

25 - 26.10.2023 | DAY 1  
Chemical Regulations and  
Sustainability Symposium 2023



Chemical  
Business  
Association

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COMPLIANCE. SUSTAINABILITY.

# UK REACH

## Registration and the Alternative Registration Model

*(What we know so far...)*

# UK REACH Registration and the Alternative Registration Model

## Agenda

1. UK REACH Registration Basics
2. Registration Deadline Extensions
3. NRES - How Does it Work?
4. New Registration Model - What We Know So Far
5. Conclusions
6. Quick Q&A

**Duration: 35 min**

- 1. UK REACH REGISTRATION BASICS**
- 2. EXTENSION OF THE REGISTRATION DEADLINES**
- 3. NEW REGISTRATION OF EXISTING SUBSTANCE (NRES)**
- 4. NEW REGISTRATION MODEL - WHAT WE KNOW SO FAR**
- 5. CONCLUSIONS**
- 6. QUICK Q&A**

# UK REACH Registration Basics

## Basic Requirement

- Basic UK REACH market access requirements:

**Substances manufactured in or imported into Great Britain at 1 t/a or more must be Registered**

- Same as the EU REACH Regulation → ***“No Data, No Market”*** (Art. 6)

# UK REACH Registration Basics

## Overview (Same as EU REACH)

- Registration tonnage bands: (*Same as EU REACH*)

1 - 10 t/a

10 - 100 t/a

100 - 1 000 t/a

≥1 000 t/a

- Registration types:

1. Full substance
2. On-Site Isolated Intermediate > *Strictly Controlled Conditions (“SCC”) must apply*
3. Transported isolated intermediate > *SCC must apply in the whole supply chain*

- Joint Submission (*One-Substance-One-Registration*): Lead Registrant + Co-Registrant(s)
- Data and Cost Sharing - *Fair, Transparent and Non-discriminatory*
- Keeping information up-to-date ...etc

# UK REACH Registration Basics

## Registrations - Joint Submission Concept



# UK REACH Registration Basics

## Registration and Related Deadlines

**POM** = Placing on the Market in GB  
\* Discussed further under the section  
“**Extension of the Registration Deadlines**”

Before POM

### Non-Existing Supply Substances / NRES Substances

Substances that cannot benefit from Transitional timelines at  $\geq 1$  t/a

30.4.2021 ✓

### Grandfathering notification deadline

Applicable only to GB based EU REACH registration holders

27.10.2021 ✓

### Downstream User Import Notification (DUIN) deadline (*Late DUIN possible*)

Applicable to GB importers of substances from the EU/EEA/NI and Only Representatives that will need to UK REACH register substances at 1 t/a or more

Today

### Registration deadline 1

- $\geq 1000$  t/a substances
- $\geq 100$  t/a Very toxic to aquatic organisms (acute or chronic)
- $\geq 1$  t/a Carcinogenic, Mutagenic, or toxic for Reproduction (CMR) substances
- $\geq 1$  t/a Candidate list SVHCs as on EU List on 31 December 2020 (transposed to UK)

27.10.2026\*

### Registration deadline 2

- 100 - 1000 t/a substances
- $\geq 1$  t/a Candidate list substances (*unless already covered above*) that are added to the candidate list between 1 January 2024 and 27 October 2026.

27.10.2028\*

### Registration deadline 3

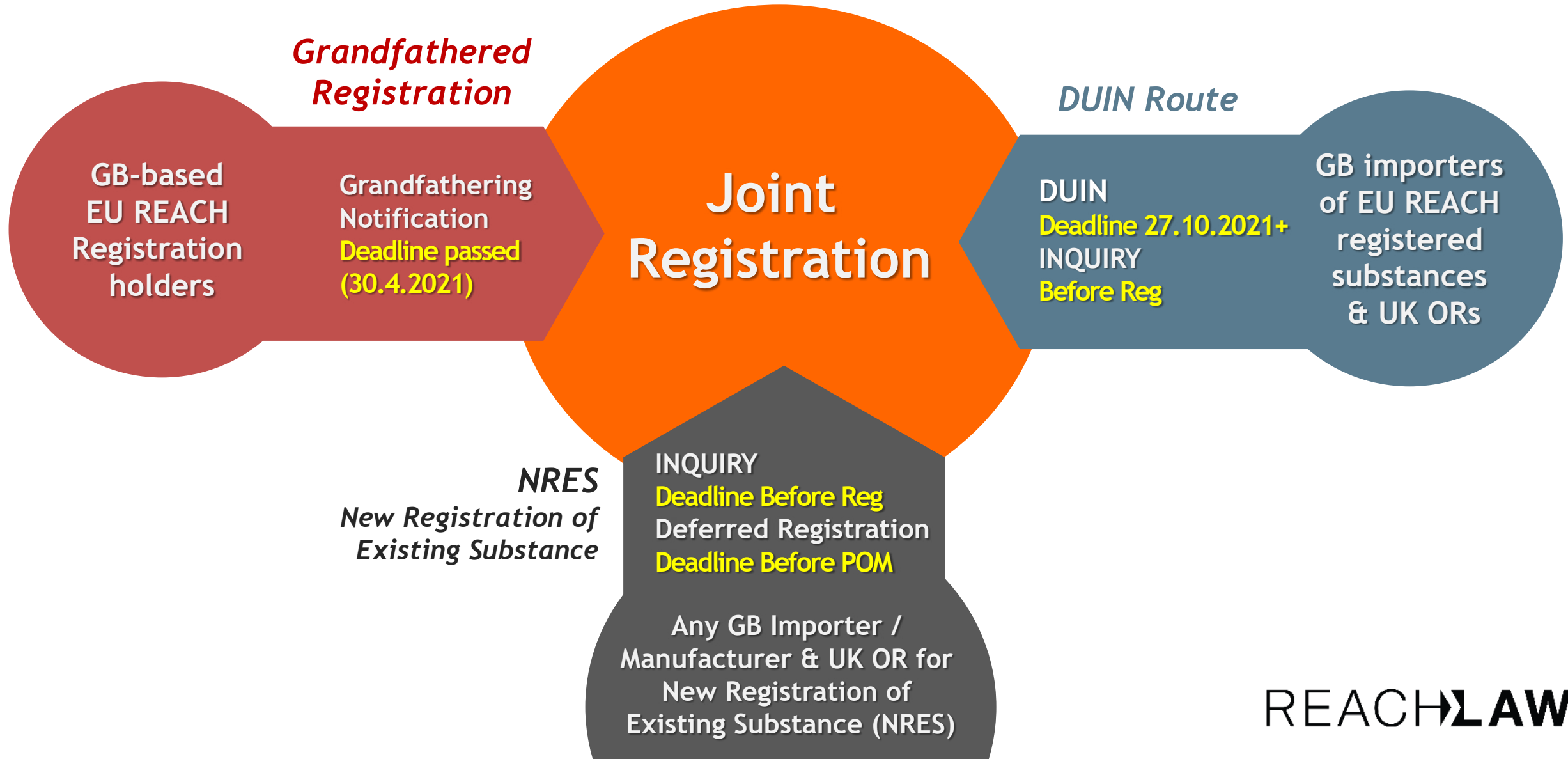
- 1 - 100 t/a substances

27.10.2030\*



# UK REACH Registration Basics

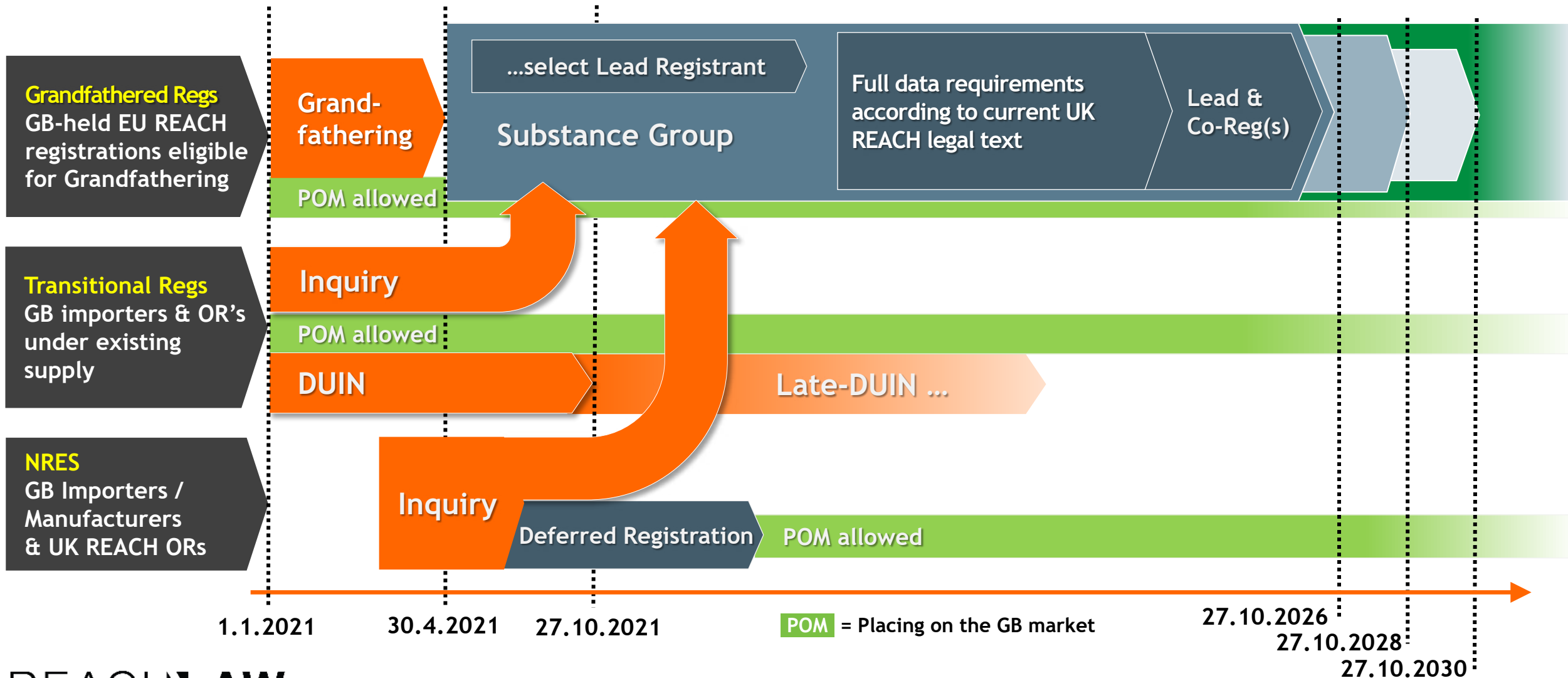
## Grandfathered Registrations, “Transitional Registrations” & NRES





# UK REACH Registration Basics

## Current Registration Process



***Novel Substances (new, not existing substances) must be registered before being placed on the GB-market at 1 t/a or more.***

# UK REACH Registration Basics

## HSE Registration Fees (*Large Sized Enterprise Example*)

HSE Fee Type	Fee (GBP)
HSE inquiry fee	0 £ / substance / Legal Entity
HSE registration fee per substance for <b>1 - 10 t/a</b> regular substance as a member of a Joint Submission as well as On-Site / Transported isolated intermediates at $\geq 1$ t/a	1 138 £ / substance / Legal Entity
HSE registration fee per substance for <b>10 - 100 t/a</b> regular substance as a member of a Joint Submission	3 061 £ / substance / Legal Entity
HSE registration fee per substance for <b>100 - 1 000 t/a</b> regular substance as a member of a Joint Submission	8 185 £ / substance / Legal Entity
HSE registration fee per substance for <b>&gt;1 000 t/a</b> regular substance as a member of a Joint Submission	22 064 £ / substance / Legal Entity

***Not Applicable to Grandfathered registrations!***

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# Extension of the Registration Deadlines

## Why?

- To ensure that there is sufficient time to develop a ***New transitional Registration Model***, and to make the necessary operational and legislative changes to implement a new model, the UK Government wanted to **extend the transitional registration deadlines**.
- A public consultation was held **July - September 2022** to give feedback from stakeholder to the UK government.



# Extension of the Registration Deadlines

## Background: 3 Options for Extending the Registration Deadlines

Type of Substances	Transitional Registration Deadlines		
	<u>Option 0</u> (Current DL)	<u>Option 1</u> (3:3:3)	<u>Option 2</u> (3:2:1)
Substances at $\geq 1000$ t/a and CMR substances at $\geq 1$ t/a <i>and</i> substances Very toxic to aquatic organisms ( <i>acute or chronic</i> ) at $\geq 100$ t/a <i>and</i> Candidate list substances ( <i>as of 31 December 2020</i> ) at $\geq 1$ t/a	<del>27 October 2023</del>	27 October 2026 (= Current DL + 3 years)	<del>27 October 2026 (= Current DL + 3 years)</del>
Substances at 100 - 1000 t/a <i>and</i> substances that are added to the Candidate List between 1 January 2024 and 27 October 2026 at $\geq 1$ t/a	<del>27 October 2025</del>	27 October 2028 (= Current DL + 3 years)	<del>27 October 2027 (= Current DL + 2 years)</del>
Substances at 1 - 100 t/a	27 October 2027	27 October 2030 (= Current DL + 3 years)	27 October 2028 (= Current DL + 1 years)
	(Do nothing option)	<b>Selected</b>	Preferred by the GOV

# Extension of the Registration Deadlines

## The New Transitional Registration Deadlines

Type of Substances	New Transitional Registration Deadlines
Substances at $\geq 1000$ t/a and CMR substances at $\geq 1$ t/a <i>and</i> substances Very toxic to aquatic organisms ( <i>acute or chronic</i> ) at $\geq 100$ t/a <i>and</i> Candidate list substances ( <i>as of 31 December 2020</i> ) at $\geq 1$ t/a	27 October 2026
Substances at 100 - 1000 t/a <i>and</i> substances that are added to the Candidate List between 1 January 2024 and 27 October 2026 at $\geq 1$ t/a	27 October 2028
Substances at 1 - 100 t/a	27 October 2030



The New Registration deadlines have become UK Law

**SI 2023 No.722**

*In force as of 19 July 2023*

These apply to **Grandfathering**, **DUIN** and **NRES** (*Joining the joint submission part*) only.  
 New substances must still be fully registered before placing on the GB market at  $\geq 1$  t/a.

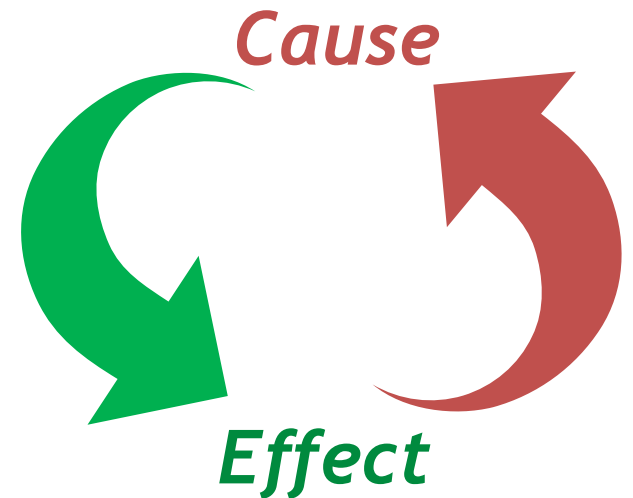


# Extension of the Registration Deadlines

## Who's Affected

The following businesses are **affected by the extension** of the transitional registration deadlines:

1. Who **Grandfathered registrations** into UK REACH from EU REACH (*EU REACH Registration holders located in GB*)
2. Who have **submitted DUINs** and are intending to go ahead with registrations for those substances (*GB importers, Only Representatives*)
3. Who have **submitted or are going to submit a Deferred Registration** (“Part 1”) of the NRES process



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# ***NRES***

***New Registration of Existing Substance***

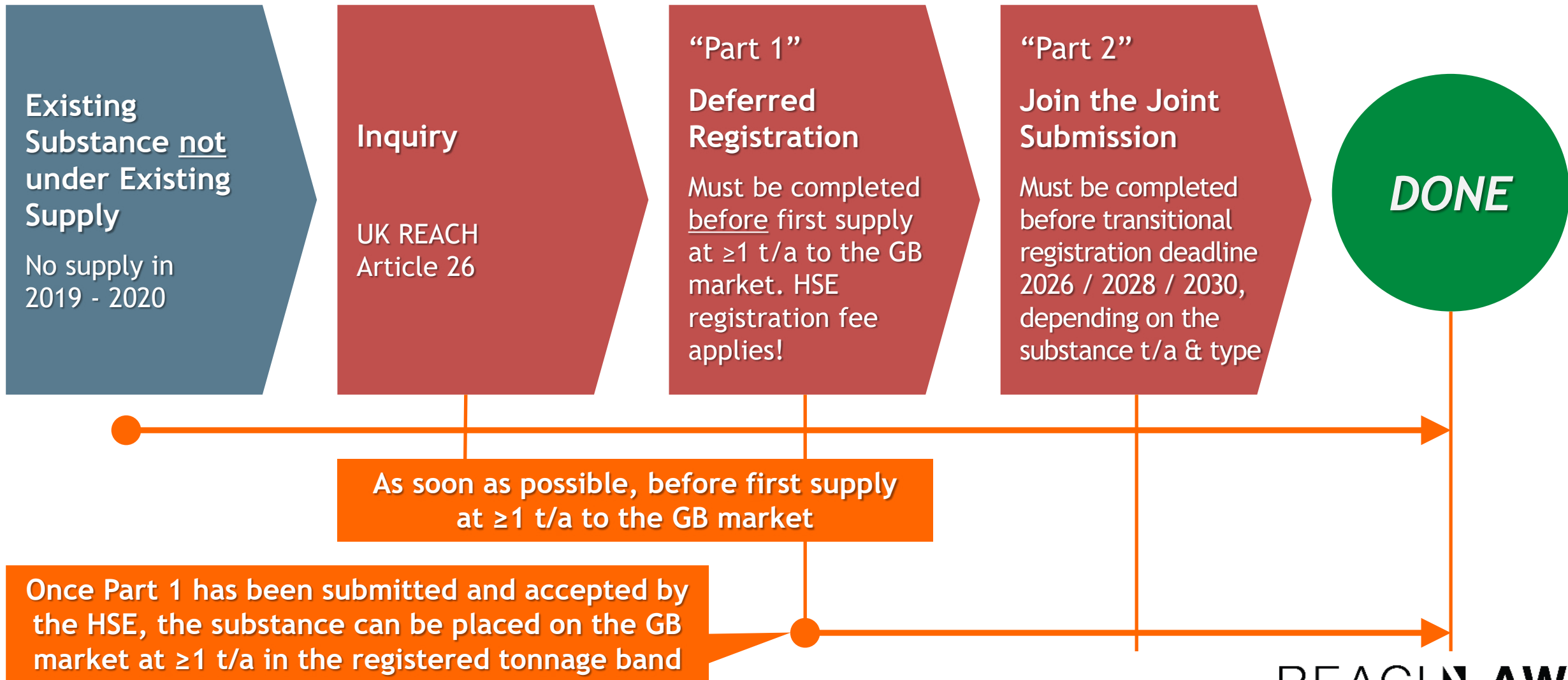
# New Registration of Existing Substance (NRES)

## Overview

- Companies that cannot benefit from DUIS or Grandfathering for substances under “*Existing Supply*”, **must first register before they can place the substance on the GB market at  $\geq 1$  t/a.**
- However, if the substance has been EU REACH registered (*by anyone*), hence an “*Existing Substance*”, the company may be able to, as part of a **New Registration of Existing Substance (NRES)** process, to **defer the submission of the full information requirement to a later time so that the company can joint the Joint Registration work and share data with other transitional registrants and grandfathered registrants.**
- Whether this NRES process applies to your case will be informed to you by the HSE when your inquiry dossier has been successfully submitted.

# New Registration of Existing Substance (NRES)

## The NRES Process



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# New Registration Model - What We (*Think We*) Know So Far

## Background

- *“Defra has committed to exploring alternative arrangements for UK REACH transitional registrations in order to support chemical businesses whilst upholding the highest standards to safeguard public health and the environment”*
- Defra with the HSE and the Environment Agency are exploring an **alternative model for transitional registrations:**
  - *“The model aims to reduce the need for replicating EU REACH data packages by placing a greater emphasis on improving our understanding of the uses and exposures of chemicals in the context of Great Britain”*
- The work is still **on-going...**



Some additional information available at:  
<https://www.gov.uk/government/news/deadline-for-uk-reach-to-be-extended>





# *Warning*



*This section is  
highly speculative*

# New Registration Model - What We (*Think We*) Know So Far

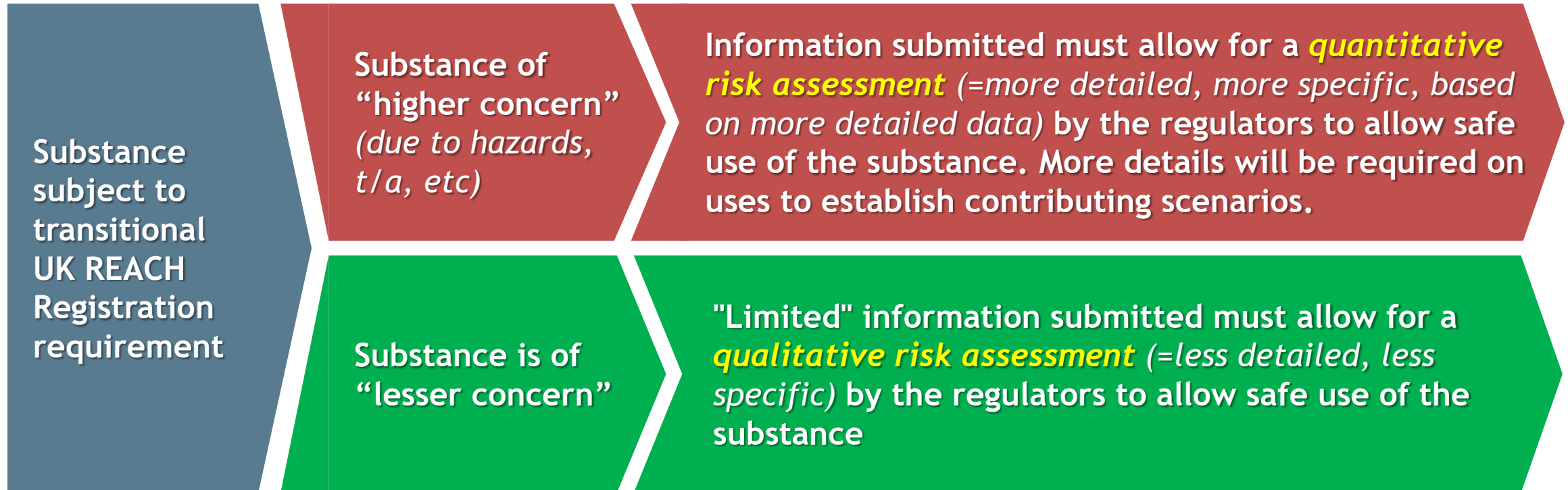
## The Possible “*Two Tracked*” Approach

27.10.2026

27.10.2028

27.10.2030

Extended registration deadlines apply! →



Should be populated with “publicly available data” (*without IPR issues...*) and data held within the substance group

# New Registration Model - What We (*Think We*) Know So Far

## Possible Practicalities

- The Alternative Transitional Registration Model (“ATRm”) would **apply to all transitional registrations**
- For both types of ATRm registrations, a **Lead Registrant would be selected/elected** within the **substance group** (*access via Inquiry or Grandfathering*) to submit the phys-chem/tox/ecotox information (*where applicable*) in a **Lead Dossier** as part of a **Joint submission**
- **Co-Registrants** (*member registrants*) can then join the Joint Submission (*typically*) via **Letter of Access** and submit their own Co-registration (IUCLID *sections 1 & 3*).
- Dossers would be prepared in IUCLID - **registration templates** to be determined - and submitted to the HSE via the “**Comply with UK REACH**” service
- Standard **HSE registration fees would apply**

*Companies would only need to provide  
full data sets for chemicals “Novel”  
substances*

# New Registration Model - What We Know So Far

## Going Forward

- The UK Government is working on the New Registration Model in **two stages**:
  1. Determine **how to access hazard information without the industry having to buy data packages** (*by far the biggest pain point...*)
  2. How to **improve existing information about exposure** to chemical substances in the UK.
- The UK government said that plans to unveil the new registration model **later in 2023** with an aim to **legislate in 2024**.
  - Public consultation (*maybe*) planned for later in 2023 / early 2024 on the new registration model > We will then know more
- *The government has said it **does not yet know whether the new model will work and that it will not compromise the level of protection for human health and the environment**, which remains an absolute priority.*

The UK Gov has said that “*a balance must be struck between industry costs and the information the UK regulator receives*”

# New Registration Model - What We Know So Far

## Use of Existing and (*Publicly*) Available Data

- Use of existing and (*publicly*) available data is **problematic** as very little information can be regarded as publicly available and free for use.
- However, the following sources could be used for populating the ***Substance Hazard Profile***:
  - Existing EU REACH data owned by GB holders, albeit this will likely **not be free for use**
  - Published articles on substance endpoint data - Albeit fairly inexpensive, this data **is not free for use either**
  - **12-Year Rule**: 12-year-old EU REACH (robust) study summaries **held / owned by GB-based companies (only) can be used for free**, albeit how much of such data is truly available across multiple substances...?
    - The 12-year rule does NOT apply between different legal jurisdictions: EU <-> UK, only within each jurisdiction "*in isolation*".
  - Free publicly available data where IPR is not an issue (*needs to be verified case-by-case, which can be painstaking*) **can be used for free**, but one would expect very little data to fall under this category...
  - Government owned/created/modelled data (?) *...etc*

***The New UK REACH Registration Model is still in development, and, according to Defra, we will know more later in 2023...***



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# UK REACH Registration and the Alternative Registration Model

## Conclusions

- As a result of a public consultation by Defra, **the transitional registration deadlines have been extended to 27.10.2026 / 27.10.2028 / 27.10.2030** based on the substance type and annual tonnages.
- A new registration model **is still under discussion**, details are very scarce, but more information will be available later in **2023** and with the aim of passing the changes into UK law in 2024
- It is **not certain that the alternative registration model will prevail**, and the current “full” registration process may continue to apply → **Follow the developments closely**

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# *Quick Q&A*

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## REACHLaw

Aleksanterinkatu 19  
FI-00100 Helsinki  
Finland

[www.reachlaw.fi](http://www.reachlaw.fi)

[info@reachlaw.fi](mailto:info@reachlaw.fi)

[sales@reachlaw.fi](mailto:sales@reachlaw.fi)

## FREDERIK JOHANSON

*Partner, Sales*

Mobile: +358 40 059 5918

Office: +358 9 412 3055

E-mail: [frederik.johanson@reachlaw.fi](mailto:frederik.johanson@reachlaw.fi)

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