October 2nd - 3rd

INTERNATIONAL CHEMICAL CONFERENCE 2018

CIS Center Russia

ASTANA

REACH Implementation in Turkey (KKDIK- Turkish REACH)

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REACH

- European Union (2006)

- **R**egistration,
- **E**valuation,
- **A**uthorization
- Restrication of **Ch**emicals (**REACH**)

KKDİK

- Turkey (2017)

- **K**imyasalların
- **K**aydı,
- **D**eğerlendirilmesi,
- **İ**zni ve
- **K**ısıtlanması (**KKDİK**)

STRUCTURE OF KKDIK

- Regulation is formed of
  - 12 Titles
  - 67 Articles
  - 18 Annexes
  - 28 Pages – Main text
  - 405 Pages including all annexes (with blank) Annex 14

STRUCTURE OF KKDIK

❖Titles from 1 to 9 are listed & named as same as EU REACH Regulation

- Title I - GENERAL ISSUES
- Title II - REGISTRATION OF SUBSTANCES
- Title III - DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING
- Title IV - INFORMATION IN THE SUPPLY CHAIN
- Title V - DOWNSTREAM USERS

STRUCTURE OF KKDIK

❖Titles from 1 to 9 are listed & named as same as EU REACH Regulation

- Title VI - EVALUATION
- Title VII - AUTHORISATION
- Title VIII - RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES
- Title IX - FEES

Comparison with EU REACH

Structure of the legal text:

- Title X (Agency) & XI (CLI) of REACH does not exist in KKDİK
- Title XII of REACH → Title X of KKDİK
- Title XIII& XIV of REACH → Title XI of KKDİK
- Title XV of EU REACH → Title XII of KKDİK

STRUCTURE OF KKDIK

Annexes

ANNEX I	GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS
ANNEX II	REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS
ANNEX III	CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES
ANNEX IV	EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(a)
ANNEX V	EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)
ANNEX VI	INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10
ANNEX VII	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 TONNE OR MORE
ANNEX VIII	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE

STRUCTURE OF KKDIK

Annexes

ANNEX IX	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE
ANNEX X	STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE
ANNEX XI	GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X
ANNEX XII	GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS
ANNEX XIII	CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES
ANNEX XIV	LIST OF SUBSTANCES SUBJECT TO AUTHORISATION
ANNEX XV	DOSSIERS
ANNEX XVI	SOCIO-ECONOMIC ANALYSIS
ANNEX XVII	RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS
ANNEX XVIII	CONDITIONS FOR BEING GRANTED AS A CHEMICAL ASSESMENT EXPERT

Annex XVIII of KKDIK

Subjects

- Chemical Assessment Expert
- Criteria for Training institution and Lecturer
- **Criteria for the subjects to be covered by the training programme**
- Criteria about the certification institution and exam

Annex XVIII of KKDIK

CRITERIA FOR BEING GRANTED AS A CHEMICAL ASSESSMENT EXPERT

- ✓ Attending a training on Chemical Safety Assessment (at least 64 hours) and,
- ✓ Having a Bachelor degree from fields related to chemistry, biology or environmental sciences of Faculty of Science/Science and Literature or Faculty of Engineering or,
- ✓ Having a MSc or phD degree on chemistry science or,
- ✓ Having a Bachelor degree from other branches of the universities and having at least 5 years of experience on manufacture, laboratory, quality control or chemicals management related in the Chemical industry.
- ✓ + having ≥70 points out of 100 from the exam of the certification body.

Certified Chemical Assessment Expert - Annex 18

- There is no criteria for being a citizen of Turkey
- The CA expects to have legal power on the cCAE and communicate in Turkish
- Thus ; although being a legal person in Turkey is not a must for being a cCAE, CA does not appreciate the cCAE to be some one who is not resident and a legal citizen of Turkey.

Comparison with EU REACH

Similarities:

- Scope: All substances manufactured or imported ≥ 1mta
- Definitions : identical concept and approach
- Restricted substances: Identical with Annex XVII of EU REACH (with different dates for implementation.)

Comparison with EU REACH

Similarities:

- Guidance: Mostly translated versions of ECHA Guidance (versions from 2014) http://kimyasallar.csb.gov.tr/rehber-dokumanlar/18

Some missing (R7a-R7b-R7c-R8-R10-R20)

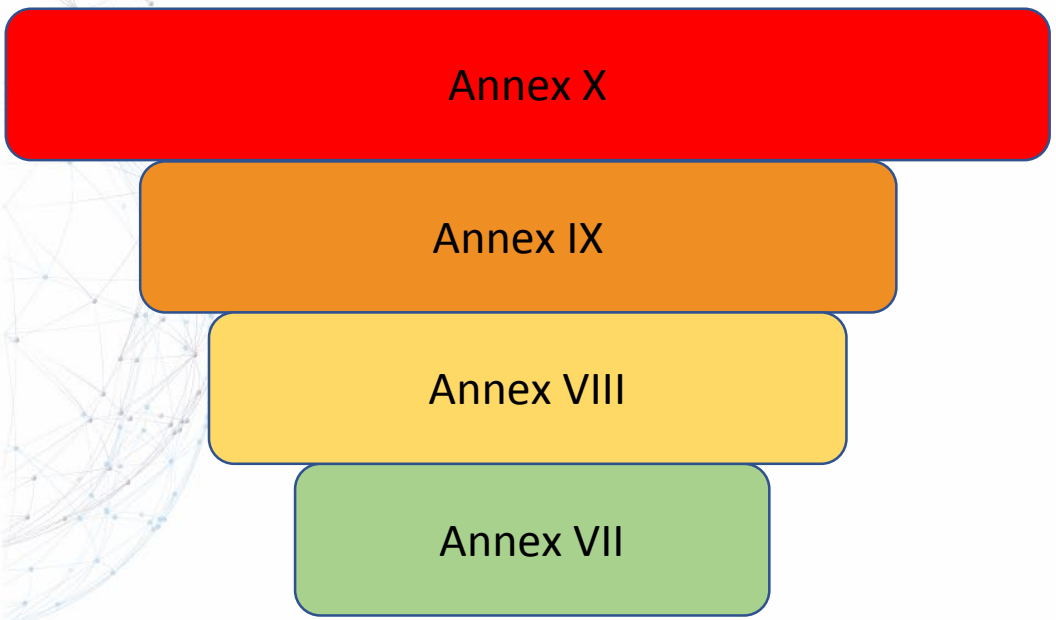
Comparison with EU REACH

Similarities:

- Data required for Registration is exactly same as the EU REACH
- No new testing or local testing required if the data is already available
- Identical data set requirement for tonnage bands
- Similarity between Legal text & guidance documents (few nuance)
- Annex IV&V of KKDİK are same as REACH (40 substances listed in Annex IV)

Comparison with EU REACH

Similarities: Information and data Requirements



≥1000 mta

100-1000 mta

10-100 mta

1-10 mta

Comparison with EU REACH

Similarities: Substances and mixtures out of the scope of KKDİK

-Radioactive substances and mixtures

- Substances mixtures and articles that are under customs supervision /temporary storage/ FTZ /in transit (with the condition that they dont under go any process)

-Non-isolated intermediates

-Wastes (defined as waste under the waste regulation)

-Substances and mixtures which are manufactured or imported for the purpose of defense

Comparison with EU REACH

Similarities: Substances and mixtures with partial exemption

- Exempt from obligations of Part II (Reg),V (DU),VI (Evaluation) & VII(authorization)

-medicinal products for human or veterinary use

-food additives authorised for use in foodstuffs (Turkish food codex)

-Feed stuff

Comparison with EU REACH

Similarities: Substances and mixtures with partial exemption

- Exempt from Part IV obligations (Information in the supply chain) (following preparations in the finished state, intended for the final user)

-medicinal products for human or veterinary use

-Cosmetic products

-medical devices which are invasive or used in direct physical contact with the human body

-food or feding stuffs

Comparison with EU REACH

Similarities: Substances and mixtures with partial exemption

- Exempt from obligations of Part II (Reg) & VI (Evaluation)

-Polymers

-Same as EU REACH (Monomers that are used for producing polymers are to be registered. (Art. 7 Prg (3))

-Recycled substances needs to be registered if the original material from which these are manufactured are not registered beforehand by an actor up the supply chain

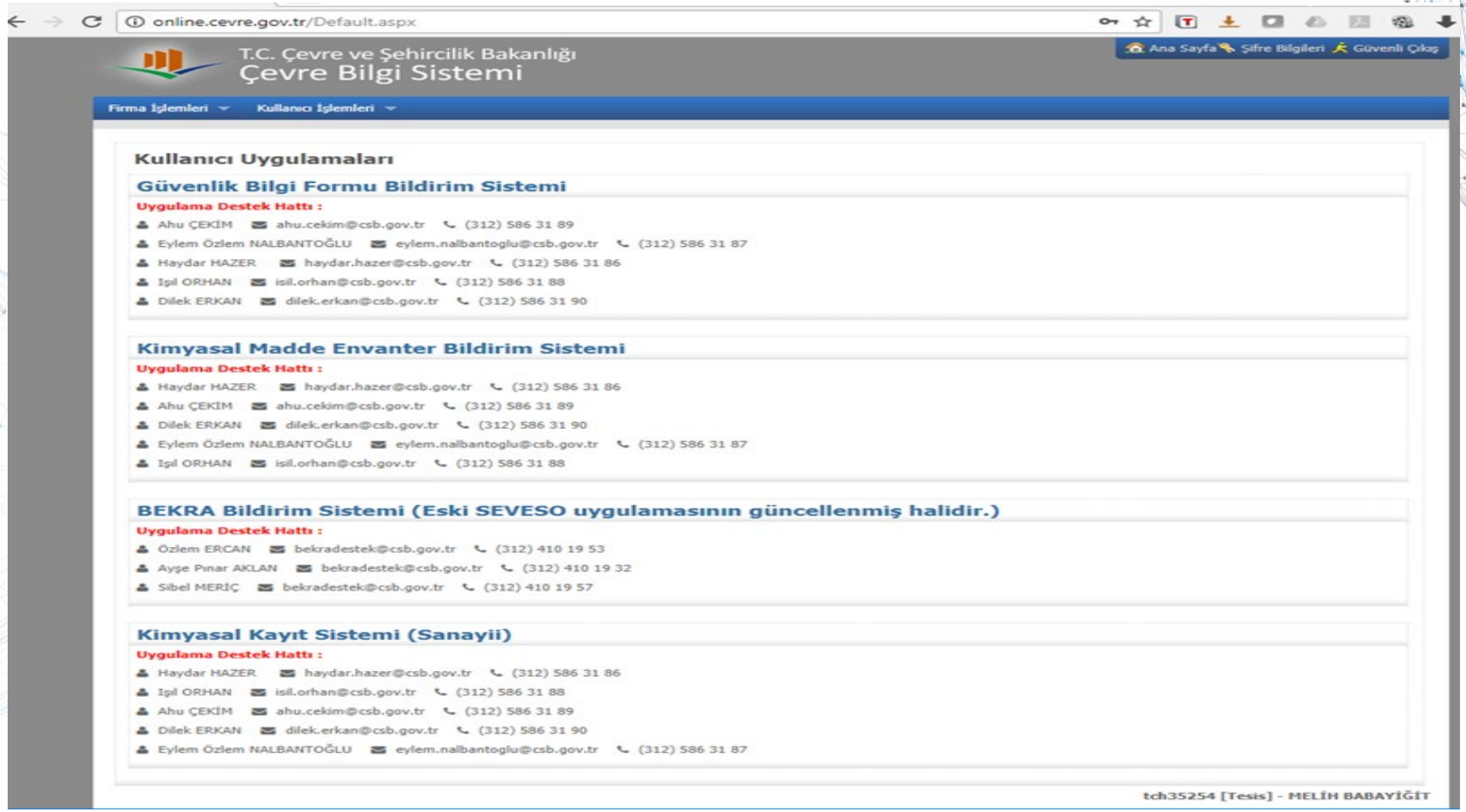
Comparison with EU REACH

Differences:

- Robust study summaries, CSR, CSA have to be in Turkish
- ELINICS listed substances have to be registered
- Requirement of a certified Chemical Assesment Expert (cCAE)

KKDIK IT System

❖IT module built in EIS named as KKS (a type of REACH-IT)

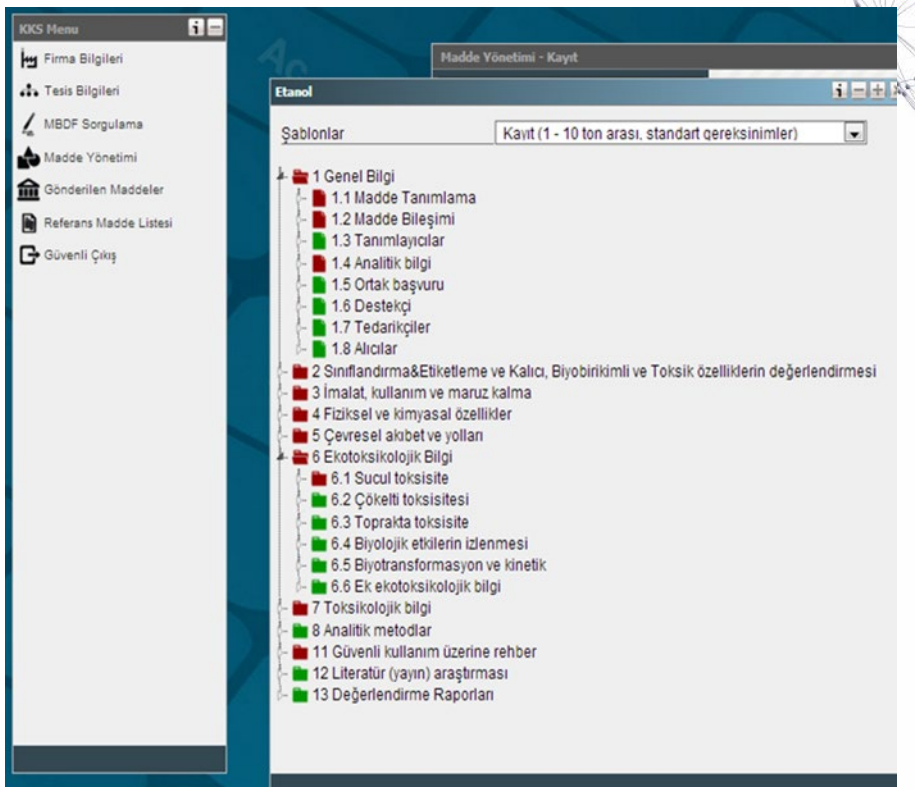


KKDIK IT System- KKS

- No xml or bulk Registration utility
- No standalone download version
- Web Access was from

http://online.cevre.gov.tr

Now the login is via https://www.turkiye.gov.tr



KKDIK Critical dates & chronology

23.06.2017

- KKDİK (30105) Published on Official Gazette
- Chemical Inventory and Control Regulation (CICR-27092) repealed
- Article 64 (b) repealing the CICR is the only provision enforced on the date of publication

KKDIK Critical dates & chronology

Pre-Registration & Registration

23.12.2017 – 31.12.2020

❖Pre-Registration term

31.12.2020 – 31.12.2023

❖Registration term

KKDIK Critical dates & chronology

Annex XVII

23.12.2017

- Regulation on Restrictions for the Manufacture, Marketing and Use of Certain Dangerous Substances & Preparations (27092) repealed

- Gorup I entries in Annex XVII came in to force

- (Group 1)Entries 1 to27- 43,46.b,47,50,51.a,51.b,51.c,52.a,52.b,52.c, 56,59, 61, 63,64 are in force

KKDIK Critical dates & chronology

Annex XVII

31.12.2018

❖(Group 2) Entries 28, 29, 30, 31, 32, 34, 35, 36, 37, 38, 40, 41, 45, 48, 49, 54, 55, 57, 58, 60 will be inforce

31.12.2019

❖(Group 3) Entry 62 will be inforce

31.12.2021

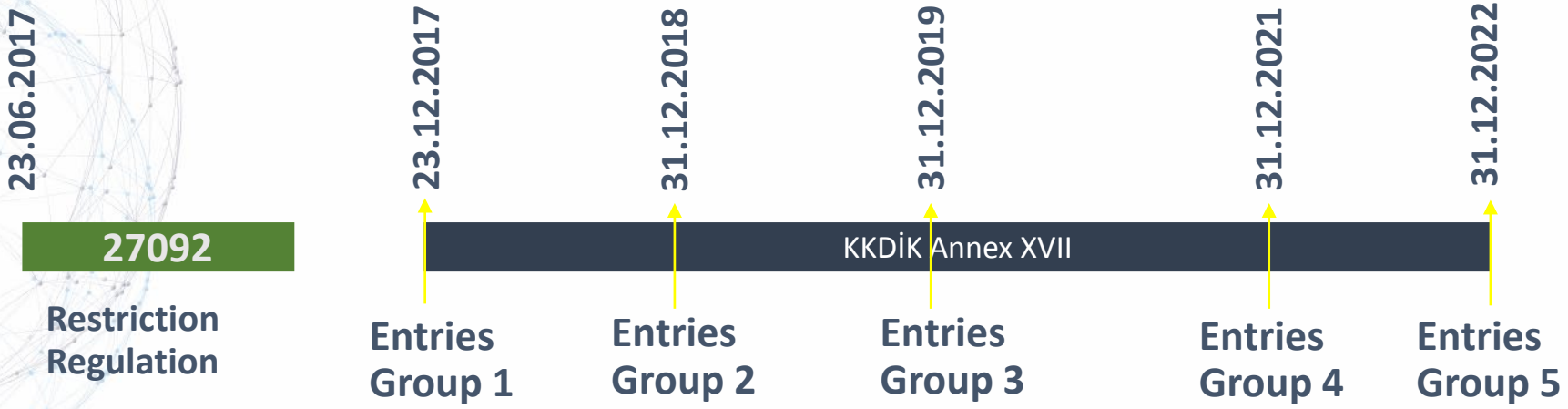
❖(Group 4) Entires 46a, 47 (1st & 4th prg) ,65 will be inforce

31.12.2022

❖(Group 5) Entry 66 will be inforce

KKDIK Critical dates & chronology

Annex XVII



KKDIK Critical dates & chronology

SDS

23.12.2017 – 31.12.2023

- SDS Regulation 29204 will be in force

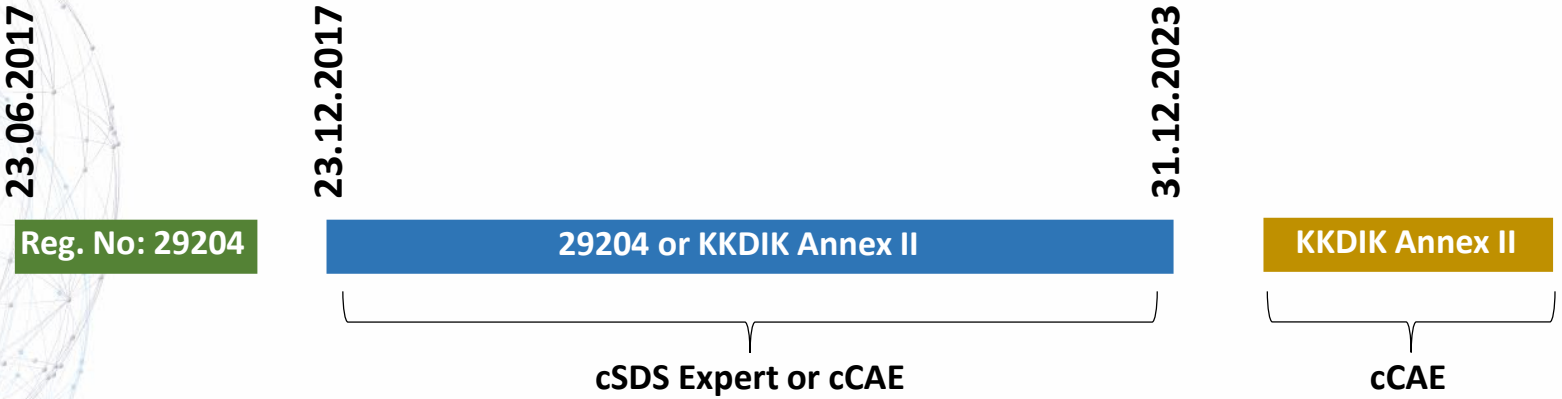
Also for the same term

- Annex II of the KKDIK will be in force

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

KKDIK Critical dates & chronology

SDS



KKDIK Critical dates & chronology

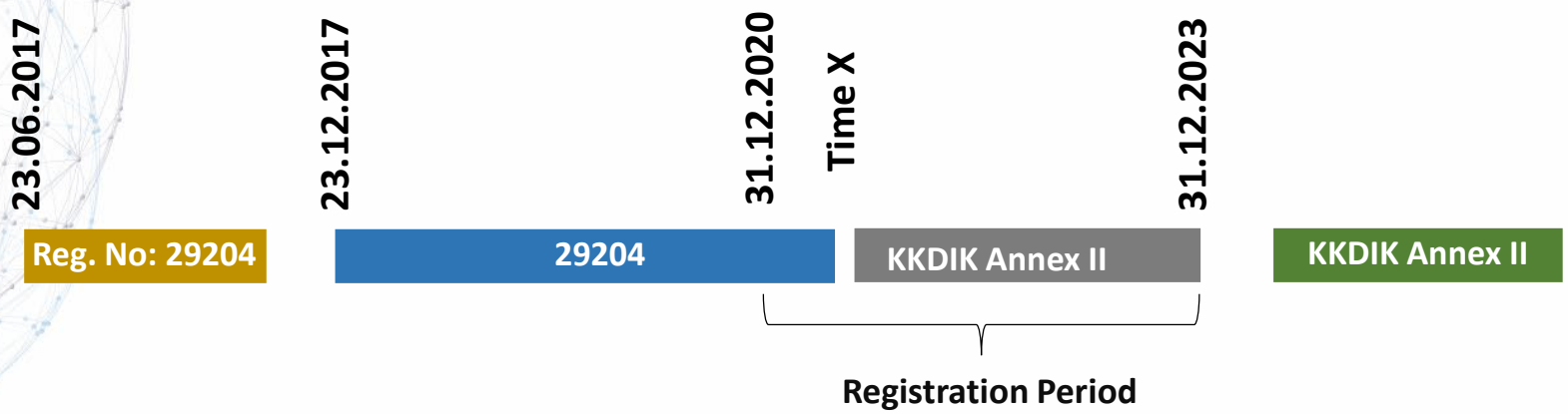
SDS (in pactice)

From 23.12.2017 to (a date between 31.12.2020 &31.12.2023)

- ❖SDS Regulation 29204 will be used because
- ❖Very few number of cCAE 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

KKDIK Critical dates & chronology

SDS (in pactice)



Critical points of KKDIK

- 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 Assessment Experts will be eligible to compile the SDS and e-SDS where required.

KKDIK Critical dates & chronology

Pre-Registration / Registration

31.12.2023

- Registration term will end
- Former SDS Regulation 29204 will be repealed
- No substance willl be manufactured or imported ≥ 1 mta before being regitered under the scope of KKDIK

KKDIK Critical dates & chronology

31.12.2023

- Identification of SVHC substances will start
- Authority will initiate forming the Candidate List of substances of very high concern for Authorisation
- The SVHC Candidate list will be published on CA web site when identified as candidate

KKDIK Official Fees

- KKDIK Official fees are identified in Article 59.
- Such fees are referred to the ‘’Schedule of Service fees’’
- This above mentioned list of fees are to be published on the CA web site.
- Registration of Substances which are registered between 1-10 mta in accordance with Annex VII are free

KKDIK Official Fees

REGISTRATION

AUTHORIZATION

REGISTRATION UPDATE

PPORD NOTIFICATION

Subject to official fee.

Options for the global industry

Appointment of OR (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 are to be imported into Turkey, may, by mutual agreement, appoint a natural or legal person established in Turkey as his only representative, to fulfil the obligations on importers under the scope of this regulation. Under such case Only Representative shall comply with all obligations of importers under this Regulation.

Options for the global industry

Appointment of OR (Article 9)

- (2) The Only 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 up to date of the safety data sheet referred to in Article 27.
- (3) If a representative is appointed in accordance with paragraphs 1 and 2, the non-Turkish resident manufacturer shall inform the importer(s) within the same supply chain of the appointment of Only Representative. These importers shall be regarded as downstream users for the purposes of this regulation.

Critical points of KKDIK

Article 16 (Substances deemed as registered)

- Active substances used in PPP under the scope of Turkish Regulation on PPP
- Active Substances used in Biocidal Products that are covered by the scope of Turkish Biocidal Regulation

are deemed as registered under thescope of KKDİK if they are already in Compliance with the above mention regulations only when they are used for such products.

Tips to beat the challenges

- Identify your OR / Consultant on time
- Any substance that is subject to Registration under the scope of EU REACH is subject to Registration under the scope of KKDİK (Tonnage bands may differ EU vs Turkey)
- Start early so that you don’t face a bottleneck in 2022 & 2023
- Borderline cases are expected to be handled with the same logic (Article or Mixture case/ Complex articles/intended release)

Thank you for your attention.

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