Turkey
2. KKDIK Overview
3. SEA and GBF Overview
4. Q&A

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KKDIK has been finalized!

- The Regulation on Chemicals Registration, Evaluation, Authorisation and Restriction (KKDIK) prepared by the Ministry of Environment and Urban Planning (MoEU) was published in the Official Gazette on 23th of June 2017.
- The Regulation will enter into force on ***December 23rd, 2017***, six months after its publication, except the provisions for which a transitional period is granted.

Regulations Revoked by KKDIK:

Regulation	Date of Revocation
The Regulation on Inventory and Control of Chemicals “KEK” (dated as 26 th of December, 2008 and numbered as 27092)	23.06.2017
The Regulation on the Restriction and Prohibition of Hazardous Substances and Mixtures (dated as 26 th of December, 2008 and numbered as 27092)	23.12.2017
The Regulation on Preparation and Issue of Safety Data Sheets for Dangerous Substances and Preparations “GBF Regulation” (dated as 13 th of December, 2014 and numbered as 29204)	31.12.2023

Chemical Safety Experts

- Unlike REACH, the chemical safety report must be signed by a Chemical Safety Expert with the necessary qualifications as detailed in Annex-18 of KKDIK.
- It is stated that this practice is implemented due to the problems experienced in REACH implementation in Europe.

How to Manage KKDIK? Strategic Decisions:

For an international company exporting their chemical products to Turkey there are three main options to choose from:

- A. Firstly, regulatory compliance with these new regulations may be left to the Turkish importers but that requires that the importers are provided with detailed, potentially confidential business information necessary for compliance
- B. Alternatively, the exporter may appoint their Turkish subsidiary as representative to comply with the regulations (The expert work can be outsourced from a reliable service provider)
- C. Finally, the work can be outsourced directly by naming as representative a professional service provider operating in Turkey

REACHLaw supports both options B&C from Istanbul and Helsinki

Chemical Control Reform: KKDIK



Harmonisation of Turkish Chemicals Regulations with EU REACH&CLP Expected By 2023

Key Authority: Ministry of Environment and Urbanization



~~Old GBF~~

GBF

It is in force till 31st
of December 2023.

~~KEK~~

KKDIK

~~Old SEA~~

SEA

Continuous Work to Maintain Compliance: The Nature of Activities Before/After Registration



Adapted from "Managing the Patchwork"
Specialty Chemicals Magazine
Tim Becker, Chief REACH Officer / REACHLaw

Turkish Regulations

- **KKDIK** stands for *Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması* which translates into Chemicals Registration, Evaluation, Authorisation and Restriction i.e. REACH
- **SEA** stands for *Maddelerin Ve Karışımların Sınıflandırılması, Etiketlenmesi Ve Ambalajlanması Yönetmeliği* which translates into Regulation on Classification, Labelling and Packaging of Dangerous Substances and Preparations i.e. CLP
- **GBF** stands for *Zararlı Maddeler ve Karışımlara İlişkin Güvenlik Bilgi Formları Hakkında Yönetmelik* which translates into Regulation on Preparation and Issue of Safety Data Sheets for Dangerous Substances and Preparations i.e. SDS
- SEA classification and labelling regulation implemented two years before KKDIK, whereas in the EU REACH came first

New Chemicals Regulatory Obligations

KKDIK Pre-SIEF (Ön-MBDF)

- All registrants must register the substance's identity and its role in the supply chain through the Chemical Registry System on the web page of the MoEU from ön-MBDF section by the date of 31st of December, 2020.
- Companies that have done Classification-Inventory Notification (SEA) will be able to move this information to the ön-MBDF entry screen.
- The registration process will begin after the ön-MBDF period lasting until 31st of December 2020 and will be completed by 31st of December 2023 for all chemical substances above 1 tonne.

New Chemicals Regulatory Obligations

KKDIK Registrations

- All substances manufactured or imported in its own form or in a mixture of 1 tonne or more per year before 31st of December, 2023 must be registered at the latest by the date of 31st of December, 2023.
- The registration process is carried out by submitting a registration dossier including specific information (test data and etc.) to the MoEU for the raw materials placed in Turkish market and subject to registration by the regulation.

Present Chemicals Regulatory Obligations

KKDIK Deadlines

Obligations	Application Date
Pre-registration (ön-MBDF)	until 31.12.2020 – the application system is open now.
Registration	until 31.12.2023
Restrictions	It will enter into force in 5 different dates. (Article 66)
Authorisation	Date will be determined for each substance separately once the addition is completed to the Annex 14.

SDS Related Chemicals Regulatory Obligations

GBF - Safety Data Sheets

- The Regulation on Preparation and Issue of Safety Data Sheets for Hazardous Substances and Preparations (Zararlı Maddeler ve Karışımlara İlişkin Güvenlik Bilgi Formları Hakkında Yönetmelik “GBF”) of December 13, 2014 requires companies to prepare compliant SDS in Turkish language by a certified expert (in Turkey) and submitted to the MoEU.
- Validated and certified Turkish SDS needs to be submitted to the MoEU and a copy is provided to the customer.

Labelling: Chemicals Regulatory Obligations

Labels

- In accordance with The Regulation on Classification, Labelling and Packaging (Maddelerin Ve Karışımların Sınıflandırılması, Etiketlenmesi Ve Ambalajlanması Yönetmeliği “**SEA**”) of December 11, 2013 requires that labels of hazardous substances and mixtures have to be harmonized with the regulation.
- Submission of labels is not required to the MoE.

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One Page Overview of KKDIK:

From pre-registration to registration & the rest

- Repeals and replaces KEK, the Inventory and Control Regulation (Art. 64(1b))
- Min. of Env. and Urb. (MEU) named as Competent Authority (Art. 4(oo))
- Pre-registration by 31 Dec 2020 and registration by 31 Dec 2023 (Trans. Art. 2(1))
- No Data, No Market (Art. 6)
- General obligation to register substances over 1 tonne per year (Art. 7)
 - Polymers excluded (2(7)a), but not monomers in polymers (Art. 7(3))
- CL-substances in articles >1 tonne/annum, >0,1% w/w, notification to MEU (Art.8.2)
- Only Representative, natural or legal person resident in Turkey (Art. 9)
- REACH-type full registration dossier required (Art. 11)
- New testing according to GLP (Art 14(4))
- Data sharing in MBDFs (SIEFs) (Art. 25)
- Dossier evaluations and compliance checks (Art. 36-37) carried out
- Substance evaluations (Art. 40) based on a risk-based approach
- Authorisation process for CRM and PBT, vPvB- substances (Art. 47-49)
- Authorisations granted for limited time upon application (Art. 50-54)
- Restriction process for substances presenting an unacceptable risk (Art. 57-58)

KKDIK Restrictions

- The Regulation on the Restriction and Prohibition of Hazardous Substances and Mixtures, published in the Official Gazette and dated as 26th of December, 2008 and numbered as 27092, already transferred some REACH restrictions to the domestic legislation.
- With the entering into force of the KKDIK Regulation, the number of list of restriction increased to 66 certain lines (entries) will enter into force at the end of the specified transition periods, but the ones not having specific date will start to be applied once the Regulation enters into force.
- Restrictions restrict or completely prohibit the use of certain chemical substances on the market and / or the application of the certain chemical substance in the market.

Authorization Application

- Hazardous substances carried specific criteria will be subject to the permission if they are included on the List of Substances Requiring Authorisation.
- Substances nominated to be listed will be determined by the MoEU in accordance with the REACH Regulation and will be published on the website of the MoEU.
- The materials listed shall not be supplied or used in the market unless the authorization is received within the period of time specified by the manufacturer, importer or downstream user.

Planned Registration Fees & SME Reductions

- Prices shall be specified on the unit price list to be published every year on the internet page of MoEU.
- Within the scope of the KKDIK, discounts will apply to SME companies for the fees that changes by depending on tonnage band and size of the companies.

Additional Fees

- Joint registration cost will be determined according to mutually agreed cost sharing principles among the companies. This cost will be determined for the MBDF and is an additional cost, independent from the application cost to the MoEU.
- Keeping some information confidential during registration process is possible, but may require payment of additional fees.
- The requirement of having an Only representative for companies that do not have legal entities in Turkey is also an additional (separate) cost that needs to be taken into consideration.

What the OR in Turkey Should Be Doing When KKDIK Takes Effect:

1. Has a **written OR agreement** in place, which clearly sets out parties' responsibilities
2. Submits **classification and labelling notifications**
3. **Registers** his client's substances once KKDIK takes effect
4. **Draws up GBF-compliant safety data sheets for substances**
5. Is available and responds duly to **third party requests for information**
6. Keeps available **import volume and importer info**
7. Keeps available information on importers and volumes **synchronized with the client**
8. Determines the **importers in terms of KKDIK** to this end
9. Monitors **KKDIK (& SEA, GBF) developments**
10. Complies with **continuous post-registration obligations**, e.g. dossier and SDS updates...
11. Has the required **chemical, legal, data handling/IT, organisation & other skills** to fulfil its duties and compliance management systems in place

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SEA: C&L Inventory Notifications: Scope

- Classification and labelling inventory notifications (Art. 40-43, Annex 8)
 - Hazardous substances on their own or in mixtures either on their own or in a mixture above the concentration limits specified in SEA Annex 2, which results in the classification of the mixture as hazardous must be notified (Art- 40(1)b)
 - Notification obligation applies to the Annex 8 list (Art. 40(1)a):
 - Substance or mixture produced or imported one tonne or more per year per producer,
 - Substances intended to be released one tonne per year per goods producer or importer,
 - Substances present as monomer material or chemically bound in the polymer at a rate of 2% (w/w), and present in an amount of one tonne per year or more per producer or importer and,
 - Substances that are found in goods in an amount of one ton or more per goods producer or importer, and with a concentration (w/w) of over 0.1 % in the goods;
 - Classified as category 1A, 1B (CMR category 1A, 1B) as carcinogenic, mutagenic, or toxic to the reproductive system, or
 - Persistent, bioaccumulative or toxic (PBT) , or
 - Very persistent, very bioaccumulative (vPvB) features, or
 - Endocrine disrupting (ED) features.

SEA Key Deadlines

Within one month of market entry

Previous deadlines:

1st June 2015 for classification and labelling of substances (T. Art. 1)

1st June 2016 for classification and labelling of mixtures (T. Art. 1)

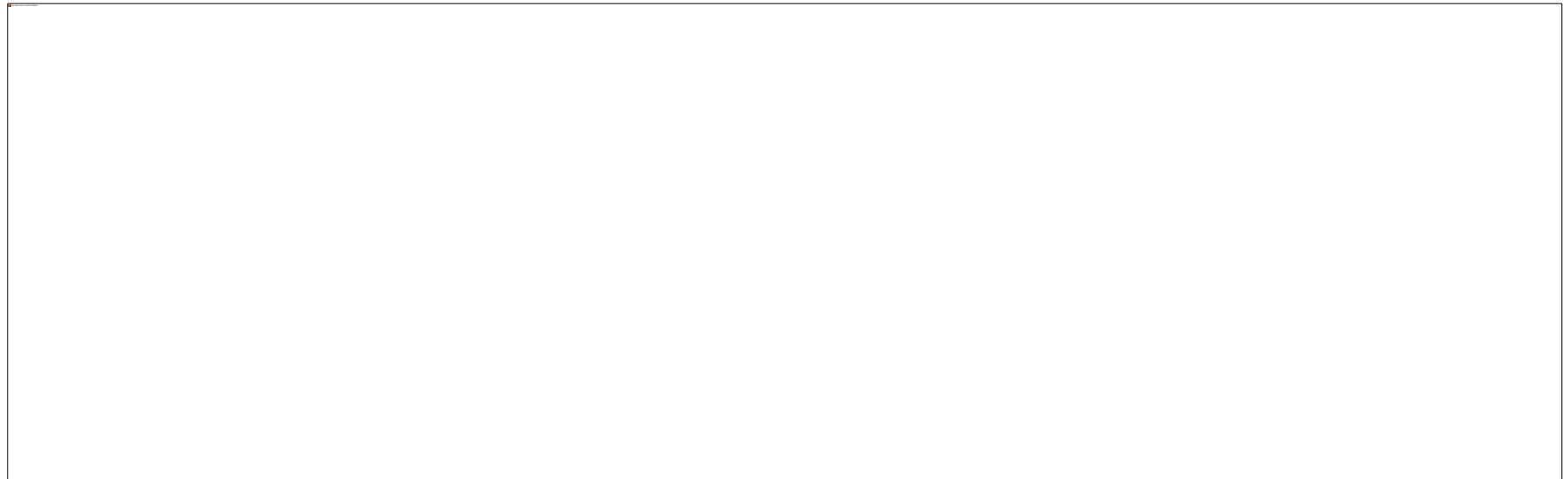
1st June 2015 for C&L inventory notifications for goods placed on the market before 1st June 2015 (Art.1) and then **within one month after the substance has been placed on the market** (Art. 52(a))

Who May and What Needs to Be Notified?

- Manufacturers or importers or manufacturer or importer groups supplying substances to the market and Representatives of Non-Turkish Companies may submit (Art. 41)
- Information to be submitted (Art. 41) :
 - Name, address, telephone number, fax number and e-mail address.
 - Name of contact person
 - Place of manufacture.
 - Substance identity
 - Substance classification
 - Information and justification must be provided when a substance cannot be classified as belonging to hazard classes or differentiations, due to lack or inconclusive
 - If appropriate, the specific concentration limit values and M-factors
 - Hazard phrases for the substance together with labeling

C&L Notification in Practice Using KKS IT-Tool

- All fields need to be filled in for notification to pass completeness check:
 - Company Information
 - Facility Information
 - Reference Material Information
 - Classification and Labelling Information



C&L Notification in Practice Using KKS IT-Tool

It comprises of two steps application:

ön-MBDF (Pre-SIEF)

- Registration of basic information of the substance (e.g. name, CAS and EC No)

Substance Management

- Classification and Labelling Registration
- Registration of the manufacturer and OR information

Safety Data Sheet Regulation - GBF

Zararlı Maddelerin ve Karisimlara İlişkin Güvenlik Bilgi Formları Hakkında Yönetmelik (GBF Regulation) [13/12/2014-29204 - sayılı resmi gazete]

- *GBF provisions are still valid until 31st of December 2023.*
- But safety data sheets may be prepared in accordance with the provisions set out in the KDDIK from 23rd of December, 2017, depending on the company. (Provisional Article 2)

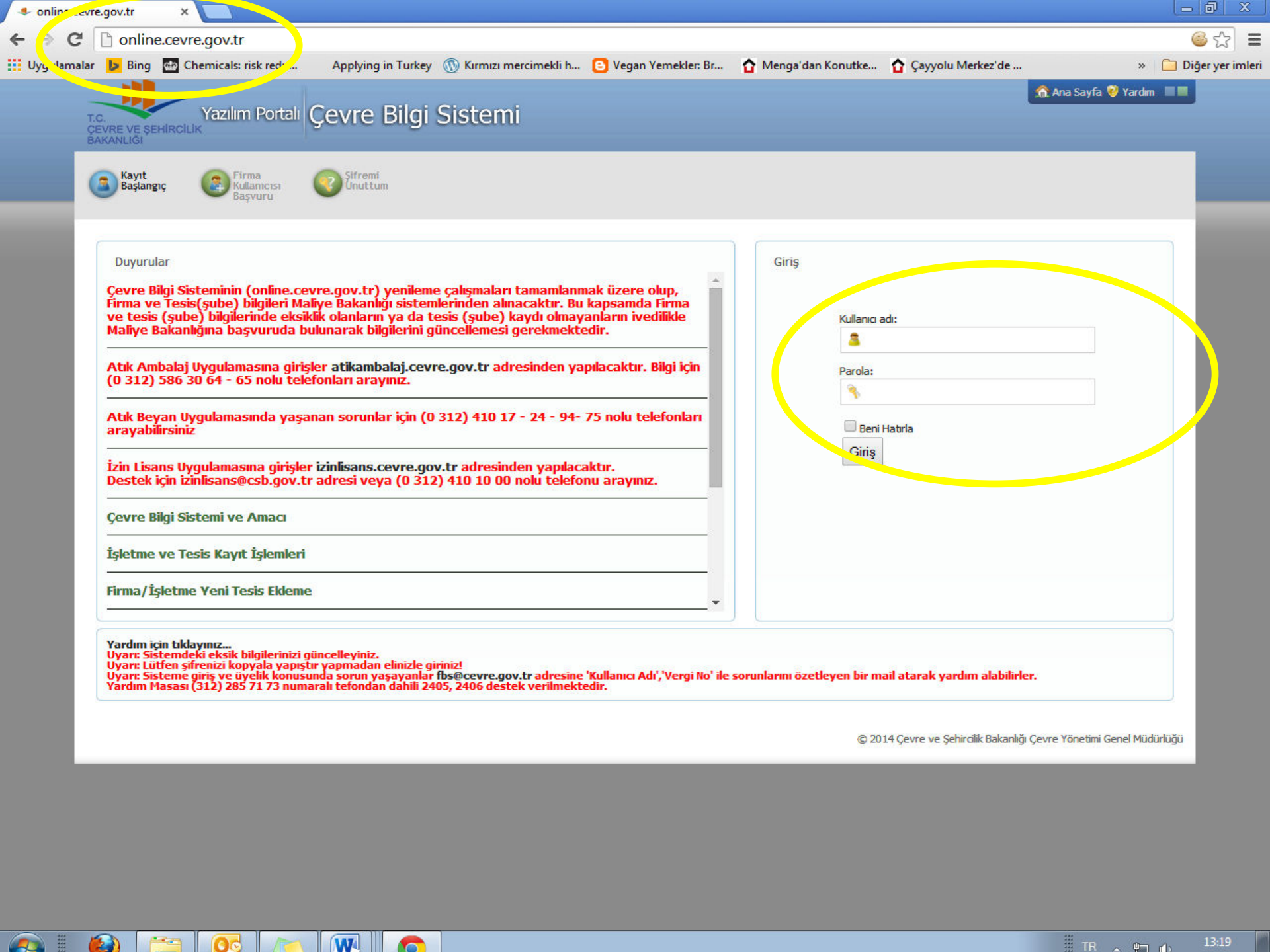
Safety Data Sheet Regulation - GBF

Requires:

- Detailed information about properties of hazardous substances and mixtures
- Precautions with respect hazardous properties of mixtures and substances
- Required information to protect human health and environment from negative properties of mixtures and substances

SDS is to be;

- Provided by supplier of substances/mixtures
- Free of charge
- In Turkish
- Authored by a person with the necessary certification
- One copy of SDS submitted to MoEUP via <http://online.cevre.gov.tr/>





HANİŞİL KAMİL

- Güvenlik Bilgi Formu Bildirim Sistemi
- Kimyasal Madde Envanter Bildirim Sistemi
- Kimyasal Kayıt Sistemi (Sanayii)

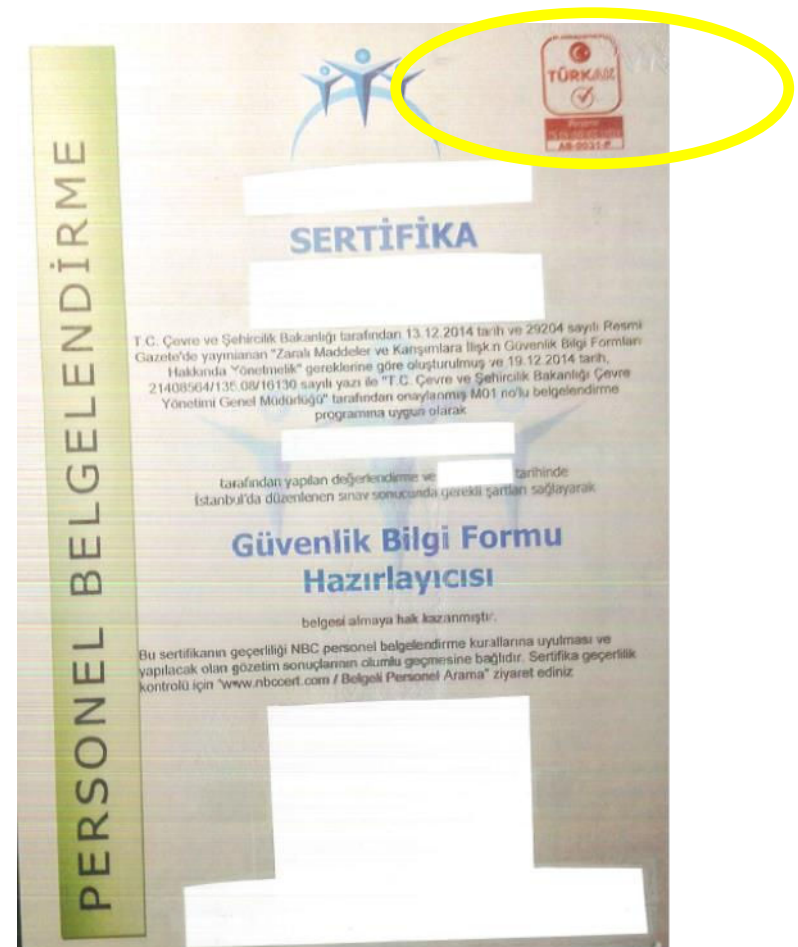
GBF Validation

Only Certified SDS Experts May Author Turkish SDSs

- Chemical Expert trained and certified by Turkish Certification Bodies
- GBF Preparation Expert trained and certified by Turkish Certification Bodies
- GBF regulation is to be followed until 31st of December 2023. Therefore, the certificate of GBF Preparation Experts is still valid till 2023 (to be renewed periodically).

GBF: Only Certified SDS Experts May Author Turkish SDSs

- The Certification Process is organised by Türkak (Turkish Accreditation Agency) (Article 7)
- Training in Turkey organised by a Türkak accredited Certification Bodies (Art. 7)
- Examination for Candidates at the end of course (Art. 8)
- Qualification Certificate is provided to the Candidate if the Examination is passed (Art. 9)
- Certificate is valid for 3 years, must be renewed periodically (Art. 9)



Turkish Certification Bodies Accredited by Türkak

- Training and Examinations in Turkish only



GBF Legal Requirements

- SDS must be prepared according to the Annex I format (Art. 5.5)

İKİNCİ BÖLÜM
GÜVENLİK BİLGİ FORMU FORMATI

GÜVENLİK BİLGİ FORMU Kısım I

Formun düzenlenmesinde kullanılan mevzuat

Madde/Karışım adı:

Hazırlama Tarihi:
Yeni Düzenleme Tarihi:
Kaçınıcı Düzenleme Olduğu:

Form No: X Sayfa No: 1/2

Kısım II

- 1) Maddenin/karışımın ve şirketin/dağıtıcının kimliği
 - 1.1. Madde / Karışımın kimliği
 - 1.2. Madde veya karışımın belirlenmiş kullanımları ve tavsiye edilmeyen kullanımları
 - 1.3. Güvenlik bilgi formu tedarikçisinin bilgileri
 - 1.4. Acil durum telefon numarası
- 2) Zararlılık tanımlanması
 - 2.1. Madde ve karışımın sınıflandırılması
 - 2.2. Etiket unsurları
 - 2.3. Diğer zararlar
- 3) Bileşimi/içindekiler hakkında bilgi
 - 3.1. Maddeler
 - 3.2. Karışımlar
- 4) İlk yardım önlemleri
 - 4.1. İlk yardım önlemlerinin açıklaması
 - 4.2. Akut ve sonradan görülen önemli belirtiler ve etkiler
 - 4.3. Tıbbi müdahale ve özel tedavi gereği için ilk işaretler
- 5) Yangınla mücadele önlemleri
 - 5.1. Yangın söndürücüler
 - 5.2. Madde veya karışımın kaynaklanan özel zararlar
 - 5.3. Yangın söndürme ekipleri için tavsiyeler
- 6) Kaza sonucu yayılmaya karşı önlemler
 - 6.1. Kişisel önlemler, koruyucu donanım ve acil durum prosedürleri
 - 6.2. Çevresel önlemler
 - 6.3. Muhafaza etme ve temizleme için yöntemler ve materyaller
 - 6.4. Diğer bölümlere atıflar
- 7) Elleçleme ve depolama
 - 7.1. Güvenli elleçleme için önlemler
 - 7.2. Uyumsuzlukları da içeren güvenli depolama için koşullar
 - 7.3. Belirli son kullanımlar
- 8) Maruz kalma kontrolleri/kişisel korunma
 - 8.1. Kontrol parametreleri
 - 8.2. Maruz kalma kontrolleri
- 9) Fiziksel ve kimyasal özellikler
 - 9.1. Temel fiziksel ve kimyasal özellikler hakkında bilgi
 - 9.2. Diğer bilgiler

GÜVENLİK BİLGİ FORMU

Formun düzenlenmesinde kullanılan mevzuat

Madde/Karışım adı:

Hazırlama Tarihi:
Yeni Düzenleme Tarihi:
Kaçınıcı Düzenleme Olduğu:

Form No: X Sayfa No: 2/2

- 10) Kararlılık ve tepkime
 - 10.1. Tepkime
 - 10.2. Kimyasal kararlılık
 - 10.3. Zararlı tepkime olasılığı
 - 10.4. Kaçınılması gereken durumlar
 - 10.5. Kaçınılması gereken maddeler
 - 10.6. Zararlı bozunma ürünleri
- 11) Toksikolojik bilgiler
 - 11.1. Toksik etkiler hakkında bilgi
- 12) Ekolojik bilgiler
 - 12.1. Toksisite
 - 12.2. Kalıcılık ve bozunabilirlik
 - 12.3. Biyobirikim potansiyeli
 - 12.4. Toprakta hareketlilik
 - 12.5. PBT ve vPvB değerlendirilmesinin sonuçları
 - 12.6. Diğer olumsuz etkiler
- 13) Bertaraf etme bilgileri
 - 13.1. Atık işleme yöntemleri
- 14) Taşımacılık bilgileri
 - 14.1. UN Numarası
 - 14.2. Uygun UN taşımacılık adı
 - 14.3. Taşımacılık zararlılık sınıfı(lar)ı
 - 14.4. Ambalajlama grubu
 - 14.5. Çevresel zararlar
 - 14.6. Kullanıcı için özel önlemler
 - 14.7. MARPOL 73/78 ek II ve IBC koduna göre toplu taşımacılık
- 15) Mevzuat bilgileri
 - 15.1. Madde veya karışımın özgü güvenlik, sağlık ve çevre mevzuatı
- 16) Diğer bilgiler

Titles of SDS Sections

# of Sections	Name of the section-GBF (SEA)	Name of the section-SDS (EU REACH)
1	Madde/Karışımın ve Şirket/ İş Sahibinin Tanımı	Identification of the Substance/Mixture and of the Compant Undertaking
2	Zararlılık Tanımlaması	Hazards Identification
3	Bileşimi / İçeriği Hakkında Bilgi	Composition/Information or Ingredients
4	İlk Yardım Önlemleri	First Aid Measures
5	Yangınla Mücadele Önlemleri	Firefighting Measures
6	Kaza Sonucu Yayılma Önlemleri	Accidental Release Measures
7	Kullanma ve Depolama	Handling and Storage
8	Maruziyet Kontrolleri/ Kişisel Koruma	Exposure Controls/Personal Protection

Titles of SDS Sections

# of Sections	Name of the section-GBF (SEA)	Name of the section-SDS (EU REACH)
9	Fiziksel ve Kimyasal Özellikler	Physical and Chemical Properties
10	Kararlılık ve Tepkime	Stability and Reactivity
11	Toksikoloji Bilgisi	Toxicological Information
12	Ekolojik Bilgi	Ecological Information
13	Bertaraf Bilgileri	Disposal Considerations
14	Taşımacılık	Transport Information
15	Mevzuat Bilgisi	Regulatory Information
16	Diğer Bilgiler	Other Information

Supplier Information Provided in Section 1.3

- Address of supplier is provided in Section 1.3. In this section, supplier needs to be company located in Turkey.
- Every importer in Turkey is a Supplier for that chemical according to Turkish Regulations. Therefore, importer's address should be provided in section 1.3.
- If there is more than one importer in Turkey and there is no main supplier company located in Turkey, same SDS requires to be reproduced for every single importer.

Author Certification Information Provided in Section 16

Information of author should be given in section 16 (Other Information).

- Name & Surname of the preparer
- Contact information
- Certificate number
- Name of institution where the author has been trained

GBF Legal Requirements

- SDS has to be prepared in Turkish (Art. 5.4)
- None of the sections is to be left blank. If there is missing information or it is insufficient for the purpose, ‘uygulaması yok (not applicable)’, ‘bilgi yoktur (no information available)’ and ‘özel hüküm yok (no special provisions)’ can be used (Art 5.9)
- An electronic copy of SDS is to be submitted to the Ministry of Environment and Urban Planning (Art 5.14)
- On each page of SDS, total page number and current page number must be provided (Art 5.7)

GBF Formatting Requirements

- If there are more than one pages in the SDS, all information included in section 1 must be placed at the header of each page (Art. 5.6)

The diagram shows a sample GBF form with the following fields and labels:

- Regulation name:** Points to the title "GÜVENLİK BİLGİ FORMU" (Safety Data Sheet).
- Form number:** Points to the field "Form No: X".
- Preparation date:** Points to the field "Hazırlama Tarihi:".
- New version date:** Points to the field "Yeni Düzenleme Tarihi:".
- Version number:** Points to the field "Kaçını Düzenleme Olduğu:".
- Page number:** Points to the field "Sayfa No: 1/2".

The form itself contains the following text:

İKİNCİ BÖLÜM
GÜVENLİK BİLGİ FORMU FORMATI

GÜVENLİK BİLGİ FORMU Kısım I

Formun düzenlenmesinde kullanılan mevzuat

Madde/Karışım adı:

Hazırlama Tarihi:
Yeni Düzenleme Tarihi:
Kaçını Düzenleme Olduğu:

Form No: X Sayfa No: 1/2

Common Mistakes in SDS Authoring

- Wrong section names
- Inappropriate or totally meaningless translations
- "Bu madde hızla hidroliz içsel ekotoksikolojik özellikleri en kritik ayrışma Ürün, izopropil alkol ile ilgili olduğu için.« → Translates into: This substance is rapidly hydrolyzed ecotoxicological properties of the critical internal decomposition products to be related to isopropyl alcohol → This is totally meaningless in both languages, it is not even a sentence.
- Wrong or outdated format for SDS is used
- Hazard classes should be provided in Turkish
- In section 15, regulatory information needs to be given. A common mistake is that CLP and REACH are mentioned. It is important to indicate that the SDS is prepared according to Turkish regulations. The regulations should be given in these section.

Practical issues with GBF compliance

- The commercially available SDS authoring software cannot handle Turkish SDSs
 - SEA (Turkish CLP) classifications remain in English or in incomprehensible Turkish
 - Usually only standard phrases are translated by the authoring software
 - Section names are usually translated wrong or not at all
- Having the authorised specialist certification is a strict legal requirement
 - Sufficient experience is not enough, certification is required

Conclusions

- KKDIK was published in the Official Gazette on 23th of June 2017 by MoEU.
- KKDIK will enter into force on 23rd of December 2017, six months after its publication, except the applications for which the transitional period is granted.
- SEA compliance needs to be taken care of within one month of market entry.
- There are three main ways of complying with GBF
 - Prepare SDS drafts in-house and get them certified by an authorised specialist
 - Due to numerous mistakes in the automatically generated SDSs, the scope of the certification work might be close to preparation from scratch
 - Outsource SDS preparation to an authorised specialist
 - The work is usually done on the basis of a REACH-compliant SDS in English
 - Recruit a dedicated Turkish SDS specialist

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**THANK YOU
FOR YOUR ATTENTION !**

Compliance. Sustained.

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