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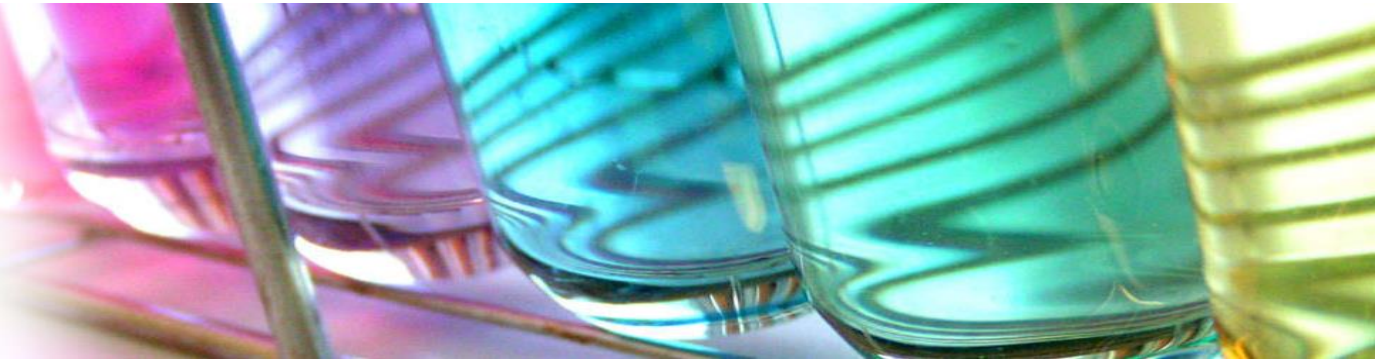
Confederation of Indian Industry

Masterclass on Key Chemical Regulatory updates

Wednesday, 19 October, 2022

14:00 – 17:00 (IST) | Virtual



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Time (IST)	Content
14:00 - 14:10	Welcome note Ashneet Gahlawat, Executive Officer, CII
14:10 - 14:30	UK chemicals regulations: Challenges and Moving Forward
14:30 - 14:40	Q&A Session
14:40 - 15:10	How to comply with Turkey REACH (KKDIK) registration: SIEFs, Consortia and Dossier Preparation
15:10 - 15:20	Q&A Session
15:20 - 15:25	Break
15:25 - 16:05	Chemicals under the EU Green Deal
16:05 - 16:10	Q&A Session addressed via email
16:10 - 16:40	Draft Chemical Regulation in India: Chemicals Management and Safety Rules
16:40 - 16:50	Q&A Session
16:50- 17:00	Closing speech Dr. Jayachandran Nair, CEO, GPC

Focused Sessions

UK chemicals regulations: Challenges and Moving Forward

Mrs. Priyanka Manapure, Senior Manage, GPC

How to comply with Turkey REACH (KKDIK) registration: SIEFs, Consortia and Dossier Preparation

Mr. Mirac Mert Pelister, Turkey Business Coordinator, GPC

Chemicals under the EU Green Deal

Mr. Daniel Toran, Regulatory Advisor, GPC

Draft Chemical Regulation in India: Chemicals Management and Safety Rules

Dr. Jayachandran Nair, CEO, GPC

UK REACH

WHAT YOU NEED TO KNOW ABOUT UK-REACH

Ms. Priyanka Manapure,
UK-REACH Regulatory Advisor
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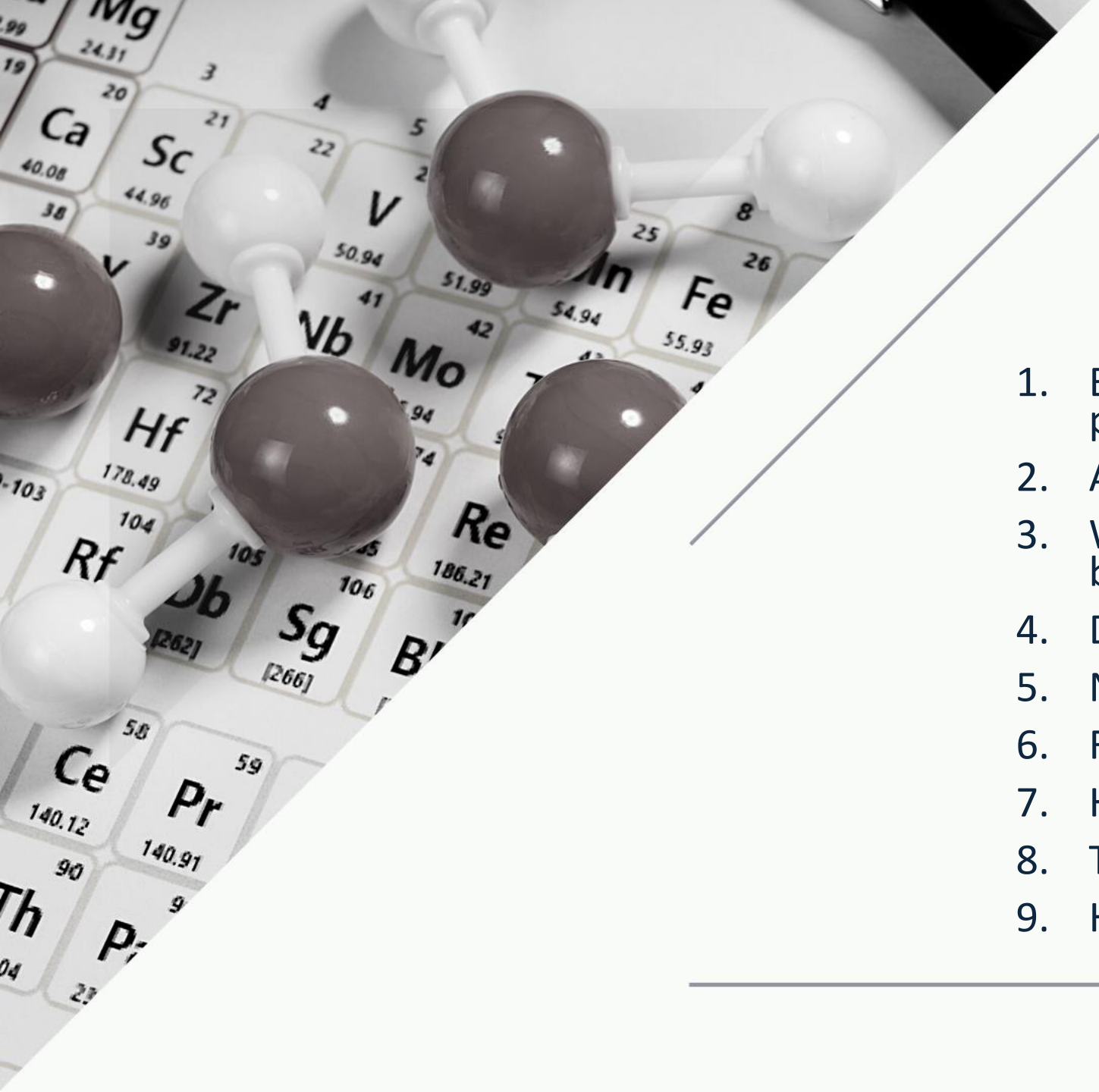

Summary of Topics

1. Background of UK REACH, timeline, basic principles and competent authority
2. Actors affected by UK REACH
3. Which UK REACH procedure applies to your business?
4. DUIN under UK REACH
5. NRES under UK REACH
6. Registration under UK REACH
7. HSE registration fees
8. Take home message
9. How can GPC help you?

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Background of UK REACH

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Background of UK REACH

- On **1st January 2021**, at the end of the Brexit Transition period, UK REACH came into force and EU REACH ceased to apply in **Great Britain**. As a consequence, chemicals may not be manufactured or imported in **Great Britain** under an EU REACH registration.

- UK REACH applies in **Great Britain**, i.e.: England, Scotland and Wales.

- Please NOTE:

  EU REACH still applies in **Northern Ireland**, as provided under the Northern Ireland Protocol agreed between the EU and the UK government.

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Background of UK REACH

- UK REACH is based on the EU REACH Regulation as amended by the **REACH (EU Exit) Regulations 2019**. UK REACH has been described as mirroring its EU counterpart.

- UK REACH contains **transitional provisions** for importers and exporters who were accessing the GB market with an EU REACH registrations prior to 1st January 2021. The purpose being to limit disruptions on the existing business.
  - **Grandfathering** – deadline expired
  - **DUIN –** deadline expired, **however DUINs can still be submitted on the government portal**

- Transitional provisions do not apply to those who wish to **place a substance on the UK market for the first time.**

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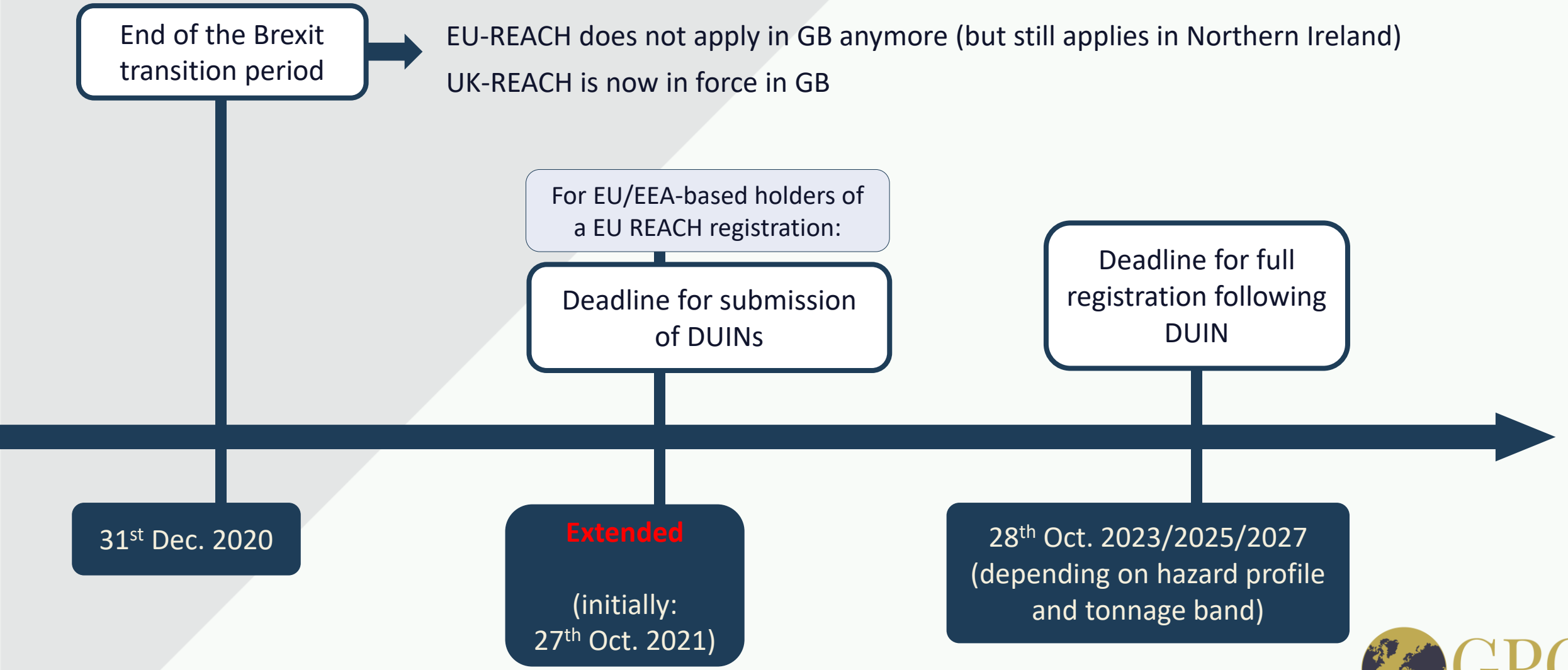
Timeline of UK REACH



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Basic principles of UK REACH

The “no data no market” principle

The last resort principle on animal testing

Access to information for workers

The precaution principle

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Competent authority

- The authority in charge of enforcing UK REACH is the Health and Safety Executive (HSE)

- Compliance with UK REACH is to be carried out through the IT platform **Comply with UK REACH**

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Actors affected by UK REACH

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Who is concerned by UK-REACH?

Manufacturers (both GB and non-GB based)

Importers

Downstream users

Only representatives (OR)

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The role of an OR

- Non-GB based manufacturers who wish to place chemical substances on the GB market may appoint a GB-based only representative (OR)

- An OR must be:
  - ✓ a natural or legal person established in Great Britain
  - ✓ equipped with sufficient background in the practical handling of substances and the information related to them
  - ✓ appointed by a mutual agreement with a manufacturer, formulator or article producer, established outside Great Britain
  - ✓ responsible for complying with the legal requirements for importers under UK REACH

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Which UK REACH procedure applies to your business?

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Which UK REACH procedure applies to your business?

Is your substance registered under EU REACH?

Yes

Did you place the substances on the GB market between **01/01/2019** and **31/12/2020?**

Yes

By submitting a **DUIN** you can maintain access to the GB market and extend the registration deadline

The substance must then be registered within 2, 4 or 6 years (depending on hazard profile and tonnage band)

No

You may place your substance on the GB market even if you are not able to submit a full technical dossier provided that

1) You submit an art. 26 Inquiry

2) You submit a registration dossier that satisfies minimum data requirement

3) You pay the HSE registration fee

You then have 2, 4 or 6 years (depending on hazard profile and tonnage band) to submit the full substance data

No

You may not place the chemical substance on the GB market unless you **register your substances** under UK REACH

(Article 26 Inquiry + Registration)

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DUIN
as a non-GB manufacturer

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What is DUIN, how does it work?

Downstream User Import Notification (DUIN) is a process set out under the UK REACH transitional arrangements.

The notification allows EU/EEA based holders of an EU REACH registration to maintain access to the GB while postponing their UK REACH registration deadline.

EU/EEA based registration holders have 2 options:

1. They may let their GB-based downstream user(importer)/distributor/formulator submit the DUIN to HSE; or
2. They may appoint a GB-based OR to submit the DUIN to HSE

DUINs were to be submitted **before October 27, 2021. However, <u>the deadline has been extended for an undisclosed period of time</u>.** Once they have been notified, the substances must be fully registered under UK REACH, within 2, 4 or 6 years depending on tonnage band and hazard profile.

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What are the benefits of DUIN?

Maintaining access to the GB market while **securing time** to complete full registration of the substance within the deadline of 2, 4 or 6 years.

During these 2, 4 or 6 years, you can asses business opportunities in Great Britain while saving on the HSE registration fees.

Remarks:

- DUIN is not a pre-registration, as the concept does not exist under UK REACH.
- DUIN is conditional upon the substance being already registered under EU REACH
- The DUIN needs to be done **only once** per legal entity, and it must cover all the substances that you are dealing with.

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What are the conditions to perform DUIN?

1. To be either:
   - A GB-based legal entity that was importing substances and mixtures into GB from the EU or from outside of the EU;
   - A non-GB based manufacturer, wishing to appoint a GB-based OR to perform the DUIN on behalf of the GB-based importer
2. The non-GB based manufacturer must hold a valid EU REACH Registration Number
3. The GB-based importer or the non-GB based manufacturer must have placed the substance into the GB market during the period between January 1st, 2019 and December 31st, 2020.

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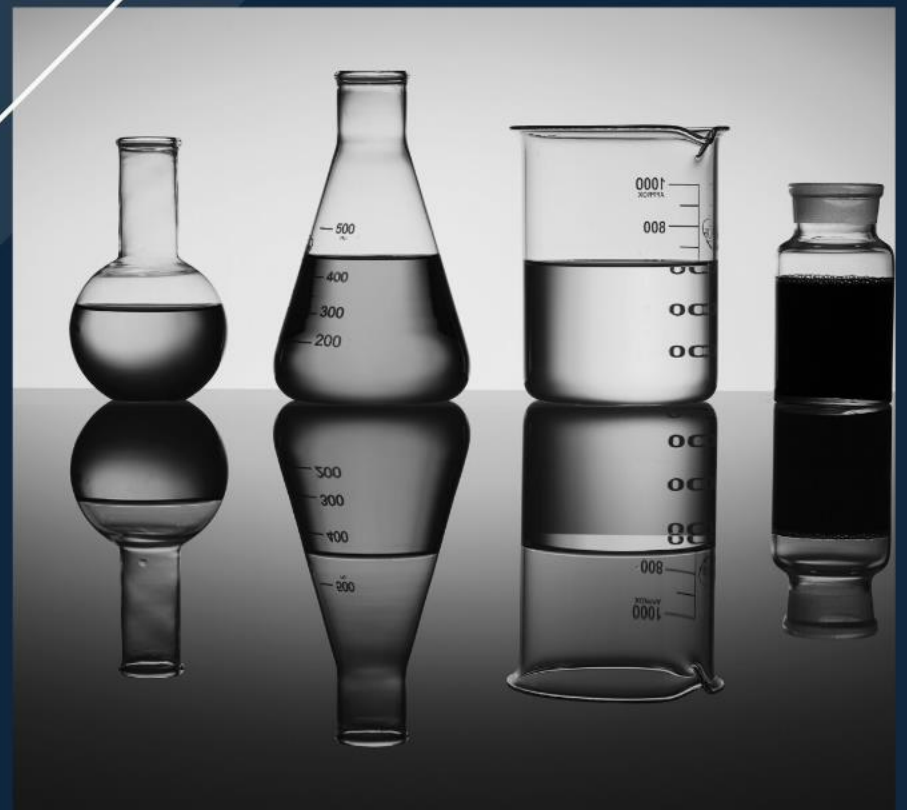
How to perform DUIN? (1/2)



- Appoint a GB-based OR if you are not going to let you GB-based importer perform the DUIN
- Open an account on HSE´s IT system “Comply with UK REACH”. A DUIN number will then be assigned to you
- Keep in mind that the deadline for DUIN has been extended by the UK government, although it is not known for how much longer

  Past the deadline, substances will need to undergo full registration

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How to perform DUIN? (2/2)

The DUIN takes the form of a standardised Excel spreadsheet, including (but not limited to) the following information: DUIN number, legal entity's name, CAS number, classification and labelling etc.

The spreadsheet then needs to be sent by email to HSE

For some of the information, it may be easier to add an attachment to the email (e.g. the Safety Data Sheet)

You must then **fully register** your substance within 2, 4 or 6 years

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DUIN as a formulator

As a non-GB based formulator, you may also submit a DUIN via your GB-based OR if:

1. The individual substances within your mixture are registered under EU REACH, and
2. You have placed those mixtures into the GB-market during the period between 1st January 2019 and 31st December 2020.

In order to submit a DUIN via a GB-based OR, you will need to fill out the excel spreadsheet mentioned earlier.

However, the ECHA registration number of the substances does not need to be disclosed. In a private communication HSE has specified that the supply just needs to be covered by an EU REACH registration higher up the supply chain.

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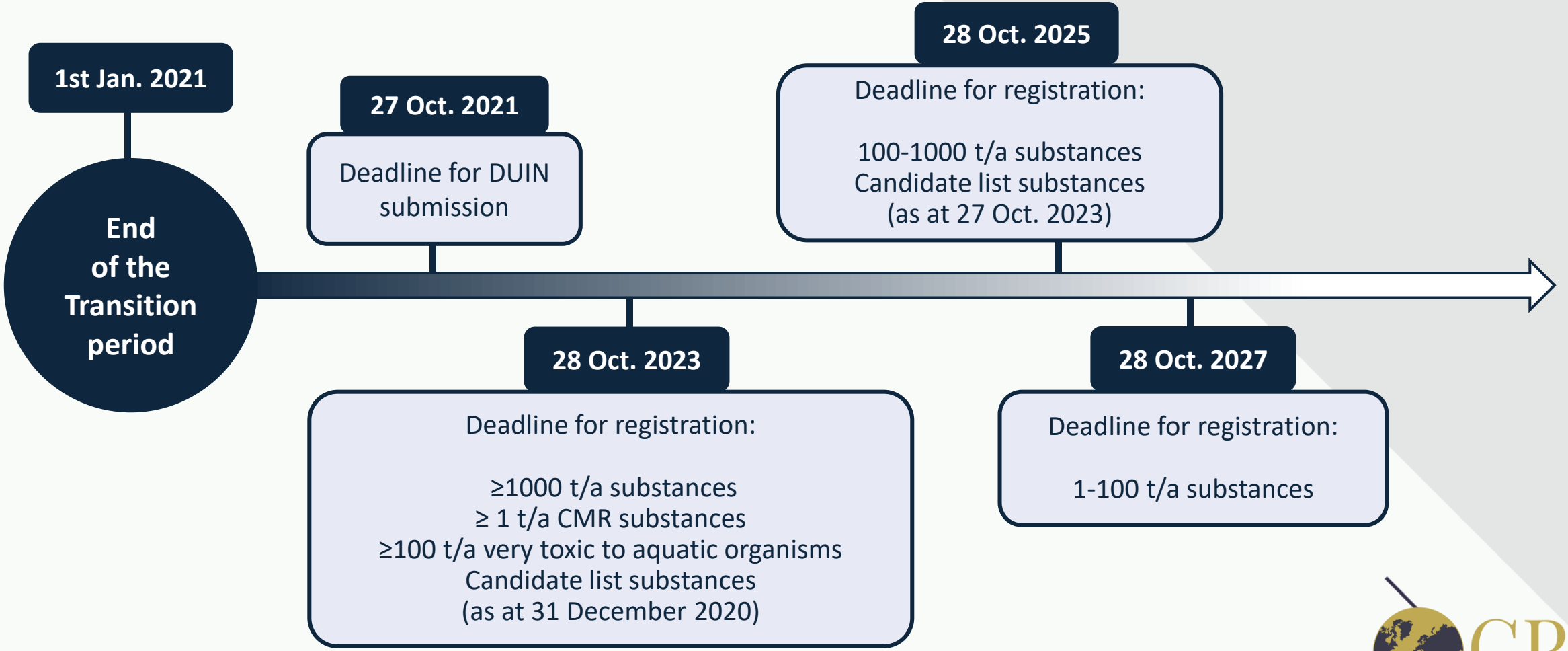
Deadlines for DUIN and post-DUIN full registration



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NRES (simplified registration process) under UK REACH

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The New Registration of an Existing Substance (NRES)

In order to provide parity between new registrants and DUIN beneficiaries, HSE recently introduced the concept of New Registration of an Existing Substance (NRES).

If you are a non-GB based manufacturer or a GB-based importer and you seek to place an EU REACH-registered substance in the GB-market for the first time, then your substance qualifies as a NRES.

Provided that you comply with a simplified registration process, you may place your substance on the GB-market and postpone the submission of the full data for your substance by 2, 4 or 6 years from 27 October 2021 (depending on tonnage band and hazard profile).

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The New Registration of an Existing Substance (NRES)

In accordance with the NRES procedure, you must:

- Submit an Article 26 Inquiry
- Submit the registration dossier, including a waiver explaining why you are not yet able to provide the full registration dossier (HSE is yet to issue a list of acceptable justifications)
- Pay the HSE authority fee

Once these steps have been completed, you are considered compliant with UK-REACH.

This means that you can start placing your substances on the GB market.

Please keep in mind that before the 2-, 4- or 6-years deadline, you will need to complete the full registration and pay the applicable LoA costs.

Note that NRES only applies to substances that were registered within EU REACH **before 31st December 2021!**

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Full Registration process under UK REACH

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Registration under UK REACH

- **The registration process applies to:**
  - Non-GB based manufacturers (via an OR) and GB-based importers who wish to place a non-EU REACH registered substance on the GB market for the first time.
    Registration should be carried out as soon as possible.
  - Non-GB based manufacturers (via an OR) and GB-based importers who have previously submitted a DUIN or have become partially compliant by the NRES process.
    Registration must be carried out within 2, 4 or 6 years.
- **The registration process consists of:**
  1) Article 26 Inquiry
  2) Registration

Remarks:

- Registration is required prior to the manufacture or import into GB reaching 1 ton/year.
- Registration is per substance, per legal entity.
- Registration is not required for mixtures (formulations).
- Registrations must be accompanied by the appropriate registration fee

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The Art. 26 Inquiry

- The first step to new registration is submission of Inquiry Dossier
- The process for compiling an inquiry dossier is analogous to the process under EU REACH and the requirements are the same.
- Inquiry dossiers must be submitted to The Agency via Comply with UK REACH.
- Upon receipt of inquiry number, your contact details will be shared with existing registrants, grandfathered registrants and other successful inquirers regarding that substance. This will enable you to engage in the data sharing process.

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The Registration (1/3)

Substance groups and joint registration

- Following the submission of an **Inquiry,** ‘Comply with UK REACH’ will organize the registrants according to substance groups (the UK REACH equivalent of SIEFs).
- Substance groups will be made up of multiple businesses that all want to submit a registration for the same substance.
- The group must then appoint a Lead Registrant (LR) to submit the joint registration dossier for that substance on behalf of all group members.
- The Lead Registrant role should be claimed on ‘Comply with UK REACH’ once the dossier is ready to be submitted.

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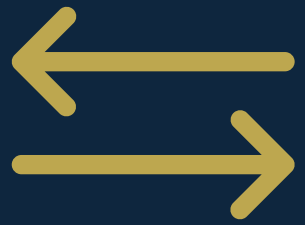
The Registration (2/3)

Data sharing



- Sharing the data needed to submit a joint registration will be an important task for substance groups.

- If the substance group is in the process of forming, members must:
  - ✓ Find out what studies are available
  - ✓ Assess any data gaps within the group
  - ✓ Consider other publicly available data

- A legal agreement or a **'Letter of Access' (LOA)** can formalize the data sharing agreement

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The Registration (3/3)

The Letter of Access (LoA)

- The LoA gives co-registrants and new members access rights to the data to be used in the dossier, for the purpose of completing their registration.
- If you seek to register under UK REACH a substance for which you had already purchased an EU REACH LoA, **there is a good chance that you may not have to purchase the LoA again**.
- To find out, we can contact your EU REACH Lead Registrant, and ask if they plan to claim the role of LR for UK REACH too.
- If so, they may decide not to charge you for a new LoA, or only charge some administrative fee.

Please keep in mind that even if you have already purchased an LoA for EU REACH purpose, the LR is under no obligation to grant you a free-of-charge LoA for UK REACH purpose

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Recent updates

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Recent updates

Following the entry into force of UK REACH, the industry strongly criticized the new regulation, as it requires registrants to replicate data that had already been generated/purchased for EU REACH registration purpose

According to the UK Chemical Industry Association data replication would cost the UK industry at least **1 billion GBP**

As a result of industry lobbying, DEFRA announced on 6 December 2021 that it will start exploring possible modifications of UK REACH, such as:

- Lowering data requirements for non-hazardous substances
- Extending the post-DUIN registration deadlines (4, 6 and 8 years instead of 2, 4 and 6 years)

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HSE Registration fees

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HSE registration fees

- UK REACH will apply fees to the same processes that were charged under EU REACH.

- The starting point for the UK REACH fees are the EU REACH fees and these have been converted from Euro to GBP, based on the average conversion rate for 2017.

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Turnover/Balance sheet ceilings for SMEs for UK REACH

Enterprise category	Headcount	Turnover or Balance sheet total	
Medium-sized	< 250	≤ £43.650 million	≤ £37.539 million
Small	< 50	≤ £8.730 million	≤ £8.730 million
Micro	< 10	≤ £1.746 million	≤ £1.746 million

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Reduced fees for SMEs

Enterprise and Tonnage Bands	Large enterprise	Medium enterprise	Small enterprise	Micro enterprise
1 to 10	£1,138	£740	£399	£57
10 to 100	£3,061	£1,990	£1,071	£153
100 to 1000	£8,185	£5,320	£2,865	£409
above 1 000 tonnes	£22,064	£14,342	£7,723	£1,103

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Take home message

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Take home message (1/3)

- ✓ Identify the substances to be placed in the GB market in qty. ≥ 1 tpa apart from your EU exports earlier
- ✓ Check- if the substance is already registered in EU-REACH as EU Registered substances may make you eligible for DUIN
- ✓ Check- if the substance will be placed in the GB for the first time - Submit inquiry and registration dossier as soon as possible
- ✓ Early submission means possibility to be a part of substance group so prioritise substances for inquiry submission immediately after DUIN

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Take home message (2/3)

- ✓ Check- if the SDS is updated or not – the substance classification should be as per the new GB CLP
- ✓ Identify the competent OR to take responsibilities towards your UK-REACH compliances.
- ✓ Be transparent to your OR and give complete information to avoid any non compliances
- ✓ Keep yourself updated on UK REACH developments - gpcgateway.com.

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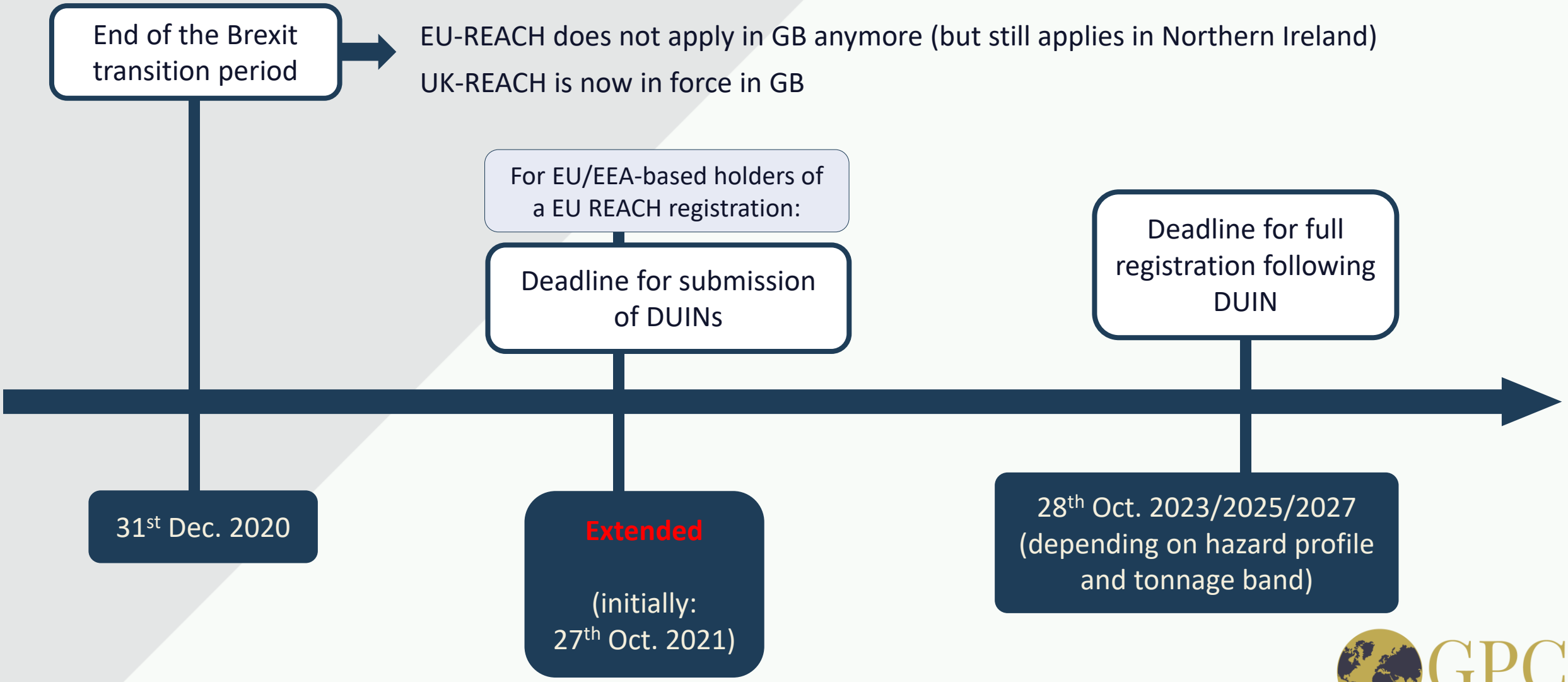
Take home message (3/3): timeline of UK REACH



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How can GPC help you?

- Registrations and DUIN Notifications and NRES
- Only Representative services
- Study Management
- Safety Data Sheet (SDS)
- Communication with Authorities
- UK-REACH Compliance Advisor (DU communications and certificates)

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Thank you.

CONTACT US FOR GLOBAL REGULATORY SERVICES

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Q&A – UK-REACH

1. Do we go for final registration of substances that are going to be placed by us in the coming years?
2. Do we have more updates from UK-REACH authority?
3. The DUIN deadline is passed, what can we do now?
4. Are polymers required to be registered under UK REACH? And monomers?
5. How can I check if our compounds are subject to REACH particularly if there are mixtures only?
6. Is there a portal where we can check DUIN processed products or UK REACH registered products
7. Can you let us know product categories which is applicable of UK REACH, Turkey REACH, EU REACH (Means in some cases Raw material and some cases Finish Goods.)
8. Is there any fees for DUIN?
9. is there any poratl which can help us to know the CMR level of the substance

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KKDIK (Turkey REACH) Registration

SIEFS, Consortia and Dossier Preparation

Mr. Mirac Mert Pelister
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Global Product Compliance Turkey
mirac@tr.gpcregulatory.com

Europe | India | South Korea | Eurasia | Turkey | UK | Taiwan | Australia | Ireland

Outline

- Introduction of Turkey REACH (KKDIK) Briefing
- Key Definitions, Timeline and updates
- Current status of Consortia and SIEF
- Types of Registrants
- Responsibilities for difference actors
- Dossier Requirement
- Our role as your OR
- Questions and Answers

KKDIK (Turkey REACH)

- Came into force on June 23rd, 2017
- EU Adaptation policy
- Competent authority: Ministry of Environment and Urbanization

«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*»

Definitions (1)

LPR	Late pre-registration, meaning the pre-registration submitted after Dec 31st 2020
LR	Lead registrant
OR	Only Representative
TPR	Third party representative
Consortium	Optional collaboration group of companies
SIEF	Substance Information Exchange Forum

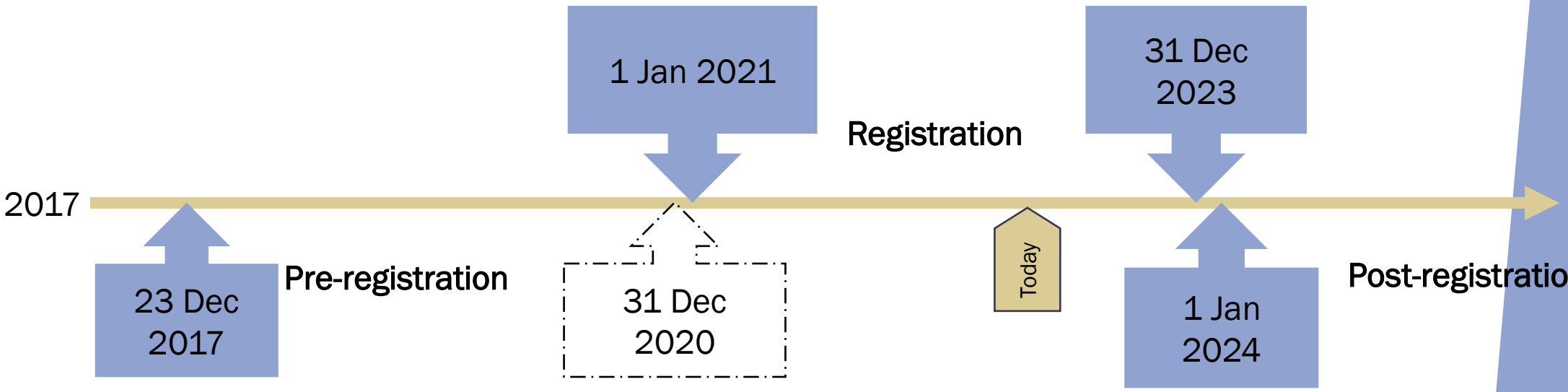
Definitions (2)

Application Number	17-18 digits number with a letter «D»
Notification Number	17 digits, 4-section number starting with «05»
JS	Joint Submission, Registration involving more than 1 company
TCC	Technical Completeness Check
Completeness Check	Inspection of the dossier by the Ministry for required dat a
Registration Dossier	Dossier providing robust study summaries and study su mmaries of the data generated to provide required information

KKDIK Timeline

- Submission of registration dossier
  - Chemical safety assessment
  - SDS
  - Test proposals

  } if needed



- Notification of substances
- CLP notification for local manufacturers & importers

- Notification of substances
- CLP notification for local manufacturers & importers

- Keeping all information up-to-date
- Evaluation communication
- Permit application if needed

Updates

- Ministry held a meeting with LRs and ORs on 11th of September
- Registrations are ongoing where there is an LR
- Update on TCC on KKS, got more detailed
- Importer information is required by the Ministry in case of non-Turkish manufacturers

Important Headlines from the Meeting

- New circular will be published
  - New criteria for OR
  - Regulating LoA costs
  - New (earlier) deadline for Lead Registrants
  - If no LR, Ministry will appoint one
- 504 registrations so far
- Deadline **will not** be postponed
- Authorization list will be available in 2024
- Monitoring of restricted substances already began

Consortia

- Not mandatory
- Can be agreed on by all or partial SIEF members
- Has to be transparent on joining conditions and members
- Cannot be anti-competitive
- Can last longer than SIEF

SIEF

- Mandatory
- Formed by companies who has pre-registered same substance
- Valid until 2026
- Purpose: Preventing repetitive tests on animals & reducing costs by sharing
- Purpose: Data sharing

Do I need to be a part of a consortium?

- Simple answer: «Not necessarily»
- Can be useful for:
  - Sharing data generation costs
  - Maintaining information even after SIEFs are dismantled
- Challanges:
  - Competition
  - Joint ownership of data
  - Decision-making process

Registrants

- Joint Registrants:
  - SIEF members who are participating in the registration dossier
  - By regulation; either Lead Registrant or Joint Registrant
- CEFIC divides into 4 types:
  - Lead Registrant
  - Active Member
  - Passive Member
  - Dormant Member
- Individual Registrants: Submitting opt-out dossier

SIEF Positions

Active member	• Actively participating in deciding on SIP, uses, data requirement • LR is also an active member
Passive member	• Not interested in preparation of the dossier but is willing to join • Only interested in registration but not the process
Dormant Member	• Not interested in registration unless stated otherwise but still part of the SIEF

Opt-out Dossier

- SIEF Members can apply for opt-out dossier if:
  - There are valid concerns of confidentiality
  - The joint dossier costs are excessive compared to individual dossier preparation
  - There is a disagreement/conflict regarding the choice of provided data between the member & the LR

Ministry approval is not guaranteed! Opt-out is always the least desired option for Ministry

Responsibilities

Responsibilities (1)

SIEF Participants

- Vote among LR candidates or become a candidate
- Gather necessary data
  to identify substance, required for sameness survey later on
- Identify uses for their substance
- Declare SME status on KKS
- Identify tonnage band

Lead Registrant (LR)

- Prepare the dossier in time
- Be transparent of the costs and the process
- Collect information from the SIEF for the dossier
- Consult SIEF opinions
- Share substance identification as well as C&L with potential registrants
- Use the highest tonnage band among the SIEF m embers for the joint dossier

Responsibilities (2)

Downstream Users

Register
on ministry's environment portal if haven't yet and share environmental identity number with suppliers

Non-Turkish Manufacturers

If pre-registered via
OR, share a list of substances:

- Including importer information as above
- Decide what to register
- Decide on which role to take

Only Representative (OR)

- Start and participate in SIEF communications
- Define the most cost-effective strategy to protect client interest
- Reflect client intention and represent in SIEFs
- Collect importer information

Dossier Requirements

Exemptions from Registration

- Recycled in Turkey that is registered before
- Exported from a supply chain and reimported by the same supply chain
- Food and feedstock
- Less than 1 ton/year

- Imported only to be used in biocidals & plant protection
- Human or veterinary medicines
- Substances in Annexes 4&5
- Polymers
- Non-isolated intermediates
- On-site and transported isolated intermediates (only from full registration)

Standard Data Requirements

Standard Data Requirements (1)

- Annex 6 information
  - Registrant info
  - Substance Identification
    - Name
    - Identifiers (CAS, EC etc.)
    - Molecular Structure
      - SMILES
      - InChI
      - Optical activity
      - Molecular Weight

Standard Data Requirements (2)

- Annex 6 Information
  - Composition
    - Degree of purity
    - Impurities
    - Additives
    - Spectral data
      - UV, IR, NMR or MS
    - Chromatogram
      - HPLC
      - GC

Standard Data Requirements (3)

- Annex 6 Information
  - Uses & Manufacture
    - Tonnage info
    - Process Info (PROC)
    - Form (subtance, mixture etc.)
    - Product categories (PC)
    - Technical function of substance
    - Industrial, professional and consumer uses (SU)
    - Service life
    - Uses advised against

Standard Data Requirements (4)

- Annex 6 Information
  - Uses & Manufacture
    - Tonnage info
    - Process Info (PROC)
    - Form (subtance, mixture etc.)
    - Product categories (PC)
    - Technical function of substance
    - Industrial, professional and end-user uses (SU)
    - Service life
    - Uses advised against
  - C&L
  - First-aid measures

1-10 TPA Requirements

1-10 TPA additional req.

- Physicochemical (Sect. 4)
  - Melting/freezing point
  - Boiling Point
  - Relative Density
  - Vapour Pressure
  - Surface Tension
  - Water Solubility
  - Partition Coefficient

1-10 TPA additional req.

- Flash Point
- Flammability
- Explosive Properties
- Self-ignition Temperature
- Oxidising properties
- Granulometry

1-10 TPA for Annex III Subs.

- If the substance does not meet Annex III criteria, only physicochemical properties are sufficient.
- If it meets (hazardous to human health and environment) toxicological & ecotoxicological information is also required.
- **Even if substance is not included in Annex III of EU REACH, it may meet criteria under Turkey REACH**

1-10 TPA for Annex III Subs.

- Environmental fate (sect. 5)
- Ecotoxicological information (sect. 6)
- Toxicological Information (sect. 7)
- Serious eye damage/irritation
- Skin sensitization
- Mutagenicity
  - In bacteria first, if positive further studies (mammalian cells etc.)
- Acute Toxicity
  - Oral Route

CSR Requirement

10 TPA and more

- Prepared for 10+ tpa unless is less then:
  - Substance is in mixture => defined threshold in Annex 1 of CLP
  - PBT/vPvB=> 0.1w% of chemical
- Includes
  - Human health hazards
  - Physicochemical hazards
  - Environmental impact & hazards
  - PBT and vPvB evalutation
- Can only be prepared by a certified **Chemical Safety Assessment Expert**

10-100 TPA Requirements

10-100 TPA Additional Req. (1)

- Environmental Fate
  - Hydrolysis
  - Water & sludge biodegradability
  - Soil biodegradability
  - Adsorption/desorption
- Ecotoxicological:
  - Short-term toxicity in fish
  - Toxicity in microorganisms

10-100 TPA Additional Req. (2)

- Toxicological:
  - Skin corrosion, serious eye damage/irritation in vivo
    - Only required if in vitro is not sufficient
  - Mutagenicity
    - Gene mutagenicity of mammalian cells if bacteria is negative
    - Cytogenicity of mammalian cells
      - May not be required if known to be carcinogenic or germ cell mutagenic
  - Acute toxicity
    - Inhalation
    - Dermal
  - Rep. Dose toxicity
    - Short term
  - Reproductive toxicity
    - Reproductive

100-1000 TPA Requirements

100-1000 Additional Req. (1)

- Physicochemical:
  - Stability in organic solvents
    - Identification of decomposition products
  - Viscosity
  - Dissociation constant
- Environmental Fate
  - Water & sludge biodegradability
  - Soil biodegradability
  - Bioaccumulation in water/sludge
  - Adsorption/desorption
  - Effects on terrestrial organisms

100-1000 Additional Req. (2)

- Ecotoxicological:
  - Long-term toxicity in fish
  - Long-term tox. in invert.
  - Fish early-life stage (FELS) toxicity
  - Fish short-term toxicity test on embryo and sac- fry stages
  - Fish, juvenile growth test
- Toxicological:
  - Mutagenecity:
    - If in vitro+ and no in vivo available, proposal for somatic cell
  - Rep. Dose:
    - Sub-chronic
  - Reproductive Toxicity:
    - Pre-natal development
    - Extended one-generation proposal

1000+ TPA Requirements

1000+ Additional Req.

- Environmental Fate:
  - Long-term plant toxicity proposal
  - Long-term sediment org. tox. proposal
  - Long-term or repr. tox. on birds (if req.)
- Ecotoxicological:
  - Biotic degredation proposal
- Toxicological:
  - Long term rep. dose tox. Proposal
  - Repro. Tox.:
    - Developmental toxicity
  - Carcinogenicity
    - Proposal

Important!

- Everything in the dossiers has to be in Turkish unless:
  - An attached file having the information of
    - Study reports
    - Spectral analysis reports
    - Weight of Evidence Reports

Dossier Submission

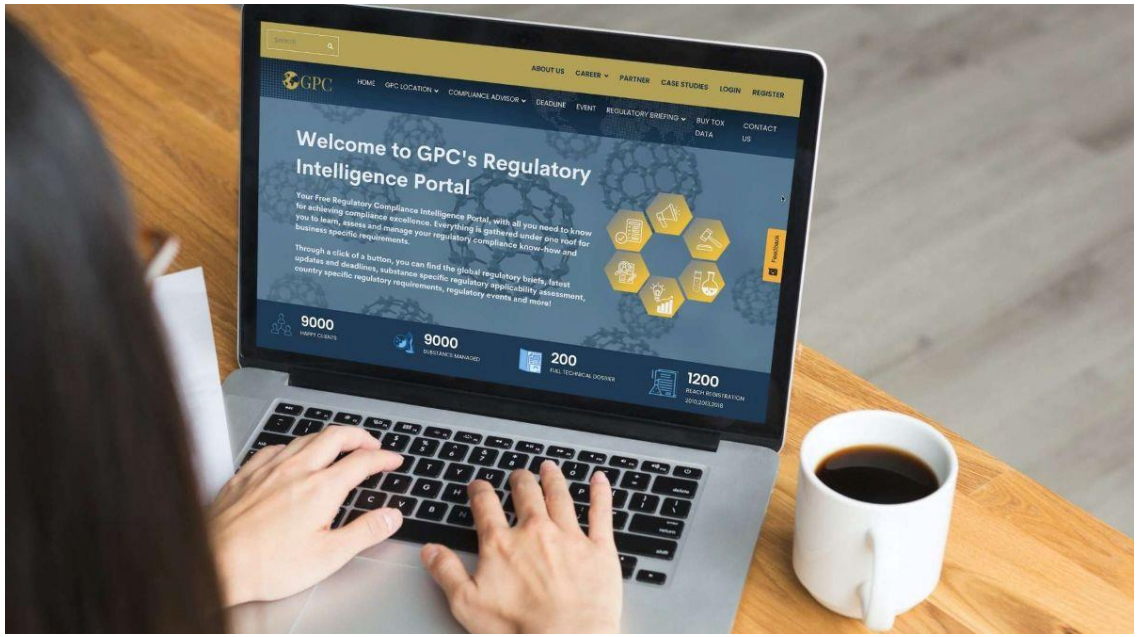
- Chemical Safety Assessor declaration
- Inclusion of all SIEF members
- Payment
- TCC & Completeness Check
- LoA announcement & management
- Approval of JS members by LR

Official Fees

	Large	Medium	Small	Micro
1-10 tpa	€ 50	€ 20	€ 10	€ 3
10-100 tpa	€ 116	€ 59	€ 30	€ 7
100-1000 tpa	€ 330	€ 132	€ 66	€ 10
1000+ tpa	€ 793	€ 330	€ 198	€ 33

Our Role

- GPC is experienced with LR and consortia management for 400+ substances before Turkey
- Currently taking lead +250 SIEFs in Turkey
- We will:
  - Manage SIEF communication as well as legal & administrative aspects
  - Prepare technical dossier
  - Perform spectral analyses
  - Conduct studies in our own labs as well as our extensive CRO network with competitive prices
  - Represent your best interests in the SIEF
  - Take LR position whenever possible & desired
  - Manage communication down the supply chain
  - Follow most economic strategies for your compliance



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2022-10-19

Q&A – Turkey REACH

1. Will the registration deadline be postponed?
2. Both OR and TPR should be located at Turkey?
3. What are the changes in criteria of OR?
4. Is there any list/ web site giving full list of chemicals exempted from KKDIK Registration?
5. Will the MoEUCC publish registrant names and also make a similar site as ECHA disseminated website where publicly you can see non-confidential data on substances?

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India's Draft Chemical (Management and Safety) Rules

Dr. Jayachandran Nair
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jmnair@gpcregulatory.com

Europe | India | South Korea | Eurasia | Turkey | Taiwan | Australia | Ireland

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About GPC

*"Our capacity has gone from **local** to **global**."*

We were founded in 2008, Lund Sweden.

We offer regulatory representative and compliance management services globally.

8 offices worldwide & 2 laboratories

Today, we have more than 1500 happy clients worldwide, 99% retention rate.

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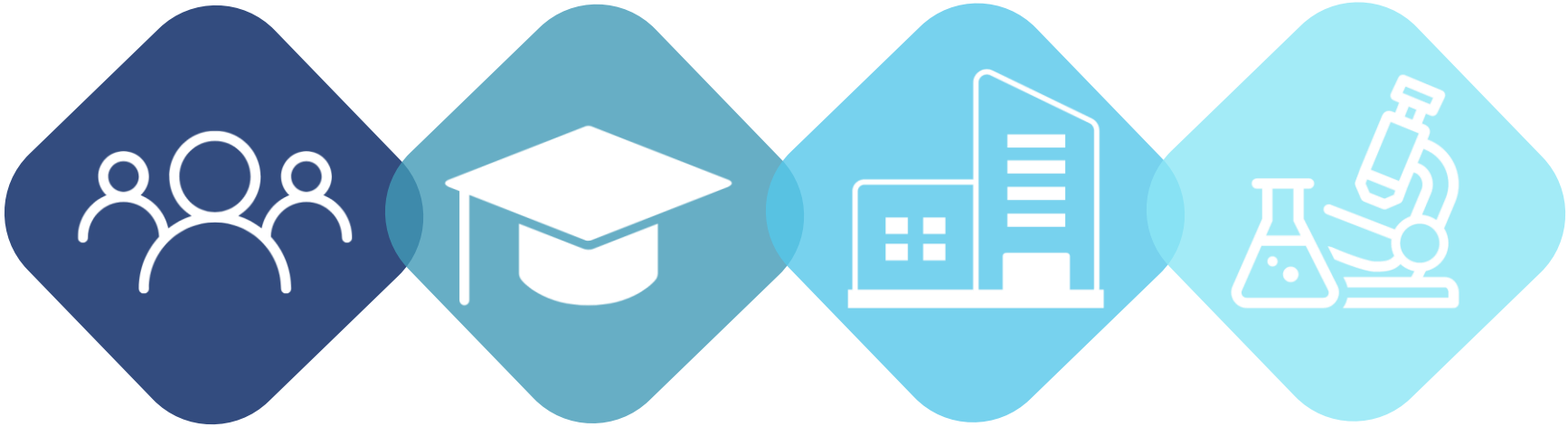
GPC's team



More than 100 professionals with extensive experience in their respective fields

25% PhDs, 75% Master's and Post Graduate Degree

8 Offices world wide: Sweden (HQ), India, South Korea, UK, Turkey, Russia, Australia & Ireland

2 Laboratory facilities in Sweden & India

Content

- Existing Chemical Management in India
- Why India REACH?
- The background of ICMSR and its schedule, scope and organizations
- Roles under ICMSR and their obligations
- Key compliance obligations and timelines
- Substances categories – with a focus on Priority Substances in Schedule II
- Comparison between EU REACH and Indian REACH
- Compliance Strategies

Chemicals Management in India

The legal basis or chemical management rules in India can be found in the Environment (Protection) Act, 1986

The objectives of this Act are:

- To protect and improve the quality of the environment
- To prevent, control, and abate environmental pollution

Currently, two main sets of rules apply to chemicals management in India

Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989	Chemicals Accidents (Emergency Planning, Preparedness and Response) Rules, 1996
• Safety reporting • Emergency planning • Import of Hazardous Chemicals	• Crisis Groups to deal with chemical accidents • Crisis Alert System

Why India REACH? (1)

- **In total these Acts, Rules, regulation in total cover a less than 2000 unique substances**
  - Manufacturing, Storage and Import of Hazardous Chemicals (MSIHC)
  - Manufacturing, Handling, Transport & Storage of Hazardous Waste
  - Chemicals Accident (Emergency Planning, Preparedness & Response) Rules
  - Quality Control Orders of Bureau of Indian Standards (BIS) *under BIS Act*.
- **Chemical Safety – Existing Regulatory Focus on:**
  - Accidents prevention
  - Safe Transport
  - Worker exposure
  - Acute impacts
- **Existing Regulations did not cover:**
  - Exposure – General Population,
  - Chronic effects of chemicals to Human – CMR / STOT
  - Impact of Chemicals on Environment (Water bodies, Soil and Air)
  - Adopting Harmonised system of Classification, Labelling and Packaging

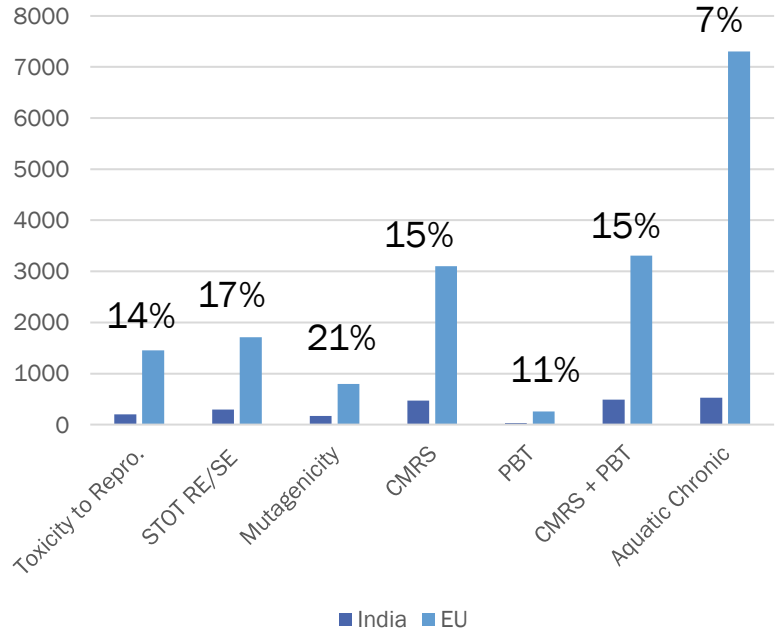


Table prepared by GPC

Why India REACH? (2)

- Technical Regulations: Product quality, Human Health, Environment
- Competitiveness of Sector
- Protection of internal market – sub-standard product dumping effects
- Examples – EU-REACH, WEEE/RoHS, ELV (Producer Responsibility Principle)

India has about 10% technical regulations as compared to equivalent economies

Reach-like Regulations and Trade Impact

- 63% of total Indian chemicals exports are subject to REACH-like regulatory compliances.
- 61% of unregulated imports from the same set of countries.
- Net value of imports from countries with Reach-like regulation exceeds by 37% in comparison to the exports from India (to those countries).

Indian Chemicals Management and Safety Rules(ICMSR)

The ICMSR will replace both sets of rules.

They establish:

- Notification, Registration and Restriction of Substances
- Labelling and Packaging requirements for Substances
- Safety procedures for the manufacturing, handling and import of chemicals
- Preparation for and management of chemical accidents

Chapter I – Definition, Objectives and Scope

Chapter I – Indian National Chemical Authority

Chapter III – Notification, Registration and Restrictions on Use

Chapter IV – Safety and Accident Preparedness

Chapter V – Labelling and Packaging

Chapter VI – Miscellaneous

Schedules (I to XIX)

Exempted Substances

The following are exempted from Registration and Notification obligations under the ICMSR:

- Radioactive substances
- Substances under customs and not being placed in Indian Territory
- Substances stored in customs free zones for re-exporting
- Substances for defence purposes
- Wastes
- Food and feeding stuff for human beings or animals
- Schedule IV Substances

GPC – Engagement with ICMSR

2010

Ministry of Commerce / Chemexcil engaged GPC (then SSS) for a Report on the Regulatory Status of EU REACH and its impact on Indian Industry.

Proposed Road-map for Indian Chemical Regulation

2011–2018

GPC (then SSS) was actively engaged in the development of the Draft National Chemical Policy.

July 2018

Within CII's National Chemicals Committee, GPC (then SSS) was engaged in drafting a proposal for chemical rules which was submitted to the government.

May 2019

CII and GPC (then SSS) were the only non-governmental representatives in a Ministry of Commerce's technical committee to review and adapt the proposed chemical rules, which were adopted as an official draft.

Currently

The draft has been circulated among industry bodies for comments.

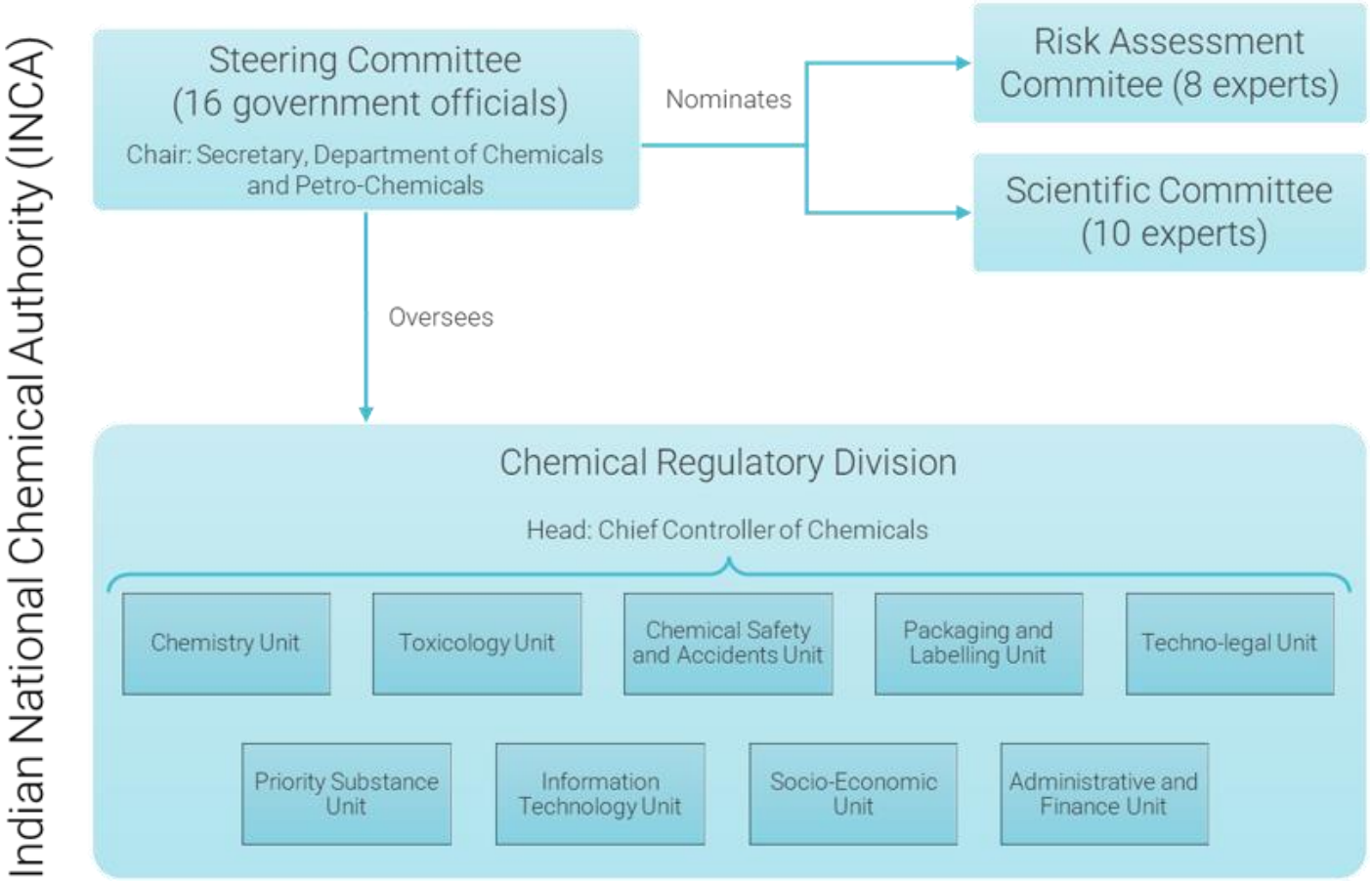
After legal vetting and ministerial feedback, a possible update and submission are expected in 2022/2023

ICMSR - Schedules

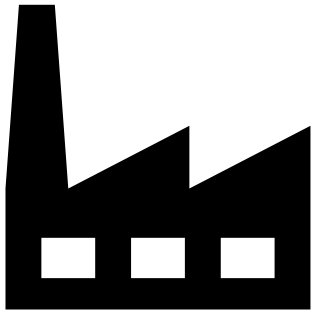
I	PBT and vPvB Assessment Criteria
II	List of Priority Substances required to be Registered
III	Concerned Authorities
IV	Substances Exempt for the purposes of Chapter III and V
V	Information to be provided for Notification
VI	Restricted or Prohibited Substances
VII	Contents of Technical Dossier
VIII	Format for Chemical Safety Report
IX	Safety Data Sheet
X	Hazardous Chemicals

XI	Isolated Storage at Installations Other Than Those Covered by Schedule XIII
XII	List of Hazardous Chemicals for Application of Chapter IV
XIII	Industrial Installations
XIV	Information to be furnished by the occupier
XV	Details to be furnished in the off-site emergency plan
XVI	Information to be furnished regarding notification of a chemical accident
XVII	Information in labelling
XVIII	Format of certificates
XIX	Fees and fines payable

Implementing Organizations

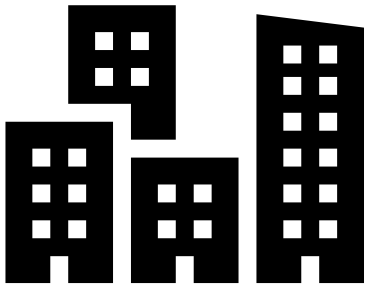


Roles under ICMSR and their obligations



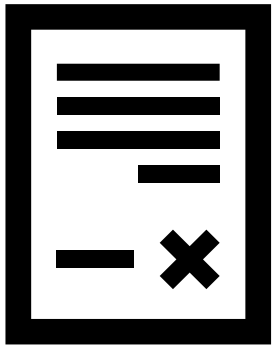
Indian Manufacturers

- Notification and Registration
- Safety and Emergency Planning
- Labelling and Packaging



Indian Importers

- Notification and Registration
- Safe Import of Hazardous Chemicals
- Labelling and Packaging

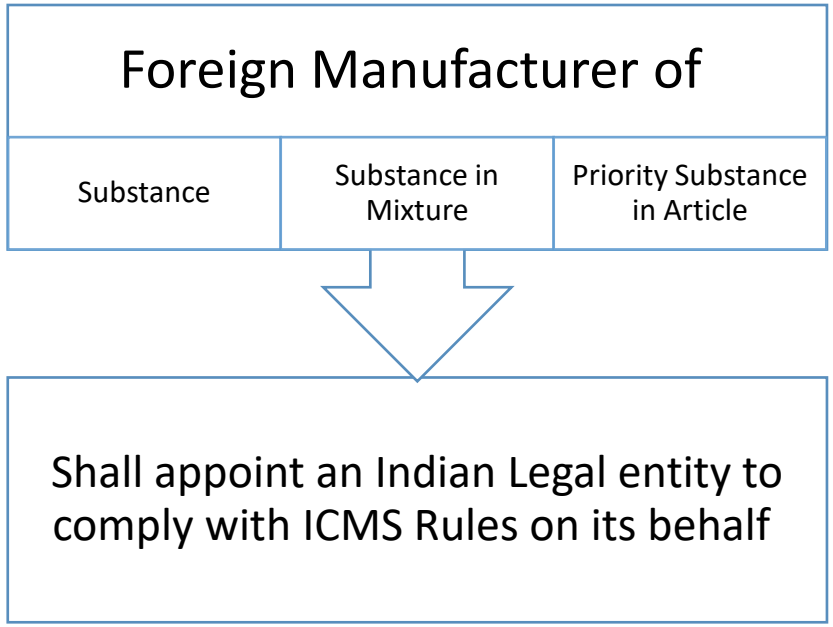


Authorized Representative (non-Indian manufacturer)

Downstream Users (DU)

- Use substances in their industrial or professional activities
- Excludes manufacturers, importers, and end-use consumers
- Must avoid procuring non-compliant Substances

Authorized Representative



Authorized Representative (non-Indian manufacturer)

- Indian national or entity registered in India
- Can be appointed by foreign entities who want to place Substances on the Indian market
- Responsible for the compliance of the foreign entity appointing them
- Authorized Representative has a similar function as "**Only Representative**" in EU-REACH & K-REACH.

Key Compliance obligations

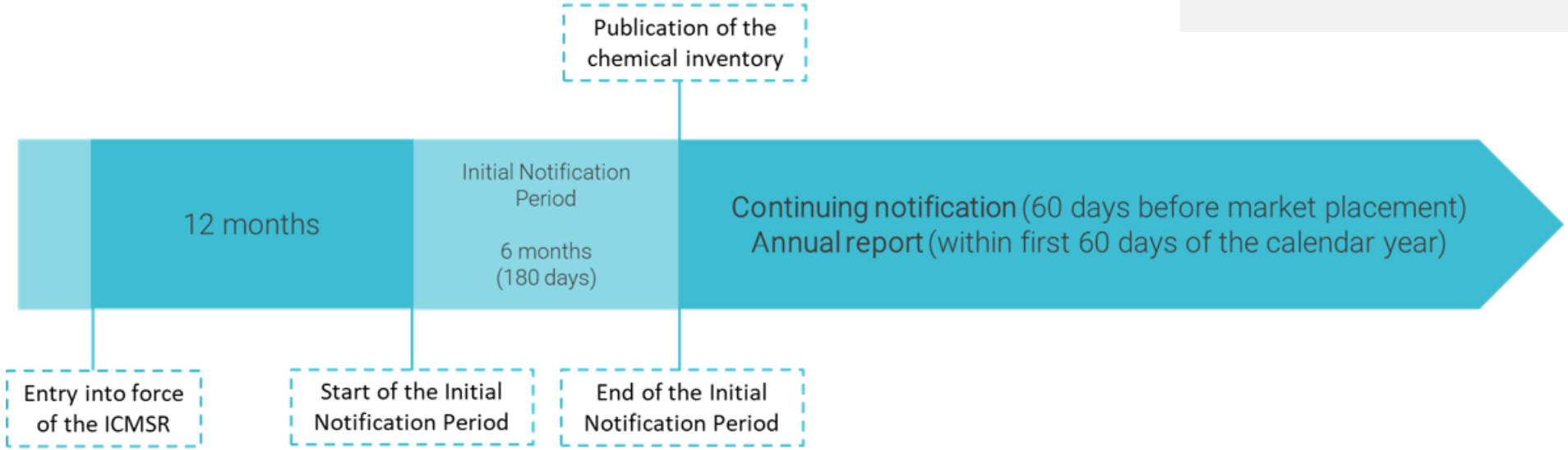
	Scope	Timeline	Updating	Subjects
Notification	All Substances	Initial Notification Period: Existing Substances New Substances: Prior to market placement	Annual report	Manufacturers Importers Authorised Representatives
Registration	Substances listed in Schedule II ("Priority Substances required to be Registered")	18 months After inclusion in Schedule II	Annual report Schedule II will be regularly updating	Manufacturers Importers Authorised Representatives

Notification Timeline

- Any operator complying with other regulations – may also notify
- Polymers are not defined within current draft.
- Require to be notified within **Initial Notification Period** – 180 days
- Any operator – that has not notified in Initial Notification Period

All Substances placed in Indian Territory in quantities above 1 tonne per annum (TPA):

- **Existing Substances:** Placed before the end of the Initial Notification Period
- **New Substances:** Placed after the end of the Initial Notification Period



Data Requirement for Notification

- Notifier Details
- Substance Identifiers
- Impurities
- Tonnage
- ***Substance Structural details & Spectra***
- ***Hazard Classification***
- ***Uses***
- ***Downstream users***
- ***Max storage capacity***
- ***SDS***

Schedule V - Information to be provided for Notification

1. Details of Notifier:
   a. Name, address, phone, email of the Notifier
   b. Name, address, phone, email of the person authorised to submit Notification
   c. Details of foreign manufacturer, if the Notifier is an Importer or Authorised Representative
   d. Location of the production and own use site(s), as appropriate
2. List main constituents of the substance with 10% (w/w) or more concentration

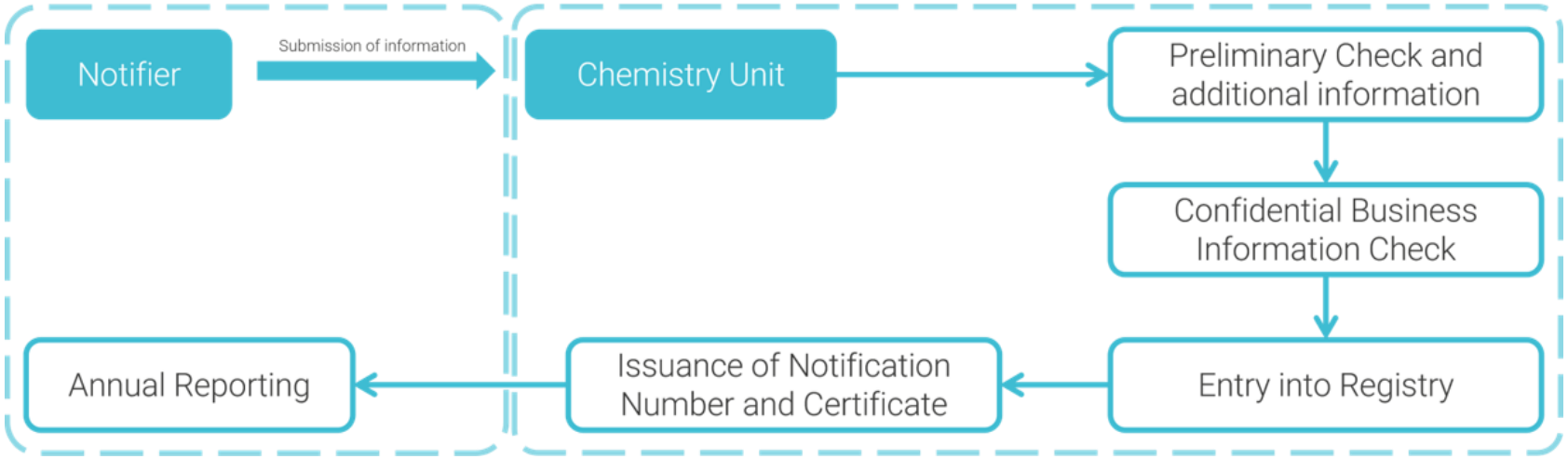
S.No.	IUPAC Name	Common Name	CAS No.	Molecular structure	Isomer	% age Conc.

3. List all impurities with more than 1.0% but less than 10% (w/w) concentration
4. For substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), give the following details:
   a. Structural representation of the constituents
   b. Reaction scheme (including the identity of the reactants and the reaction type)
   c. Process output (including identity of the precursors, the technology (method of preparation; process terms) and the typical composition)
5. Chemical Structural Details
   a. Molecular wt.
   b. Simplified Molecular Input Line Entry System (SMILES)
   c. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
   d. Spectral data:
      i) High Performance Liquid Chromatography or Gas Chromatography or Gas Chromatography Mass Spectrometry or Liquid Chromatography Mass Spectrometry
      ii) Infra Red spectra
      iii) Ultra Violet-Vis Spectrophotometer – spectra
      iv) Nuclear Magnetic Resonance
6. Hazard Classification of the Substance *(according to eighth revision of UN-GHS)*
7. Chemical uses
8. Name of known Downstream Users *(at least top 3; will be kept confidential)*
9. Actual quantity per annum in TPA (*will be kept confidential under all circumstances*)
10. Maximum Storage Capacity/Maximum quantity stored

(The information contained in the Notification must be based on test reports from NABL accredited labs or GLP labs or any other Published authentic study report.)

Source: 5th draft of ICMS Rules

Notification Procedure

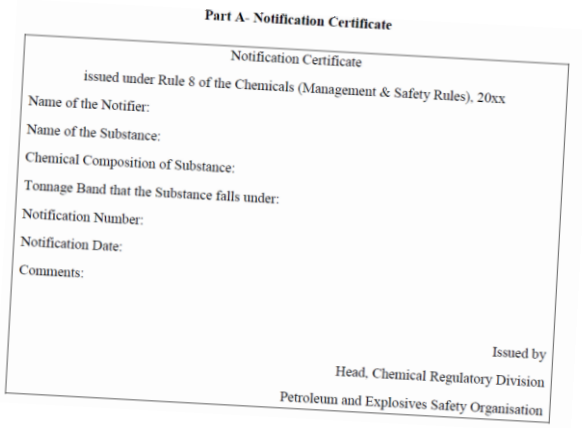


The ICMSR provides for the public availability of:
- Substance information
- Substance uses
- Substance classification

Confidentiality requests can be made on the basis of:
- Trade secrets
- Proprietary business information
- Other data and information related to intellectual property

Confidentiality may **not** be requested for:
- Substance classifications
- Endpoint summaries

Notification Fee and Certificate



Part A- Notification Certificate

Notification Certificate

issued under Rule 8 of the Chemicals (Management & Safety Rules), 20xx

Name of the Notifier:

Name of the Substance:

Chemical Composition of Substance:

Tonnage Band that the Substance falls under:

Notification Number:

Notification Date:

Comments:

Issued by

Head, Chemical Regulatory Division

Petroleum and Explosives Safety Organisation

Substance tonnage band	MSME	Large
1 – 10 TPA	10,000 ₹ (~122 $)	25,000 ₹ (~305 $)
10 – 100 TPA	30,000 ₹ (~366 $)	75,000 ₹ (~916 $)
100 – 1000 TPA	80,000 ₹ (~977 $)	200,000 ₹ (~2,444 $)
> 1000 TPA	250,000 ₹ (~3,056 $)	600,000 ₹ (~7,333 $)

Conversions current as of Sep. 2022

An Enterprise needs to be below **both** ceilings to fit in a category

Type of enterprise	Investment in Plant and Machinery or Equipment	Turnover
Micro	10,000,000 ₹ (~131,209 $)	50,000,000 ₹ (~656,046 $)
Small	100,000,000 ₹ (~1,312,093 $)	500,000,000 ₹ (~6,560,465 $)
Medium	500,000,000 ₹ (~6,560,465 $)	2,500,000,000 ₹ (~32,802,325 $)

Intermediates

- Intermediates are Substances that are manufactured for, consumed in, or used for, chemical processing in order to be **transformed into another Substance**

They can be classified into:

- Non-isolated intermediates (produced and consumed in the same process)
- Isolated intermediates
- Transported intermediates

- All Transported Isolated Intermediates (TII) needs to be notified
- Intermediates that are Priority Substances (Sch. II) to be registered:
  - Less than 1000 TPA – basic registration
  - More than 1000 TPA – full registration**

Priority Substances (1)

Priority Substances comprise:

1. **In accordance with UN – GHS Revision 8:**
   Carcinogenic, Mutagenic and Reprotoxic substances (Categories I or II)
   Specific Target Organ Toxicants (Repeated or Single Exposure, Categories I or II)

2. **In accordance with the criteria in Schedule I:**
   Persistent, Bioaccumulative and Toxic Substances (PBT)
   Very Persistent and very Bioaccumulative Substances (vPvB)

3. **Substances Listed in Schedule II**

Priority Substances (2)

Potentially 4700 substances could be implicate based upon priority substance definition

Labelling and packaging requirements (Rules 33 & 34)

Some Priority Substances may require Registeration – currently **748** substances are listed as Priority Substances for Registeration in Schedule II

Certain Priority Substances may be added in Schedule X, and/or XI, and/or XII – transport and accident prevention of hazardous substances (Rule 16(3))

Schedule II – Substances to be Registered

Registration - Substances listed in Schedule II

Joint-Registration (option)

Registration within 18 months after inclusion in Schedule II

Currently Schedule II contains 748 substances.

Deadline coincides with Initial Notification period

Technical Dossier needs to be prepared.

Chemical Safety Assessment (report) for > 10 TPA.

Registration fee is applicable – Company Size & Tonnage

Import of Priority substances requires to notify Authority 15 days before importation. (Rule 27)

Update Technical Dossiers - within 60 days of any change or revision in information

Technical Completeness of Dossier - within 60 days

Registration Fee

Substance tonnage band	MSME	Large
1 – 10 TPA	15,000 ₹ (~183 $)	37,000 ₹ (~452 $)
10 – 100 TPA	45,000 ₹ (~550 $)	112,000 ₹ (~1,370 $)
100 – 1000 TPA	120,000 ₹ (~1,468 $)	300,000 ₹ (~3,669$)
> 1000 TPA	375,000 ₹ (~4,587 $)	900,000 ₹ (~11,007 $)

Comparison between EU-REACH & ICMSR

EU REACH	ICMSR
Pre-registration (free)	Notification (fees apply)
Substance details, tonnage and company	Additionally: Uses, Downstream Users, Spectra, Hazard Class, SDS
Tonnage and data updates	Annual reports for all Substances
Registration of all Substances	Registration of Schedule II Substances only
Tonnage-specific deadlines	Common deadline (all tonnages)
Substances: SVHC, CoRAP, Restriction, Authorisation	Substances – Priority, Schedule II, Hazardous, Restriction & Authorization

Compliance preparations

- Set up a regulatory team
- Prepare an Inventory of substances being handled
- Identify the quantity placed in India
- Initiate communication with downstream users and other actors within the supply chain
- Update SDS in accordance with GHS Rev. 8
- Stay updated on the Indian REACH (ICMSR)
- Hold internal training activities on the ICMSR
- Follow up on the substance list: Substances to be registered (Schedule II), Restricted or Prohibited Substances (Schedule VI) and Hazardous Chemicals (Schedules X, XI and XII)

Thank You!

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Q&A – India REACH (ICMSR)

1. when the ICMSR will be in force?
2. Can you please elaborate exempted substances under customs and not being under Indian Territory?
3. Will the final draft come in public for comments?
4. What about notification of Mixtures?
5. What will be the timeline for initial notification?
6. Do we need to notify substances if quantity is less than 1 tonne?
7. Can we use EU REACH data for ICMSR notification?
8. Who would do Notification for raw materials will it be Manufacturer or Users?
9. Is notification is required for products in trade?
10. Do we need to follow SDS GHS version 8 or the format provided in ICMSR?
11. Why is finalisation of ICMSR getting delayed or overall progress is slow compared to other countries?
12. will the classifications be harmonised in case they differ between companies at the time of notification?
13. who will be obligated under ICMSR, initial importer or final importer?
14. any regulatory framework in place or in the process for Green Chemicals? Or would they be incorporated in the ICMSR?
15. Do we need to register impurities in the mixture as well?
16. Will the spectral data need to be conducted acc to GLP?
17. there be any significant changes in next draft or final regulation compared to fifth draft?

Chemicals under the EU Green Deal

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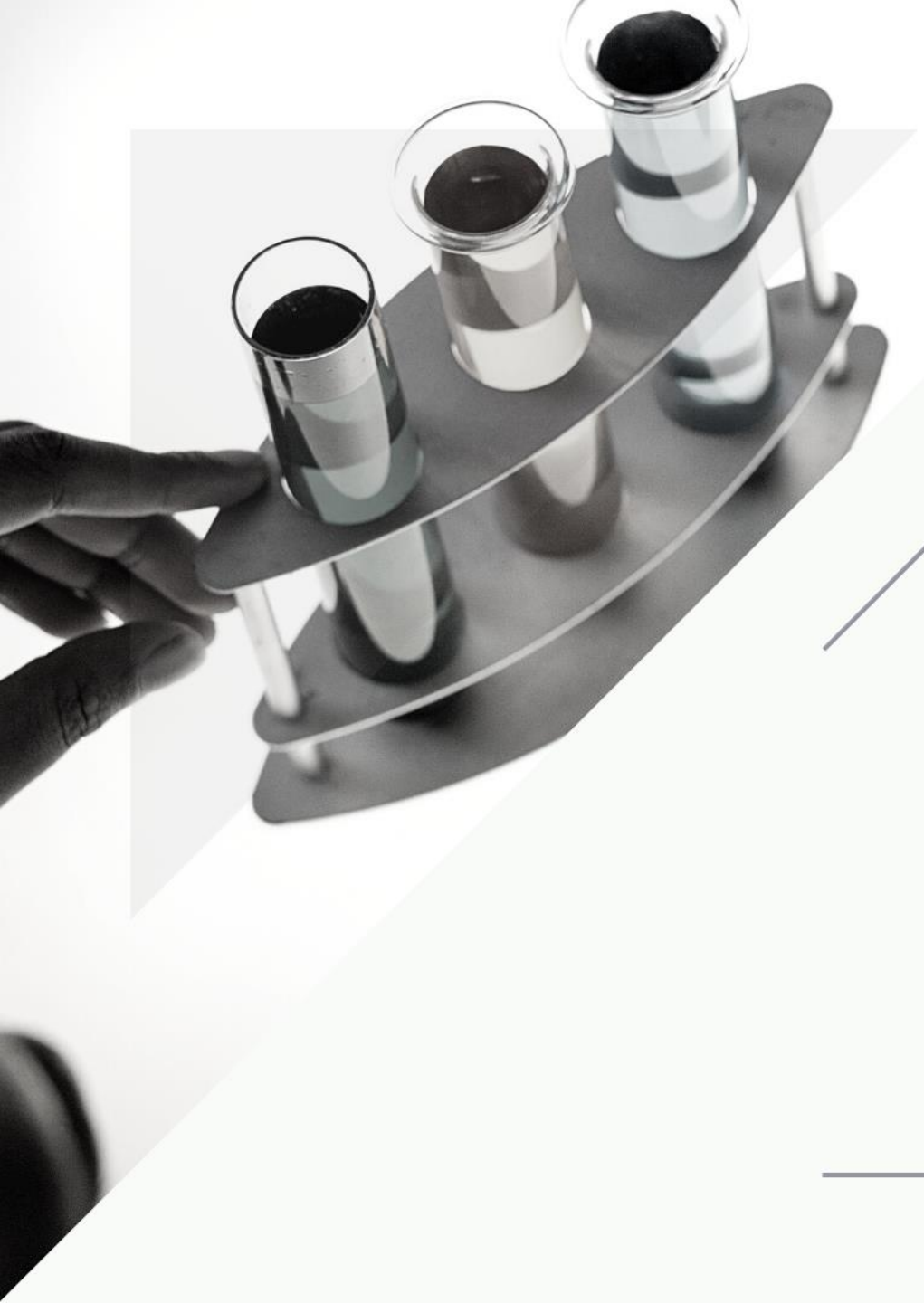

Table of contents

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General Framework

European Green Deal and Chemicals Strategy for Sustainability

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The European Green Deal

Source: COM(2019) 640 final – The European Green Deal

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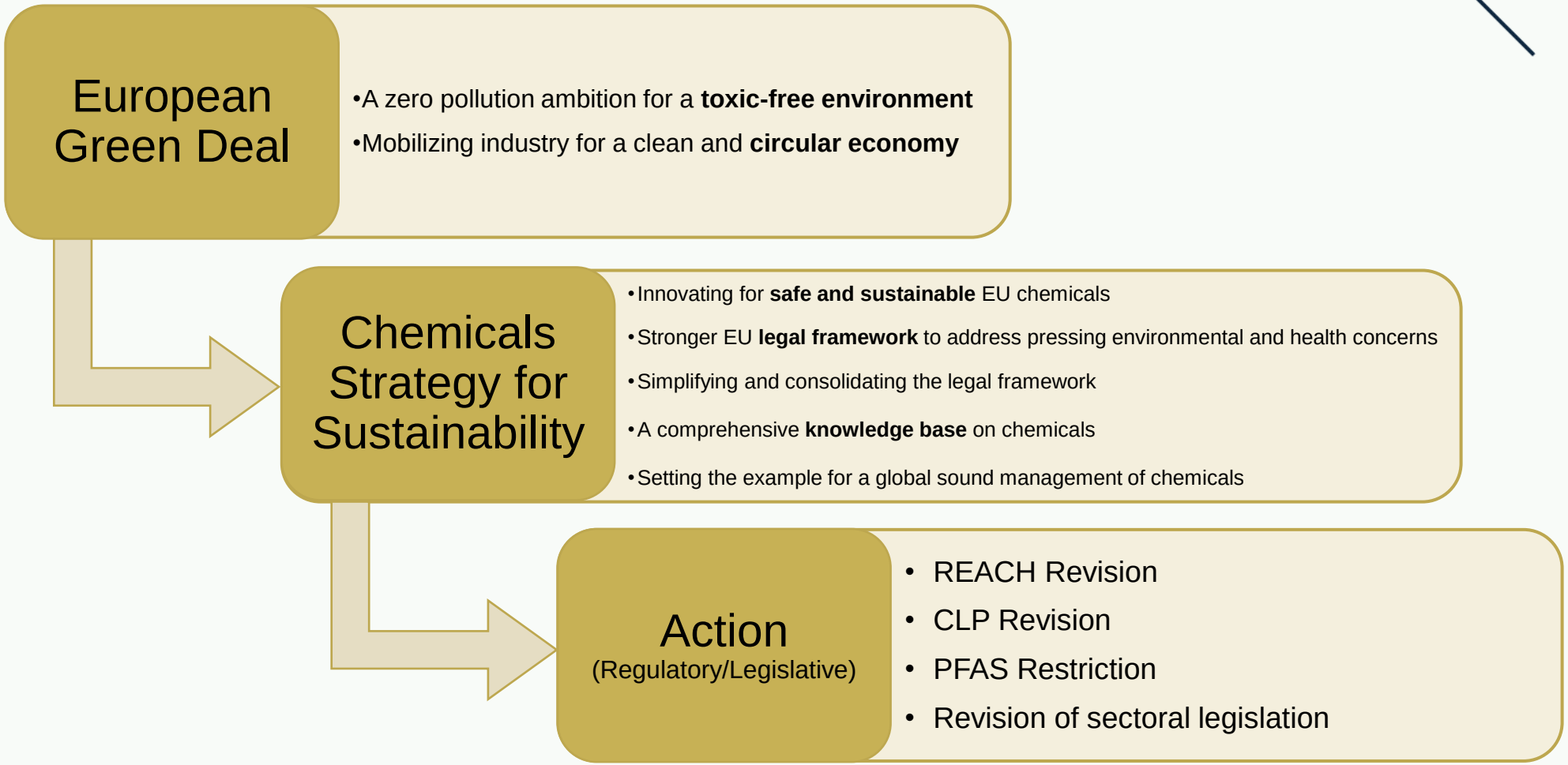
Chemicals Strategy for Sustainability



Source: COM(2020) 667 final – Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment (adapted)

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Regulatory and Legislative Action

CLP Revision
REACH Revision
PFAS Restriction

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Revision of the CLP Regulation

Problem	Proposed Solution
Incomplete information about hazards to human health and the environment	Introduction of new hazard classes (PBTs/vPvB)
	Assessing the need for specific neurotoxicity and immunotoxicity criteria
	Expansion of CLP scope (new products covered)
	Clarifications of the rules on mixture classifications

Source: Ares(2021)2969734 – CLP Regulation Revision Inception Impact Assessment

Revision of the REACH Regulation

Shortcomings	Proposed Solution
Knowledge gaps	Revision of registration requirements (content and scope)
Lacking compliance on information requirements	Revisions of provisions for dossier and substance evaluation
Lack of supply-chain communication	Improvement of safety data sheets (harmonized electronic formats)
Lack of assessment of the risk from unintentional mixtures	Introduction of a Mixtures Assesment Factor in the substance assessment
Slow and inflexible authorisation procedure	Clarifying, removing or merging with restriction
Restriction procedure: too slow and case-by-case; evaluation too complex	Extension of generic risk approach beyond CRM Essential use criteria (including for derogations)

Source: Ares(2021)2962933 – REACH Regulation Revision Inception Impact Assessment

PFAS Restriction

- Currently, some specific restrictions on PFAS

PFOS	POPs Regulation Annex I (Stockholm Convention on POPs)	In force
PFOA	POPs Regulation Annex I (Stockholm Convention on POPs)	In force
Restriction on C9-14 PFCAs	REACH Annex XVII (Restriction)	Entry into force: February 2023
PFHxA	REACH Annex XVII (Restriction)	Supported by ECHA Committees
PFHxS	REACH Annex XVII (Restriction)	Supported by ECHA Committees

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PFAS Restriction

- Two upcoming restrictions

PFAS in Fire Fighting Foams	REACH Annex XVII (Restriction) ECHA at the request of the EC	Annex XV Report open for comments (Deadline: September 2022)
All PFAS	REACH Annex XVII (Restriction) (DE, DK, NL, NO, SE)	Dossier not submitted yet (Expected: January 2023)

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Non-regulatory action

Essential Use Criteria
Safe and Sustainable by Design

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Safe and Sustainable by Design Criteria (1/2)

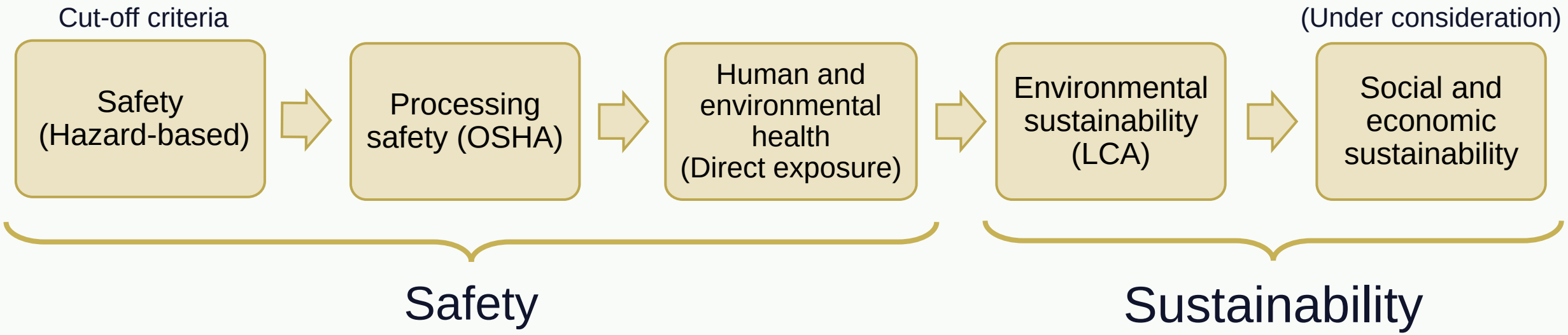
- Preliminary definition in the Chemicals Strategy for Sustainability:

> "[A] pre-market approach to chemicals that focuses on providing a function (or service), while **avoiding volumes and chemical properties that may be harmful** to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile.
>
> Overall sustainability should be ensured by **minimising the environmental footprint** of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a **lifecycle perspective**."

Source: COM(2020) 667 final – Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment

Safe and Sustainable by Design Criteria (2/2)

- Current operationalization:



Source: COM(2020) 667 final – Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment

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Essential Use Criteria

Under the Strategy, provision to develop essential use criteria:

"[D]efine criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is **necessary for health, safety or is critical for the functioning of society** and if there are **no alternatives** that are acceptable from the standpoint of environment and health.

These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments"

Source: COM(2020) 667 final – Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment

Other initiatives

Sectoral Chemicals Legislation
General Product Legislation

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Sectoral Chemical Legislation

Piece of legislation	Main changes
Toy Safety Directive	• Extension of generic risk management (including limit values for all toys and a revision of current derogations for CMRs) • Integration of limit values from other legislation and setting out positive lists • Conversion into a Regulation
Cosmetic Products Regulation	• Extension of generic risk management beyond CMRs • Revision of the definition of nanomaterials • Labelling changes
Food Contact Materials	• Shift from positive lists of components to requirements for final materials (including GMP) • Prioritisation of the assessment of substances • Possible development of a new regulatory framework

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Ecodesign Regulation Proposal (1/2)

- Part of the Circular Economy Action Plan
- Framework Regulation, expanding Ecodesign to all products
- Objectives:
  - Improving the sustainability of products
  - Establishing uniform conditions for market access
  - Boosting information exchange along supply chains
- Means – Delegated acts:
  - Setting of performance requirements
  - Setting of information requirements

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Ecodesign Regulation Proposal (2/2)

- Criteria that may be used to establish requirements (“Product parameters”) include the presence of substances of concern for reasons beyond chemical safety.

- These are defined in relation to:
  - REACH and CLP (Current and upcoming hazard categories)
  - Effects on re-use and recycling

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Business Preparation

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Summary – Legislation Tracker

Initiative	Status	Timeline
REACH	Consultation closed (15 April)	Draft expected in Q4 2022
CLP	Consultation closed (15 November 2021)	Draft expected Q4 2022
Toy Safety Directive	Consultation closed (25 May 2022)	Draft expected Q4 2022
Cosmetics Products Regulation	Consultation closed (21 June 2022)	Draft expected Q4 2022
Food Contact Materials legislation	Public consultation in Q2 of 2022	Draft expected in Q2 2023
Ecodesign Regulation	Commission draft presented (30.03)	Parliament and Council negotiations
PFAs restriction (REACH)	Preparation of restriction dossier (SE, NO, DK, DE, NL)	Submission expected for 13.01.2023 (As per restrictions roadmap)
Safe and Sustainable by Design criteria	Discussions ongoing. Mapping study and workshop on methodology completed.	Q3 Workshop on case-study criteria Q4 Publication of framework and criteria for case-studies
Essential use criteria	Discussions ongoing (not public)	Unknown

Preparing for upcoming changes

- Improving compliance with existing regulations
- Keeping track of ongoing discussions and proposals
- Working towards substitution of hazardous substances

Conclusions

- Regulation development is still in its early stages, but is evolving rapidly
- There is high pressure to phase out the most hazardous chemicals
- There are important opportunities for manufacturers who can meet rising demand for more sustainable chemicals