

UK REACH

WHAT YOU NEED TO KNOW ABOUT UK-REACH

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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?



Background of UK REACH

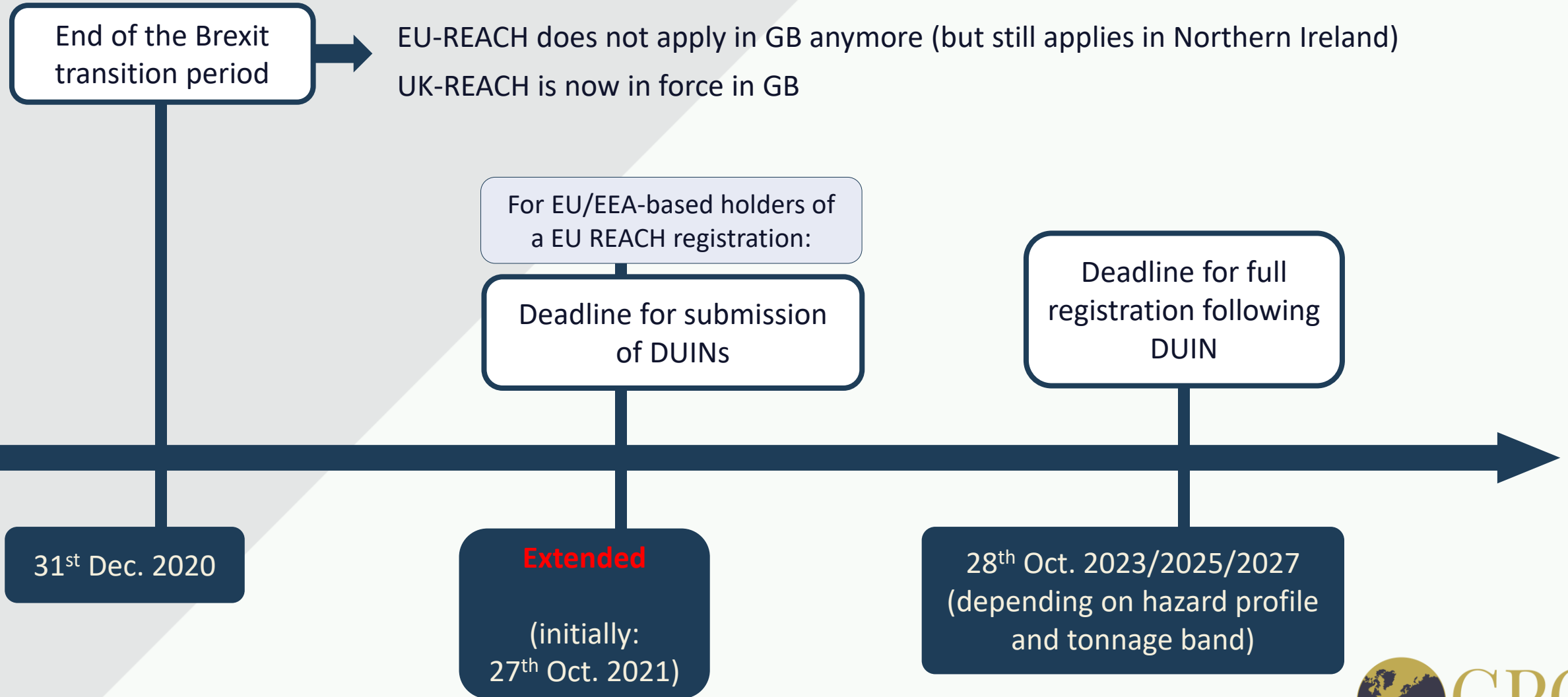
Background of UK REACH

- 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.

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.**

Timeline of UK REACH



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

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



Actors affected by UK REACH

Who is concerned by UK-REACH?



Manufacturers (both GB and non-GB based)



Importers



Downstream users



Only representatives (OR)

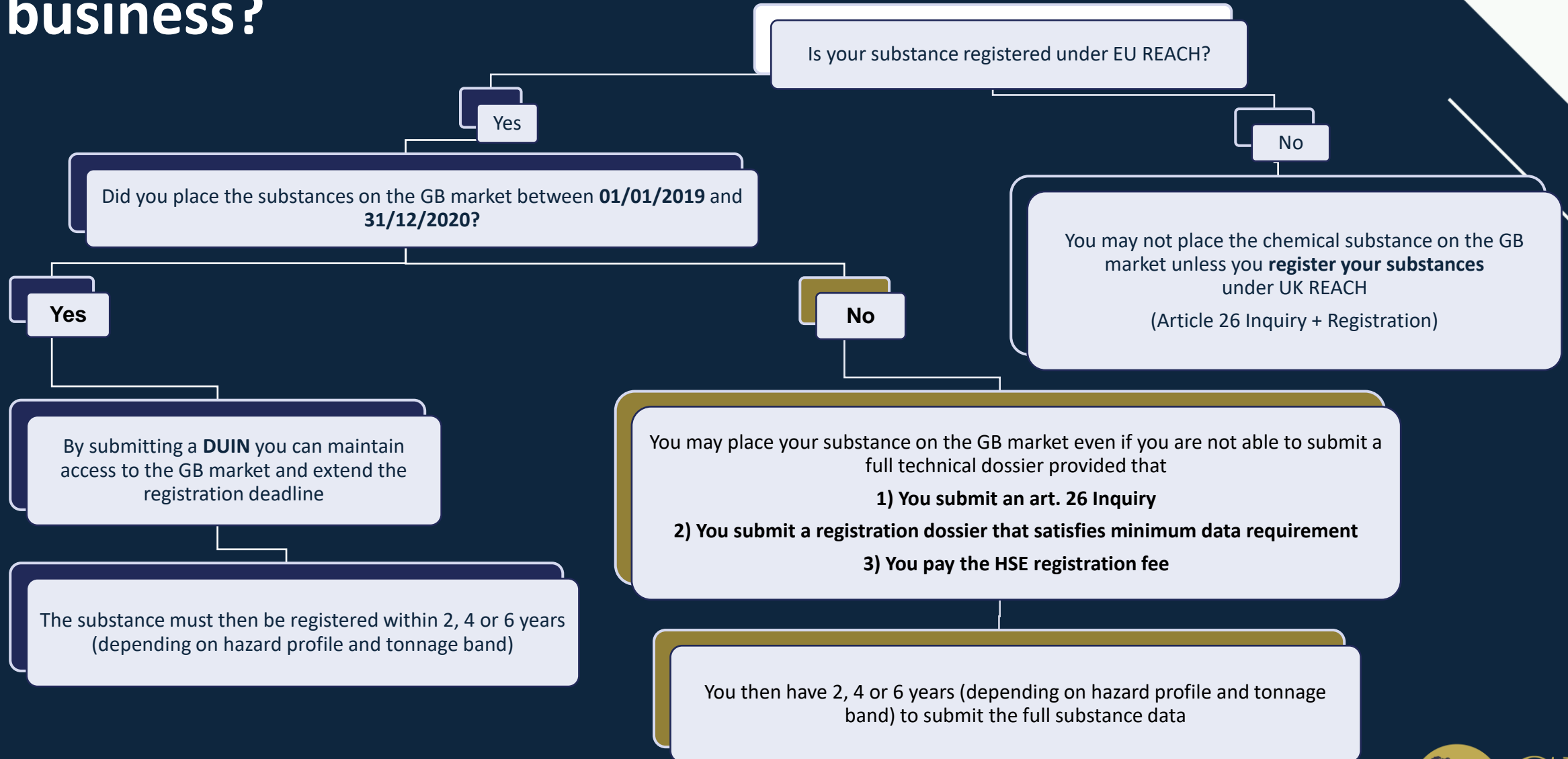
The role of an OR

- 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

**Which UK REACH
procedure applies
to your business?**



Which UK REACH procedure applies to your business?





DUIN as a non-GB manufacturer

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, the deadline has been extended for an undisclosed period of time**. 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.

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 assess 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.

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.

How to perform DUIN? (1/2)

- Appoint a GB-based OR if you are not going to let your 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



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**

DUIN as a formulator



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

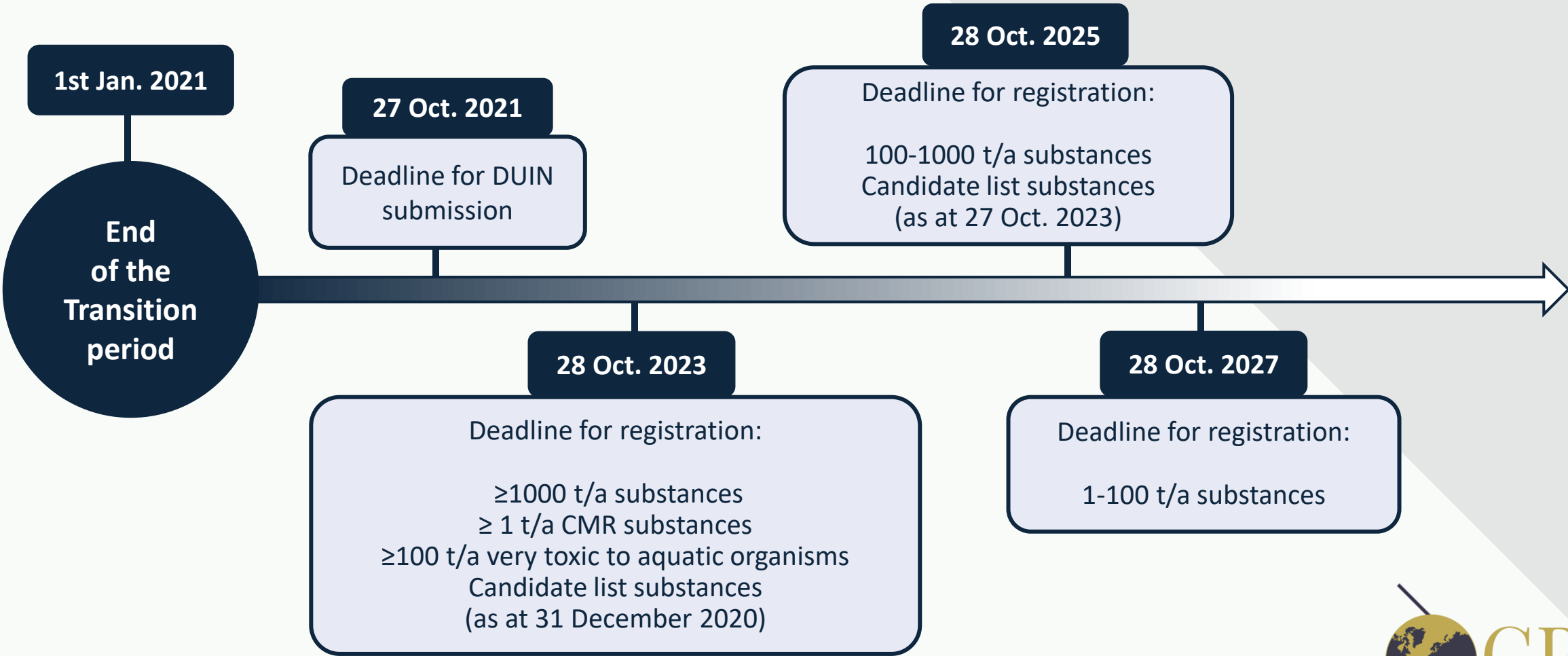
1. The individual substances within your mixture are registered under EU REACH, and
2. You have placed those mixtures into the GB-market during the period between 1st January 2019 and 31st December 2020.



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.

Deadlines for DUIN and post-DUIN full registration






NRES (simplified registration process) under UK REACH

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).

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!



Full Registration process under UK REACH

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

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.

The Registration (1/3)

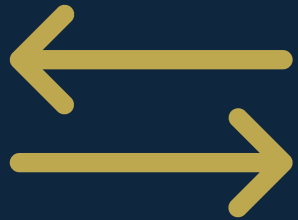
Substance groups and joint registration



- 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.

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

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



Recent updates

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)



HSE Registration fees

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.

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

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



Take home message

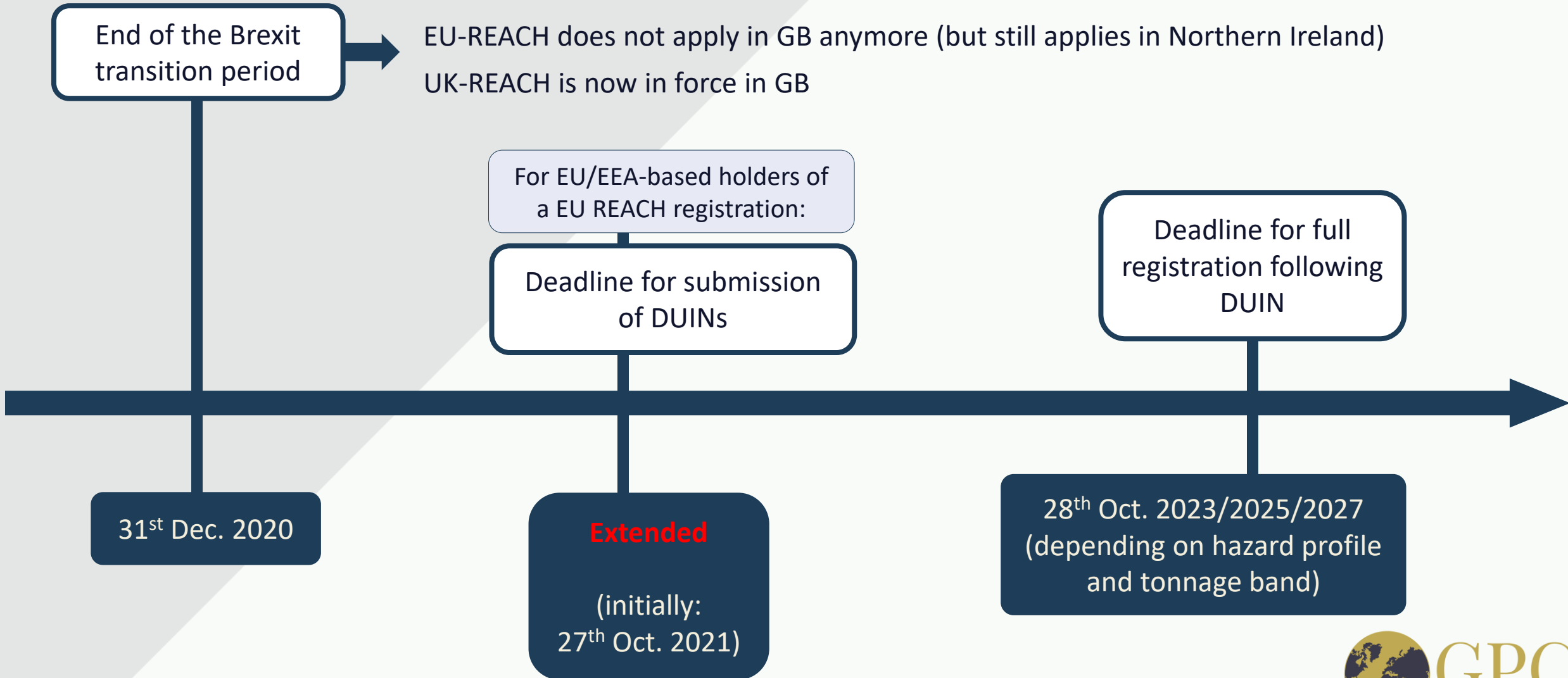
Take home message (1/3)

- ✓ 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

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.

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



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)

Thank you.

CONTACT US FOR GLOBAL REGULATORY SERVICES



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