Session 1: Turkey KKDIK Pre- registrations & Registrations Webinar

Questions & Answers

Info	Answers to Questions received before and during the webinar held on the 28th of September 2020
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#	Question	Answer
1	Are there any requirements on articles? e.g. art. 33 of EU REACH?	Yes, the requirements of Articles under Turkey KKDIK remain the same as EU REACH article 33. The substances in articles are covered under Article 8 of By-Law.
2	Is there an accessible list of pre-registrations received under KKDIK?	No, as of now the list of KKDIK pre-registrations is not publicly available.
3	Is REACH law applicable to chemicals under drugs and nutraceuticals?	According to the definition of Medicinal products for human or veterinary use, these are exempted under Article 2(a)(1) of Bylaw however, intermediates needs to be registered
4	What happens where data owners are EU REACH registrants but are not interested in Turkey-REACH registration?	1. You can approach the authority as “data holder”, and the authority shall then connect the potential registrants with your company for purchase of data for the purpose of registration 2. Alternatively, you can also pre- register and inform in the SIEF that you are data holder but not interested to register the substance.
5	If we are exporting mixtures set up by raw materials registered for KKDIK already by their manufactures is there any action required by us?	If your supplier(s) will pre-register and register the substances subject to KKDIK that are included in your mixtures then you don’t need to pre-register and register as your mixtures will be covered by your supplier’s pre-registration and registration as long as they cover the volumes your company places on the Turkish market and that are imported by your customers in Turkey. For this, it is important that you ask to the Turkish OR -appointed by your supplier(s)- a KKDIK compliance certificate.
6	(a) Is it expected to have a late preregistration phase? (b) This question is regarding Late Preregistration. If we have substances that today are less than 1 MT/year; the business is growing but small at the moment. When we know that these substances will exceed 1 MT, may we late preregister? Or should we preregister any substance currently on the market at less than 1 MT?	(a) Yes, late pre- registration is possible if you are placing a substance on the Turkish market for the first time in quantities above 1tpa after the pre-registration deadline (31.12.2020) but before the registration deadline (31.12.2023). (b) Companies can assess their business potential in the Turkish market and if it seems promising they can pre-register well in advance to secure the Turkish market Or Use late pre-registration.
7	What is the advantage of being "lead registrant"? It seems lead registrant needs to do lots of work, why do companies want to be "lead registrant"?	The advantage of becoming a lead registrant (LR) is to have control on the overall process eventually leading to the registration of the substance and guarantee to your customer(s) that businesses can continue after 2023. Even though LR needs to do lots of work, companies choose to be LR when they have a major market share

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		and the substance is strategically important, also possibly owns the data. You can expect the return on investment when additional members join your registration.
8	How, and When can we know that our substances apply SIEF?	After the pre- registration deadline i.e. 31.12.20, by default substances qualify for Pre- MBDF (pre-SIEF) which is formed from 01.01.2021. This is a communication channel between all pre-registrants of same substance.
9	If a product is manufactured in France and is EU REACH compliant (i.e. all EU REACH requirements are satisfied), what is required if the product is imported and marketed in Turkey? Is EU REACH registration sufficient to place on the market in Turkey (both initially and long-term)? What steps need to be taken.	Substances imported and marketed in Turkey shall comply with Turkey KKDIK and must undergo pre-registration by 31 December 2020 and registration by 31 December 2023. No, EU REACH registration is not applicable in Turkey.
10	what will be the biggest implication if non-Turkey manufacturer missed the pre-registration?	If non- turkey manufacturer (“supplier”) misses the deadline, after December 2020 business will be different considering following facts: • Only Turkey importers who have made pre-registrations can buy your material or you can sell your products through them, business decision lies with them. • You will no longer be able to make business if Turkish importer who decides not to pre-register but choose to work with Turkey REACH compliant suppliers. They will ask you to provide declaration to confirm compliance.
11	The substance "frit chemicals" is exempted from registration in EU REACH if there is no solubility on hazardous elements according to point 11 annex V. Could you please confirm if in KKDIK is the same?	The exemption criteria as covered under EU REACH Annex V are also applicable to KKDIK. However, this must be discussed between the SIEF members on development of these substances along with comments from authority, so that they accept similar argument.
12	For a polymer, is it really ONLY the monomer that must be registered? What about the substances used to manufacture the polymer (such as initiator) if the polymer is made in France then exported to Turkey?	Polymers will be treated in the same way as under EU REACH. To comply with KKDIK regulation, first you should identify if your product is a polymer as per definition then you will need to identify the monomers and performance additives for pre-registration if all exceeds 1tpa. Under SEA regulation, you need to also notify hazardous polymers but not monomers.
13	(a) KKDIK & REACH EU, safety data requirements are same or different? (b) will the SDS performed according to GBF will have the KKDIK registration number as in EU REACH?	(a) The SDS it is required to be certified by a GBF Expert (until Dec’23) and Chemical Assessment Expert (“KDU”) (from Jan’24) and their details should appear on the SDS. Also, the SDS should be in Turkish language. For hazardous substances or mixtures, SDS also needs to be submitted to MoEU (authority) by your Turkish importer. (b) You can place KKDIK registration number in section 1 in addition to EU if you also sell to Turkey. This requires further clarification.
14	For DU purposes, should we contact our suppliers and request KKDIK pre-registration/registration compliance evidence?	Yes, you should contact your suppliers to demonstrate compliance under KKDIK, eg. sending request to provide KKDIK OR details and KKDIK OR certificate with pre-registration numbers for your record keeping. You should also cross verify with KKDIK OR that they indeed have made these pre-registrations and are active.

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15	Is there a deadline for SEA Notification in Turkey?	The official deadline has already passed, all hazardous substances or hazardous substances in mixtures must be notified before placing them on the Turkish market.
16	Is the CSR needed only for substances imported above 10T/y only (with an exposure scenario)?	Yes, it is required.
17	Which cost can we expect for registrations depending on the tonnages?	The costs can be summarised as follows: • Authority Fee based on tonnage band and size of the company • Data cost or Letter of Access (LoA) fee depends up to data requirements for relevant tonnage band • Consultant Fee based on whether it is Co-registration or Lead registration or additional work depending upon what is included in LoA fee, including translations. • OR fee where applicable.

CONTACT FOR FURTHER QUESTIONS

- Mr Frederik Johanson, Partner, frederik.johanson@reachlaw.fi
- Mr Gagan Kumar, REACHLaw India Representative at gagan.kumar@reachlaw.fi

More information on our KKDIK related services can be found here.

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