KKDIK (Turkey REACH) No: 30105

GCCM Training 2024

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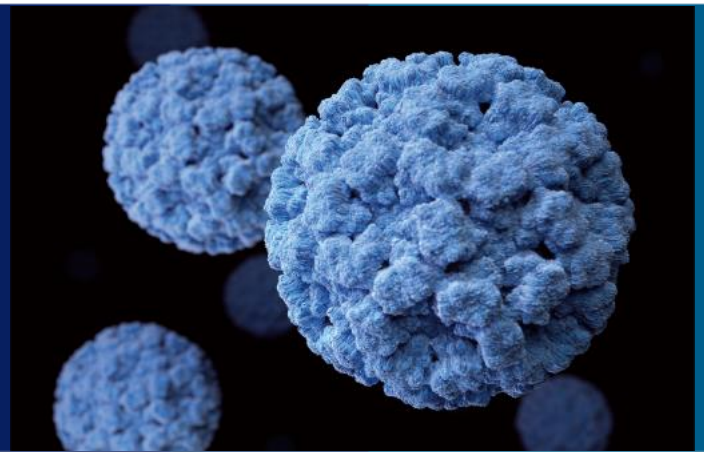
KKDIK Overview and Update



01

Overview of registration process for KKDIK

- KKDIK was developed based on EU REACH regulation with “no data, no market!”;
- Turkey located companies can do pre-registration&registration. For a company not located i Turkey can appoint an Only representative;
- Registration is mandatory for the substances above 1t/a;
- Before registration, it is mandatory to complete the pre-registration of the substance;
- Initially, the deadline for the registration of substances was 31 December 2023;
- In December 2023, the deadline was extended into different deadlines based on the tonnage band and classification categories;
- Accessing information such as SIEF members and their contact info, substance’s Lead registrant, registration completion status info via KKS;
- MoEUCC is not the party for SIEF communications;
- For a joint submission available roles are Lead registrant and Member (Co) Registrant;
- Lead registrant candidate initiates the process as e-mailing his interest to all potential registrants;
- For more than one Lead registrant volenteers, there occurs an election through KKS.

Completed registrations with numbers before the extension of deadline

- Number of the pre-registered different substances: app 21,000
- Total number of the pre-registrations: app 270,000
- Number of the Lead registrant elected substances: app 3,000
- Number of the Lead registration completed substances: app 1,300
- Number of the Co-registration completed substances: app 200
- Number of the registration completed substances (both Lead and Co roles): app 1,500
- Number of the LoA cost shared substances: app 300

New KKDIK Registration Deadlines

Registration scope for KKDIK is the same with EU REACH

1

31 December 2026

- ≥ 1000 ton/y
- ≥ 100 ton/y and classified as aquatic acute 1 or aquatic chronic 1
- ≥ 1 ton/y and classified as CMR category 1A or 1B

2

31 December 2028

- 100-1000 ton/y

3

31 December 2030

- 1-100 ton/y

After these deadlines, KKDIK is starting to show its stoper effect on Turkey market.

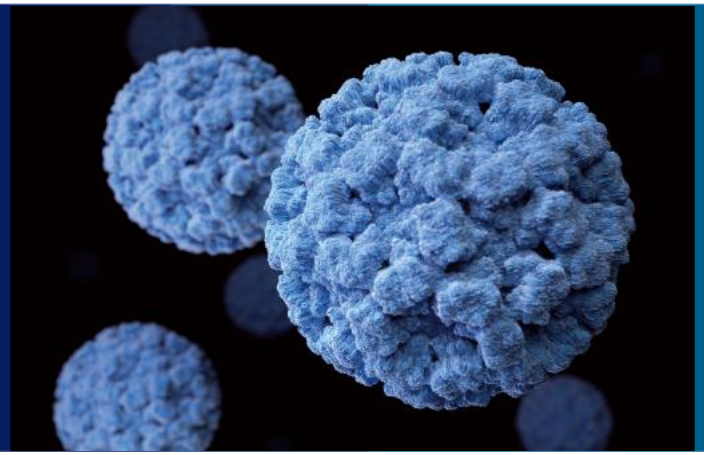
Highlights for Regulation Amending the Regulation on KKDIK, in 23/12/2023

- New actor, the Union of Chambers and Commodity Exchanges of Turkey, mentioned for Lead registrant election and data cost sharing process;
- With this amendment, it is indicated that the MoEUCC will publish «Procedures and Principles» later;
- Issues regarding the selection of leaders and data cost-sharing will be determined within the framework of «Procedures and Principles»;
- These determinations will be made as a result of collaborative efforts involving the sector, as well as the Union of Chambers and Commodity Exchanges of Turkey;
- The pre-registration deadlines are not determined yet and will be specified in the «Procedures and Principles».

Registered substances' situation after the new deadlines' announcement

- Tonnage tracking should be controlled
- Turkey based importers, covered by the supplier who appointed OR in the registration, should be tracked
- The uses should be tracked
- Registered substances' SDSs should be prepared

KKDIK Registration Process



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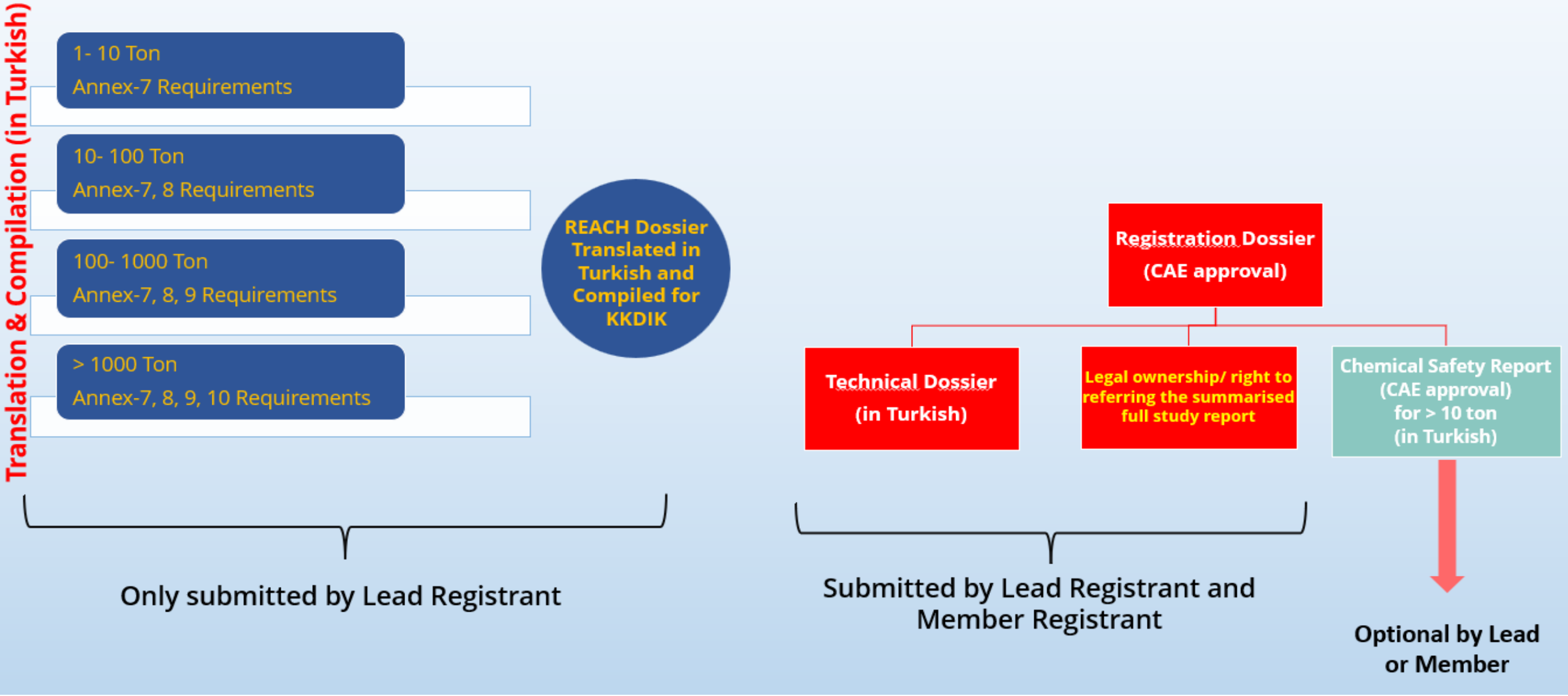
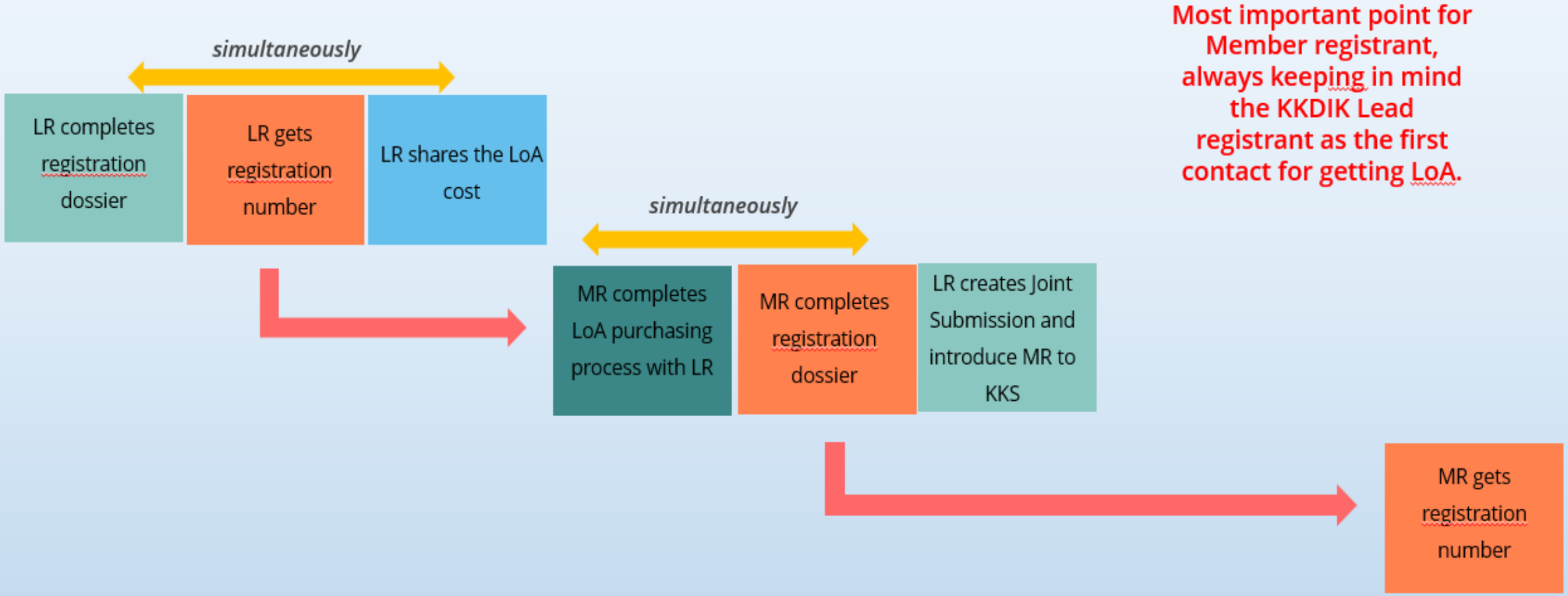
KKDIK Registration Dossier Structure for Joint Submission



Registration scheme for Joint submission

Lead registrant (LR) and Member Registrant (MR)



KKDIK Data Sharing Guidance/ Published by MoEUCC

The MoEUCC published Data sharing guidance on 25 April 2023 that has been adopted from Data Sharing Guidance published by ECHA in December.

Data Sharing Guidance requires;

- ✓ **Costs are in a fair, transparent and non-discriminatory manner;**
- ✓ **Agreement includes cost-sharing model;**
- ✓ **Agreement gives the right to access for co-registrants (at least to the endpoint results or to a copy of the robust study summary and study summaries);**
- ✓ **Agreement includes information on any possible future data needs.**

KKDIK Letter of Access (LoA) Parts

To explain the process much clearer, we will separate the LoA such two parts as Data and Administrative.

Please know that

Part 1: Data Part: means getting the right for referring data used in KKDIK registration dossier.

Part 2: Administrative Part: means any work directly related with KKDIK such as translation, submission of the dossier and any SIEF management work for KKDIK.

KKDIK Letter of Access (LoA)

Part 1: Data:

Having the Right to Refer Data

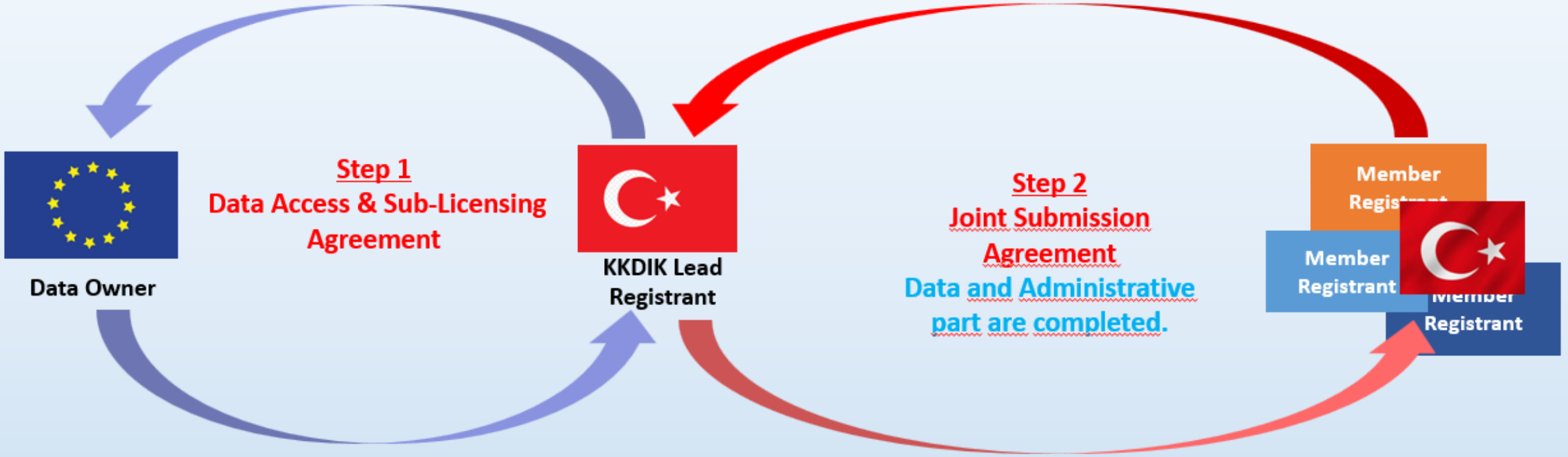
Data part can be managed by KKDIK Lead registrant or the data owner.

Part 2: Administrative

Related with KKDIK work-translation & submission & SIEF management.

It is obliged that at least administrative part is managed by KKDIK Lead registrant not to leave authorities out of play during any audit.

Letter of Access (LoA) Cost Sharing Process (Method is totally in compliance with Data Sharing Guidance)



It is signed between **Data Owner** and **KKDIK Lead Registrant** to get the sub-licensing and/or granting rights to referring data.

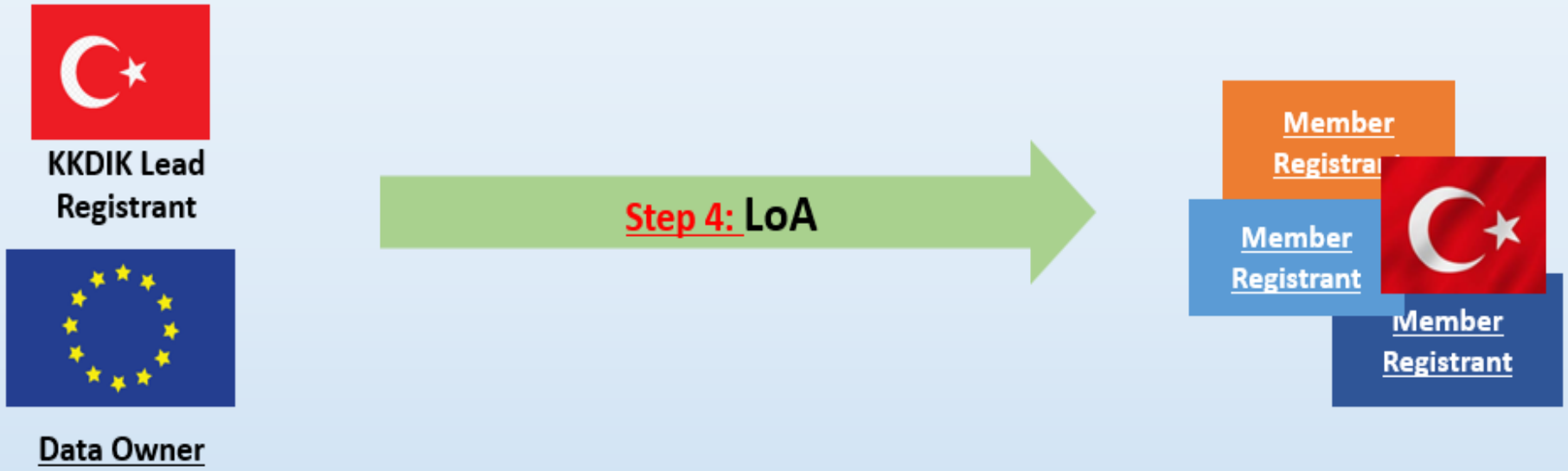
With this way, KKDIK Lead Registrant has the right to grant data referring right to the Member Registrant.

It is signed between **KKDIK Lead Registrant** and **Member Registrant** to be granted the right of referring data and to determine the SIEF management conditions.

Step 3: LoA

GENERAL APPLIED PROCESS FOR KKDIK LETTER OF ACCESS-1

GENERAL APPLIED PROCESS FOR KKDIK LETTER OF ACCESS-2



Uncertainties and Risks in the LoA Process

- *Negotiations with Data Owners often take long time for KKDIK Lead registrants;*
- *The same deadline applies to Lead registrant and Member registrants;*
- *There is no applied upper limit to the LoA fee that might be requested by the Data Owner.*
- *Some member registrants get the LoA without KKDIK Lead registrant's information which is an inconvenient way for KKDIK since creating Joint Submission on KKS is done by KKDIK Lead registrant.*
- *There are lots of uncertainties for the agreements' signature parties (responsible parties) for data sharing, joint submission or SIEF or any other agreement that are signed for KKDIK;*
- *It is expected that these issues will be handled with «Procedures and Principles» when the MoEUCC publishes it.*

Outlook for 2024 and beyond

- *Lead registrant nomination (not every REACH LR was interested to take the role)*
- *Low performance for Lead dossier submissions*
- *Low performance from Lead registrant for sharing LoA cost*
- *The same Lead registrant for Transported Isolated Intermediate (TII) nd standard Substances because of KKS property;*
- *It is a risk that the companies do not proceed with timely thinking that the delay of the deadlines too long;*
- *No clear voice from the MoEUCC related to procedures and principles publishment;*
- *The sanctions applied to Russian companies although this is not valid for Turkey.*

Advice for registrants

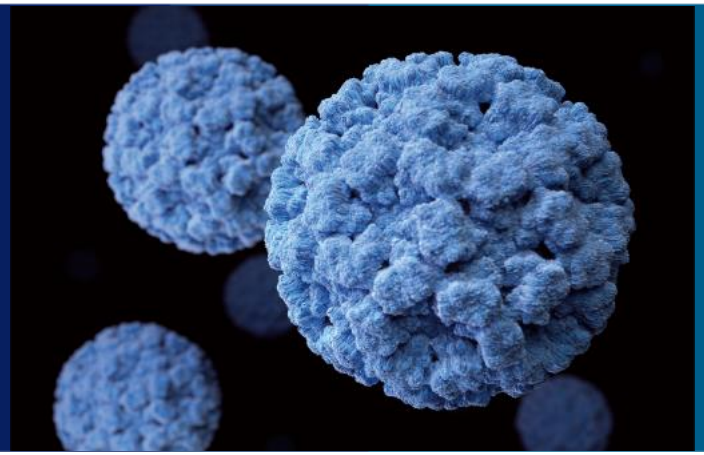
- ***Advice for established Lead Registrants: follow through with your Lead dossiers; in parallel, determine the fair LoA fee; once registered, immediately post the LoA conditions for the substance in the SIEF to enable all Members ('Co-registrants') to follow.***

- ***Advice for potential Lead registrants (for substances with no Lead yet): review your strategy and decide whether to volunteer for the Lead role; consult with other SIEF members about Lead (self) nomination.***

- ***Advice for Member registrants: continue monitoring of the SIEF status for your portfolio; enquire about LoA fee readiness inside the SIEF and outside (e.g. with former REACH substance groups).***

- ***Continuously monitor the evolution of the KKDIK regulation and related guidance in the next years!***

Turkey SDS



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Safety Data Sheet (SDS) valid for Turkey

As of 01/01/2024

- *Regulation on Safety Data Sheets for Hazardous Substances and Mixtures (Turkey SDS Regulation) repealed;*
- *SDS are prepared in compliance with KKDIK Annex-2 by the Chemical Assessment Experts (CAE)*

Main added elements on SDS prepared in compliance with KKDIK Annex-2 compared to SDS prepared in compliance with Turkey SDS Regulation;

- *SDS in compliance with KKDIK Annex-2 are allowed to be prepared by only CAE not SDS experts;*
- *Substances registration numbers are indicated on the SDS;*
- *SDS 16. Section should indicate the CAE information*
- *SDS 15.2 section includes chemical risk assessment title which indicates its availability*

Except Chemical Assessment Expert requirement, all the other elements such as classification, chemical risk assessment requirement etc. are the same with REACH Annex II.

SDS prepared in compliance with Turkey SDS Regulation are not valid if;

- *There is any change in the structure of a chemical substance;*
- *SDS expert's certificate validity expires.*

Other elements of KKDIK

❖**Authorisation**: the Authorisation process is very similar to EU REACH.

❖However, KKDIK ANNEX-XIV is currently still empty and will be published later.

❖**Restriction**: the Restriction process is also very similar to EU REACH.

❖SVHC (substances of very high concern): The Candidate List for SVHC, which should have been issued at the end of 2023, will probably only be published in 2026.

❖Important: the list of restrictions (Annex 17) should become equal to that of EU REACH as of 1 Jan. 2024.

❖**Enforcement**: inspections are possible since 23 Dec. 2017 and manufacturers, importers and Only Representatives are in scope.

Thank You!

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