

25 - 26.10.2023 | DAY 1

Chemical Regulations and Sustainability Symposium 2023

Chemical Business Association

REACHLAW COMPLIANCE. SUSTAINABILITY.

UK REACH Inquiry & Late DUIN

UK REACH Registration - A Practical Approach

UK REACH Inquiry & Late DUIN

Agenda

1. UK REACH: The journey so far
2. The Operating Platform: The “Comply with UK REACH” Service
3. Late DUIN
4. UK REACH Inquiry
5. IUCLID Note
6. Conclusions
7. Questions & Answers

Duration: 15 min

1. **UK REACH: The journey so far**
2. The operating platform: The “Comply with UK REACH” Service
3. Late DUIN
4. UK REACH Inquiry
5. IUCLID Note
6. CONCLUSIONS
7. QUESTIONS & ANSWERS

UK REACH: The journey so far



Came into force

1.1.2021

UK REACH is currently defined as

EU REACH as at 31.12.2020
+ SI 2019 No. 758
+ SI 2019 No. 857
+ SI 2019 No. 1144
SI 2020 No. 1577
SI 2021 No. 904
SI 2023 No. 722
+
Implementing Regulations
(Data-sharing etc.)

UK REACH consolidated text available at:
www.legislation.gov.uk

UK REACH: The journey so far

Important Consequences of UK REACH on Legal Roles

… Before 1.1.2021	*From 1.1.2021…*
GB Manufacturer	GB Manufacturer under UK-REACH
GB Importer, sourcing from non-EU/EEA/NI country	GB Importer under UK-REACH
GB Downstream Users and GB Distributors sourcing chemicals from EU/EEA/NI	Now GB importer under UK-REACH

UK REACH Legal Roles



1. Manufacturer
2. Importer
3. Downstream User *(formulator or end user)*
4. Distributor

GB import must be covered by a UK REACH registration

UK REACH: The journey so far

The Authority HSE & the "*Comply with UK REACH*" IT System

- **The UK HSE – Health and Safety Executive will** be equivalent to ECHA in the UK for UK REACH
  - More information at: https://www.hse.gov.uk/

- **UK REACH Dossiers are submitted to the HSE through the *"Comply with UK REACH"* IT-system that that is available at:**
  - https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations



UK REACH: The journey so far
Key Transitional Measures

The UK REACH Regulation implements Transitional Measures to ensure continuity of chemicals trade in GB (*Articles 127x*)

1. **Existing GB-held EU REACH registrations** continue to be valid ***subject to grandfathering*** *requirements*;
2. **Imported EU/EEA/NI registered substances** used by downstream GB companies and **covered by EU/EEA/NI REACH Registrations** may be used in the short term, ***subject to notification ("DUIN") and eventual registration***.
3. **Issued EU REACH authorisations** held by GB companies or covering use by GB companies *are valid in GB*, ***subject to information requirements***
4. **Special provisions** for use of substances subject to **recent sunset dates** or covered by **undecided EU/EEA based Applications for Authorisation** (not covered)

UK REACH: The journey so far
"Existing Supply"



- **UK REACH Transitional Measures, including DUIN, apply to substances that were in active trade into the UK during 2019 or 2020 at any annual volumes**
  - **These substances are considered to be under Existing Supply**
- **Only GB Importers & Only Representatives (OR) can DUIN notify substances under existing supply**
- If substances were **actively imported into GB,** covered by an EU/EEA OR, a **UK OR can be appointed** to **DUIN notify** and **cover import obligations of the same recipient(s) (DUs)**
  - The **GB importer** *(as such or covered by a UK REACH OR)* **must be able to show active trade** even if importing from a different supplier

In all other cases you must first Inquire and Register substances before placing on the GB market ≥1 t/a

Just as it would be without Brexit…!

UK REACH Inquire → New Registration of an Existing Substance (NRES)

The journey so far
Registration and Related Deadlines

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

Before POM

30.4.2021 ✓

27.10.2021 ✓

Today

27.10.2026*

27.10.2028*

27.10.2030*

Non-Existing Supply Substances / NRES Substances
Substances that cannot benefit from Transitional timelines at **≥ 1 t/a**

Grandfathering notification deadline (Deadline passed)
Applicable only to GB based EU REACH registration holders

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

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

Registration deadline 2
100 - 1000 t/a substances
≥ 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.

Registration deadline 3
1 - 100 t/a substances

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"Late DUIN"

Home | News | Guidance | About HSE | Books | Free updates | Contact

HSE > Guidance > Topics > UK REACH > Authorisation > Notification of status as a GB-based downstream user or distributor under EU REACH

https://www.hse.gov.uk/reach/duin.htm

- ← UK REACH
- Registration overview
- New registration
- Grandfathering EU registrations
- Downstream user notification
- DUIN Template
- Lead registrants in UK REACH
- Research and Development (PPORD) →
- Northern Ireland Notification (NIP-NOTS)

Notification of status as a GB-based downstream user or distributor under EU REACH

News: Extension of submission deadlines

Defra has committed to exploring alternative arrangements for transitional registrations including extending deadlines to provide full registration data.

Subject to parliamentary approval, Defra is extending the submission deadlines for full registration data in order to explore and develop an alternative model for transitional registrations.

To facilitate this, the current deadlines are being extended by 3 years to 27 October 2026, 27 October 2028 and 27 October 2030 depending on tonnage and toxicity.

The legislation necessary to give effect to these changes was laid in Parliament on 20 April 2023 and is expected to come into force in the summer of 2023.

Any GB-based legal entity continuing to import a substance into Great Britain (England, Scotland and Wales) at or above 1 tonne per year must submit a registration to HSE for that substance (unless an exemption applies). This obligation to register includes the import of substances from the EU.

If in the 2 years prior to 1 January 2021 you were a downstream user or distributor under EU REACH, or you were regarded as a downstream user by virtue of an Only Representative (OR) agreement, you were able to submit a downstream user import notification (DUIN) before 27 October 2021(300 days from January 2021). By submitting a DUIN you effectively defer your registration obligation for 2, 4 or 6 years, depending on the tonnage band and/or hazard profile, beginning after those 300 days.

If you did not notify HSE and wish to continue to import EU REACH registered substances into Great Britain at or above one tonne per year, you can still submit a notification, if eligible to do so. You should do this as soon as possible.

If you were **not** previously a registrant, downstream user or distributor under EU REACH, and you wish to import chemicals into Great Britain for the first time, at or above one tonne per year, you may need to submit a new registration under UK REACH.

1. UK REACH: The journey so far
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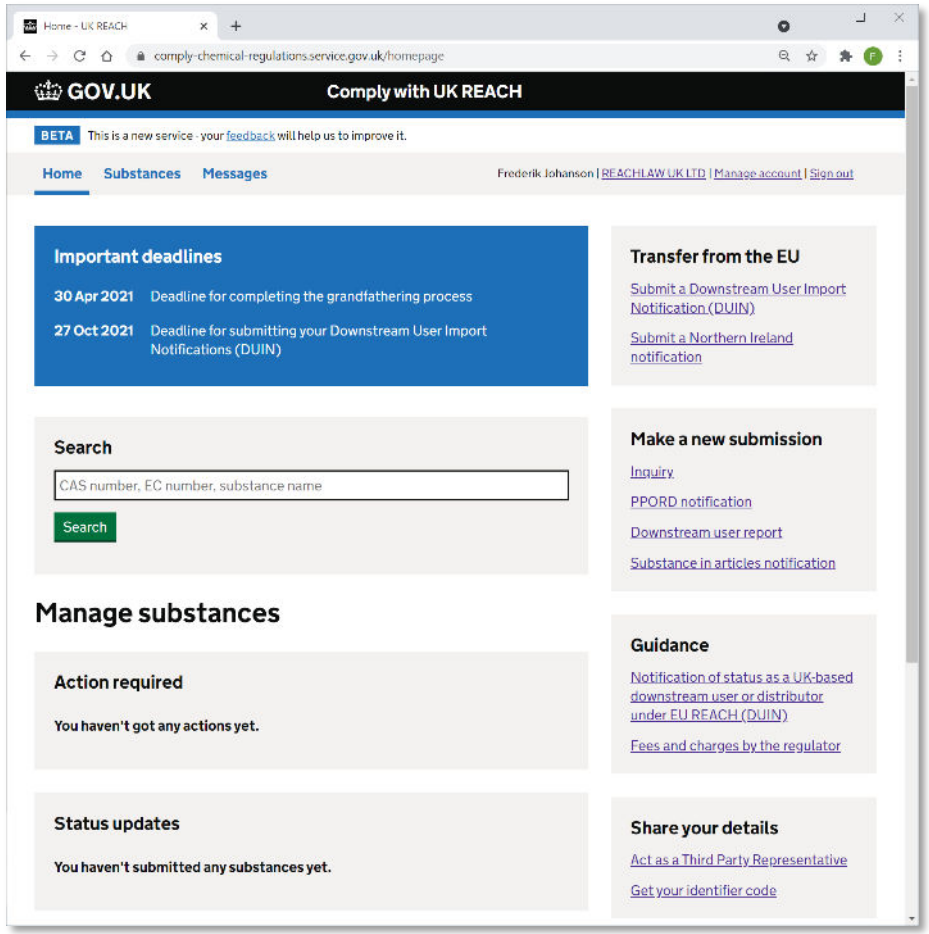
The "Comply with UK REACH" Service
What is It and Why Do I Need It?

- **Before** you can do any Registration related compliance work, such as *DUIN, Inquiry, Registration, NRES* etc, you need to have the ***Comply with UK REACH Service*** **activated for the company needing to comply with the UK REACH regulation.**
  - *"Comply with UK REACH"* is an IT service linked to your ***Government Gateway account*** and your ***Defra account***
- You have to create a ***Government Gateway Account*** and related ***Defra Account*** **before** you can activate the *"Comply with UK REACH"* IT service.

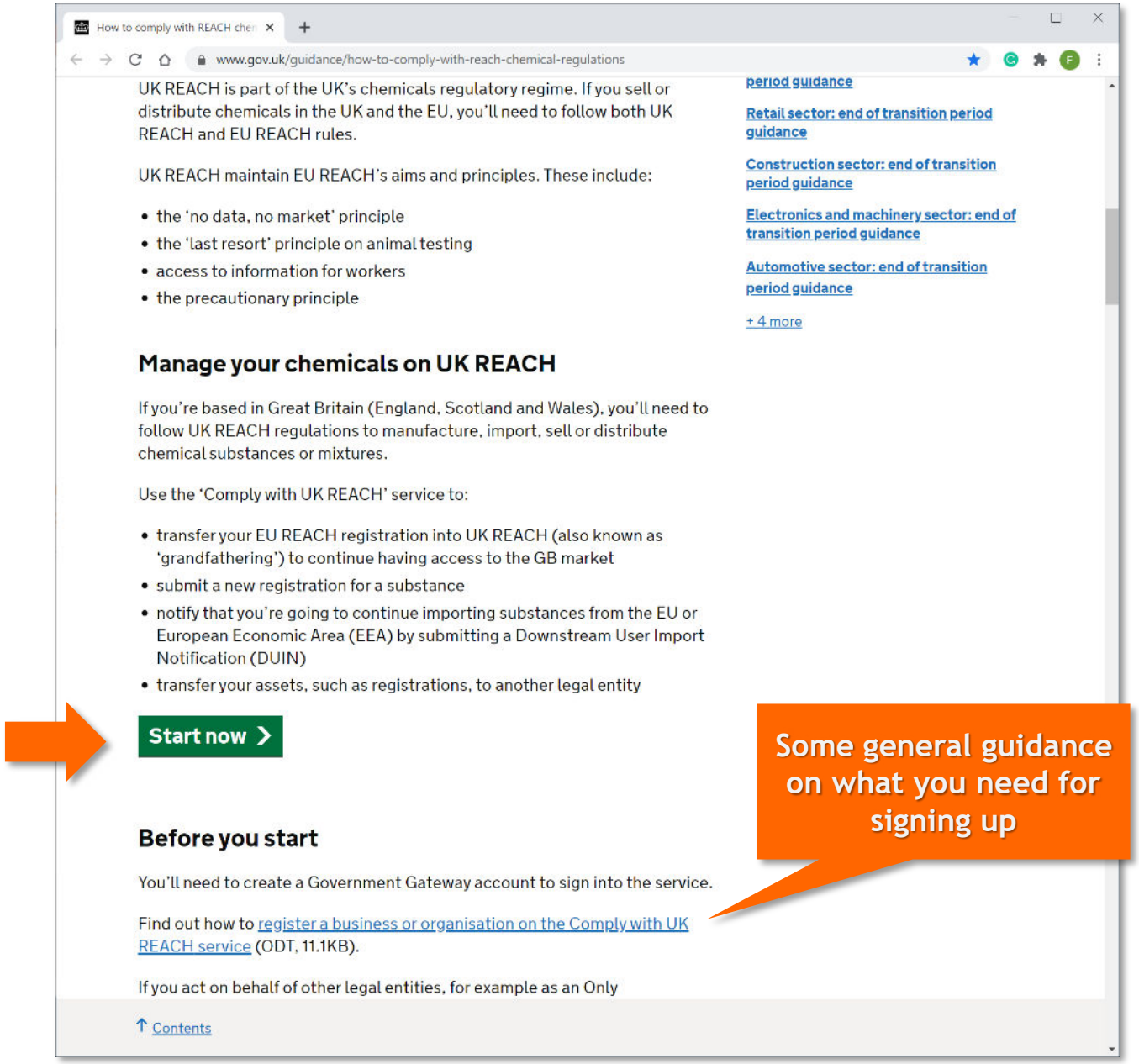


The “Comply with UK REACH” Service

Where to Get Started

1. Go to "**Comply with UK REACH**" account at https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations

2. Select “**Start Now**”



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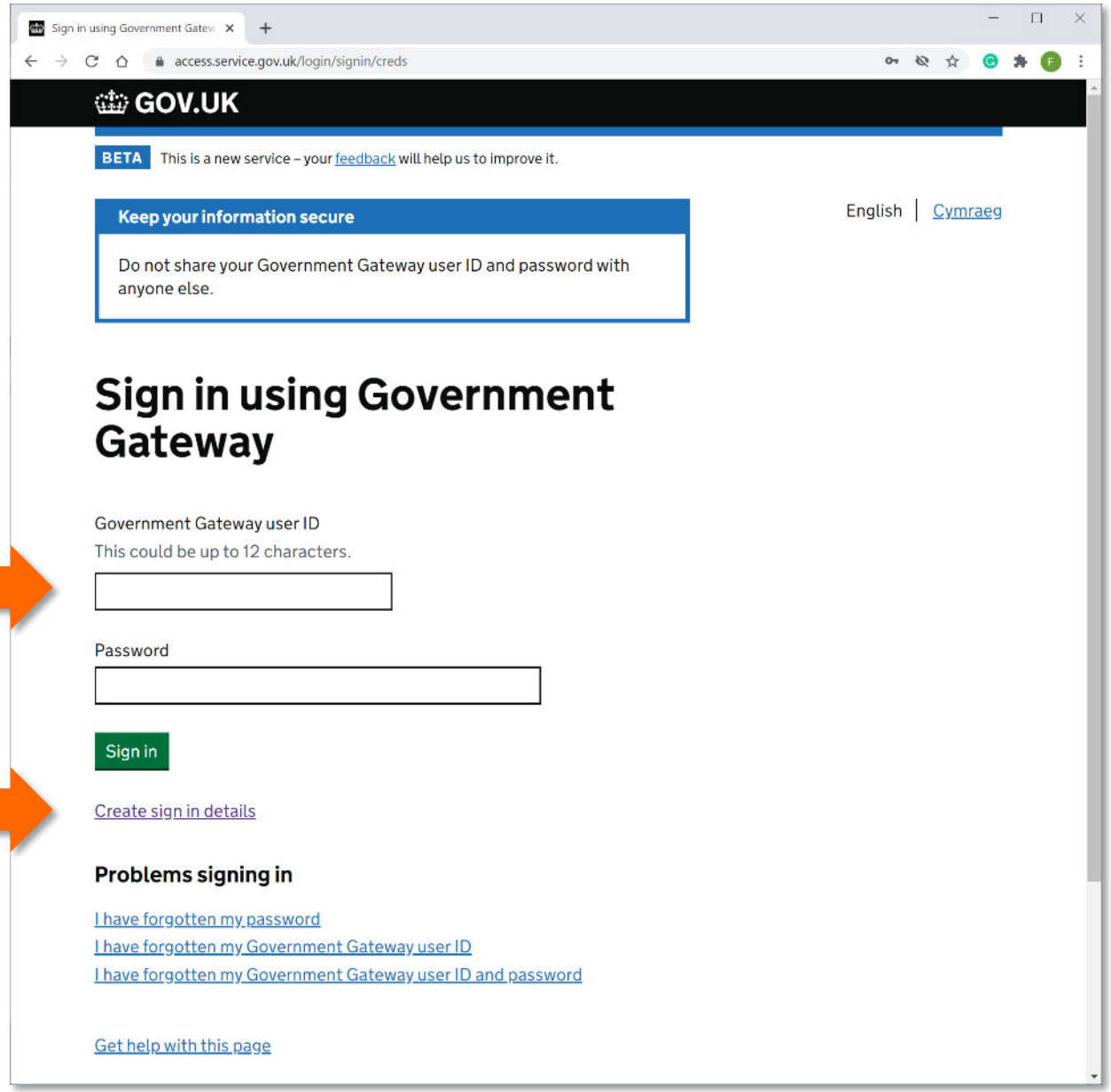
The “Comply with UK REACH” Service
Where to Get Started

Login with your existing ***Gateway user ID*** and ***Password***

If you **do not have these**, you need to create them first by selecting “***Create Sign-in Details***”

You will need your:

1. Email address
2. Full Name
3. Phone number



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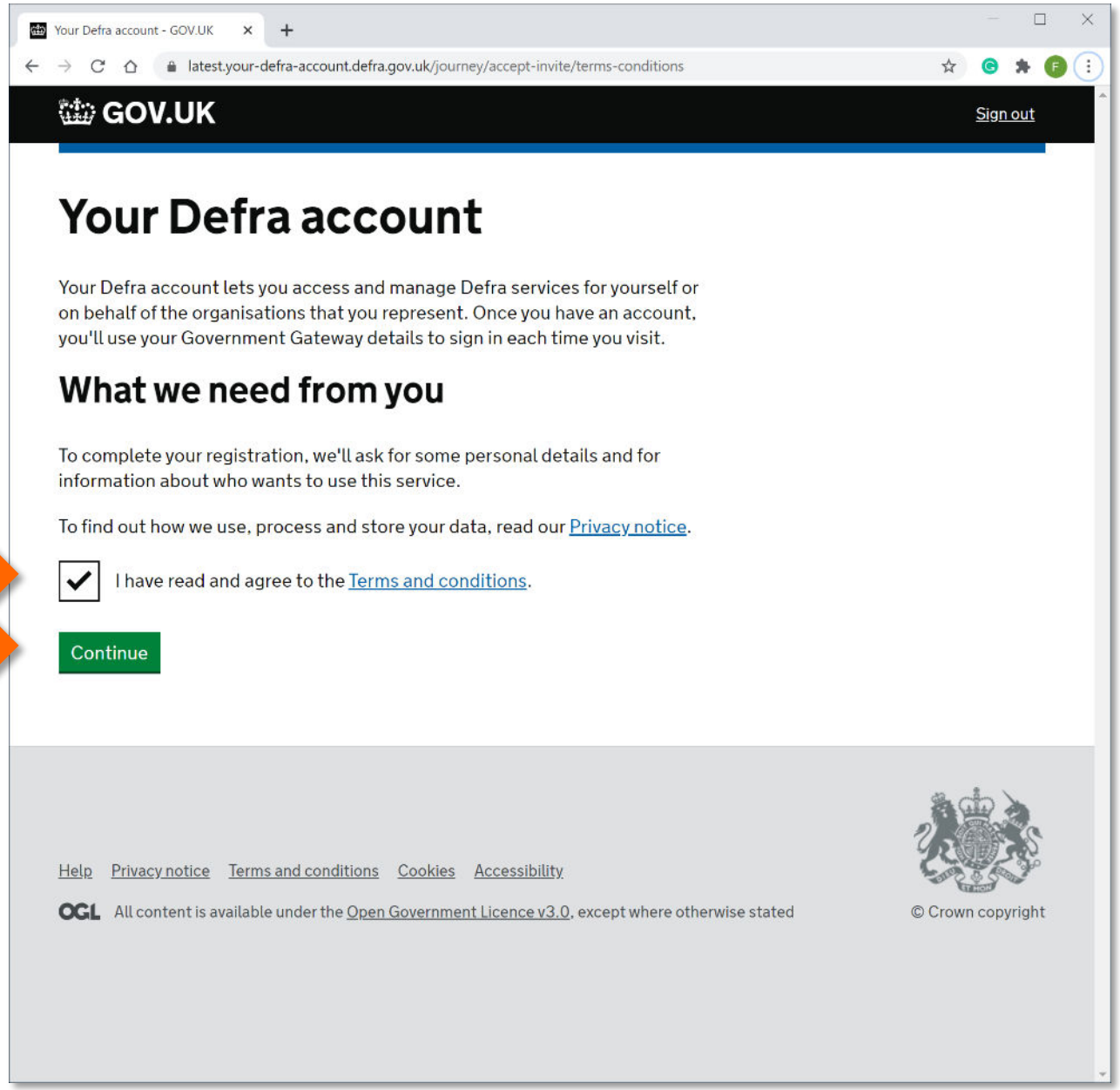
The “Comply with UK REACH” Service
Defra Account Activation

During the sign-up process or from your Government Gateway account you can activate the Defra Account for your company

Accept Terms and Conditions and Select “***Continue***”



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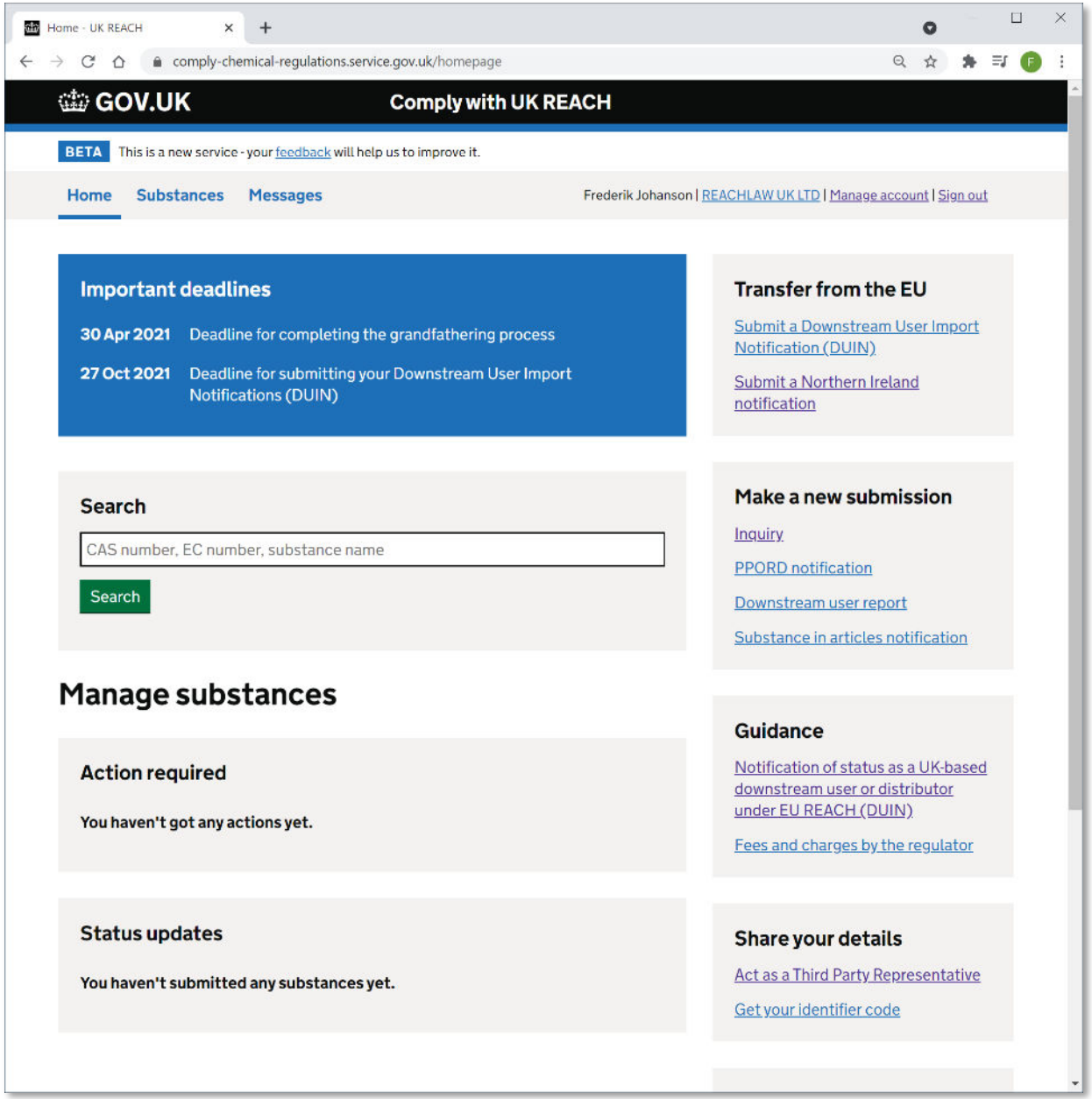
The “Comply with UK REACH” Service

Comply with UK REACH

Once all is set up, you can access your “Comply with UK REACH” account



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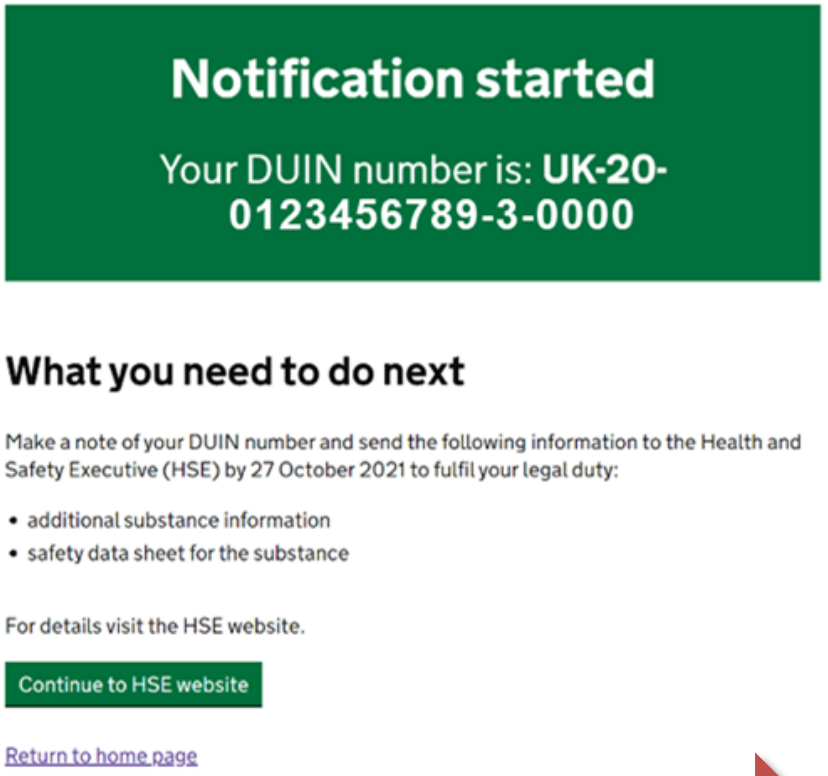
Late DUIN
Overview Guidance (*from HSE website + REACHLaw additions*)

STEP 1: Get your DUIN number from *Comply with UK REACH*:

- Use the **Comply with UK REACH service** to indicate that you are **an existing downstream user or distributor or Only Representative**. At this point your UK REACH DUIN number will be issued to you (***one DUIN number per Legal Entity***). This **only needs to be done once per legal entity** and covers all substances that you wish to continue importing from the EU.
  - This fulfils the Article 10(a)(i) information requirement of Article 127E.



Step 2 next

Late DUIN and Inquiry
Overview Guidance (*from HSE website + REACHLaw additions*)

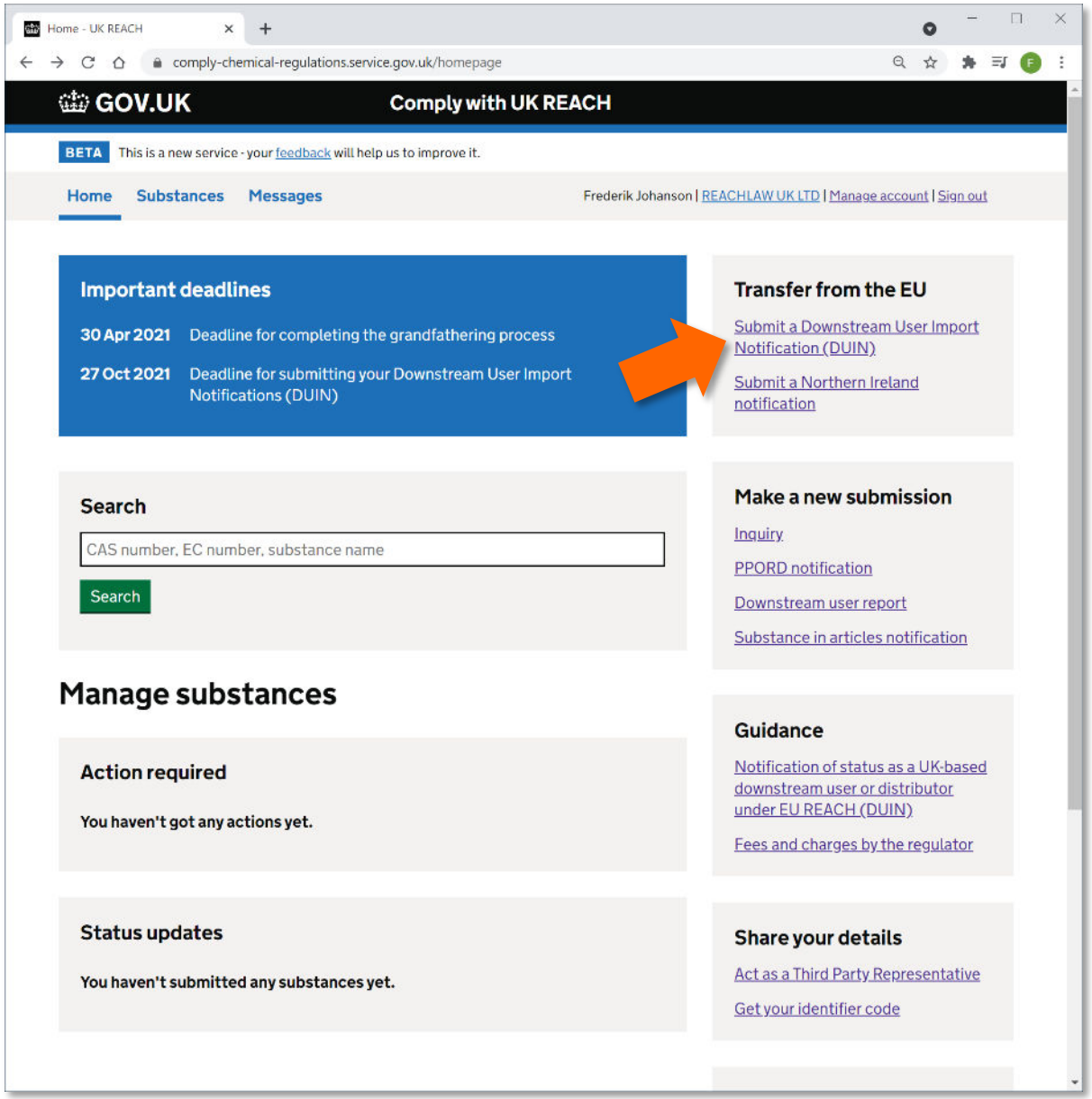
STEP 2: Submit detailed DUIN information by email:

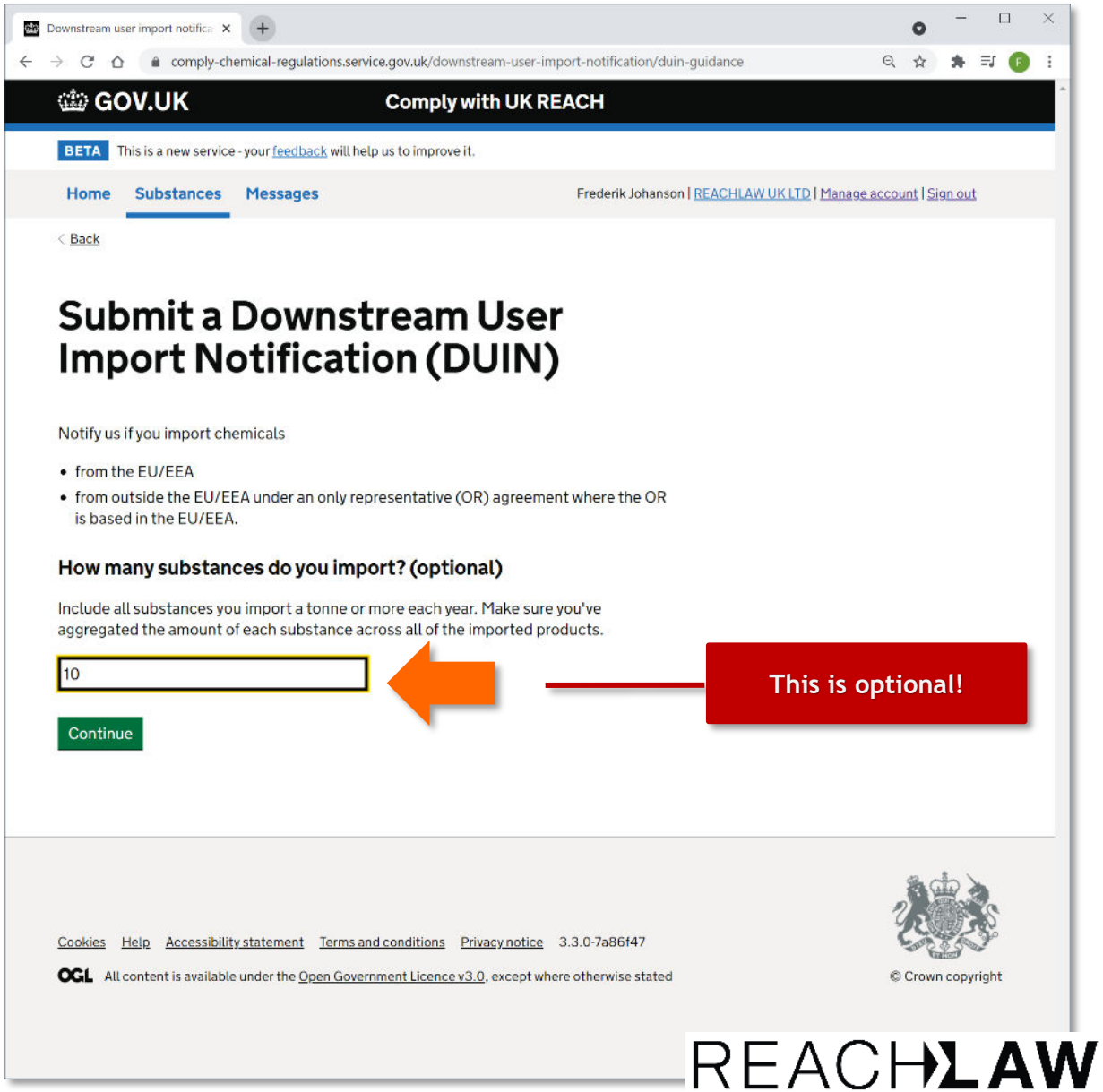
- Populate the DUIN additional information spreadsheet template (.xlsx) - **Microsoft Excel spreadsheet** with information about the substances that you wish to continue importing.
  - For information that is available to you, your should list individually all of the substances that you wish to continue importing from the EU, one per line in the Excel.
  - Where a substance is included in the spreadsheet, it must contain at least one of the following identifiers: **Substance name, CAS number, EC number.**
    - It may be easier to fulfil some of the information requirements by attaching a Safety Data Sheet (SDS) for the substances in question to the email rather than including it in the spreadsheet, e.g. the Article 10(a)(iv) information pertaining to classification. **However, including an SDS is not a requirement!**
    - Where an SDS for a substance is attached to the email along with the spreadsheet, the spreadsheet must also list that substance.
- **Send the completed spreadsheet to the Agency at ukreach.dunotification@hse.gov.uk.**
  - You must include your legal entity name and DUIN number in the subject line of the email.



Late DUIN and Inquiry

Step 1: Get your DUIN number from Comply with UK REACH (1 / 2)





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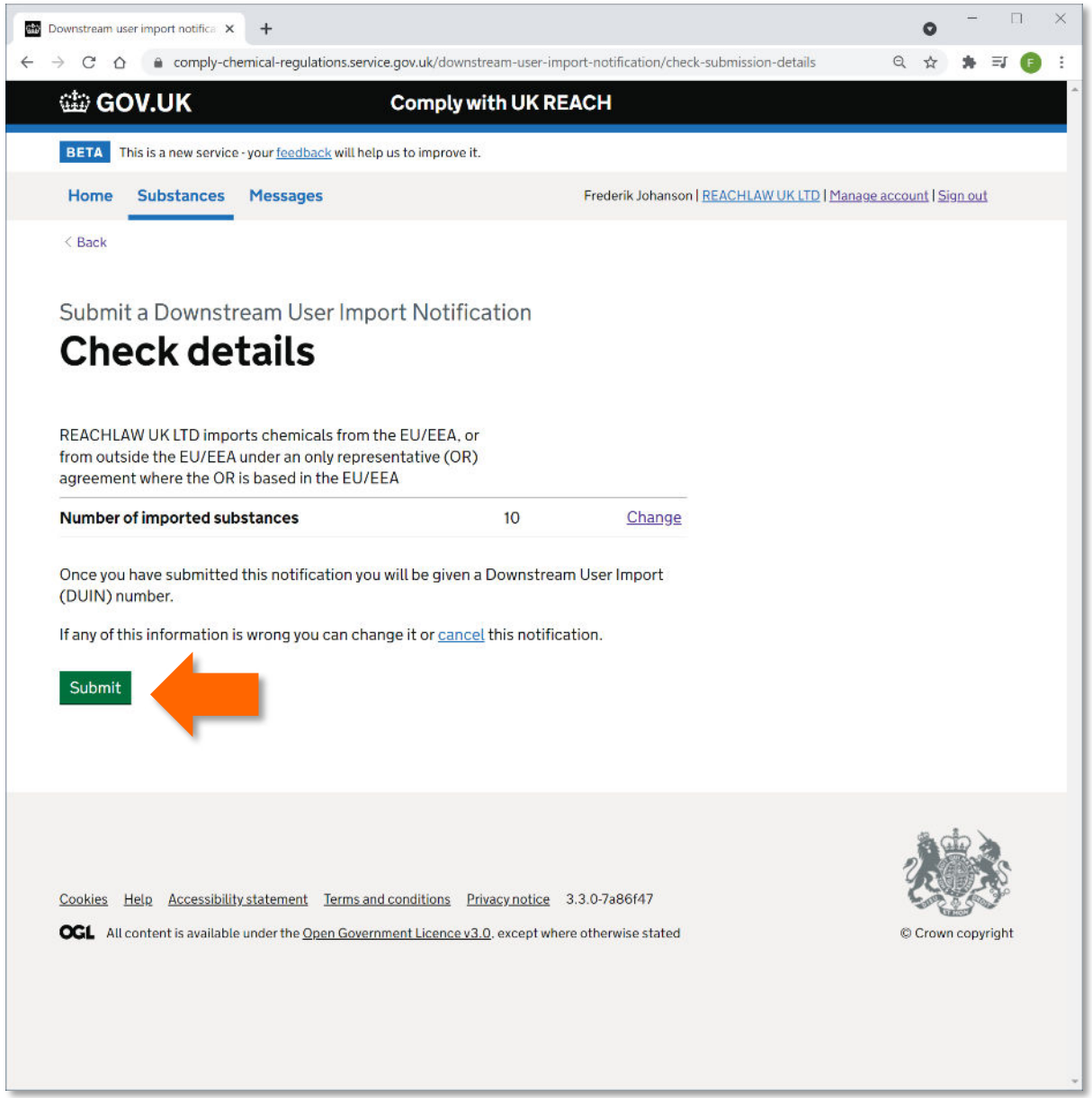
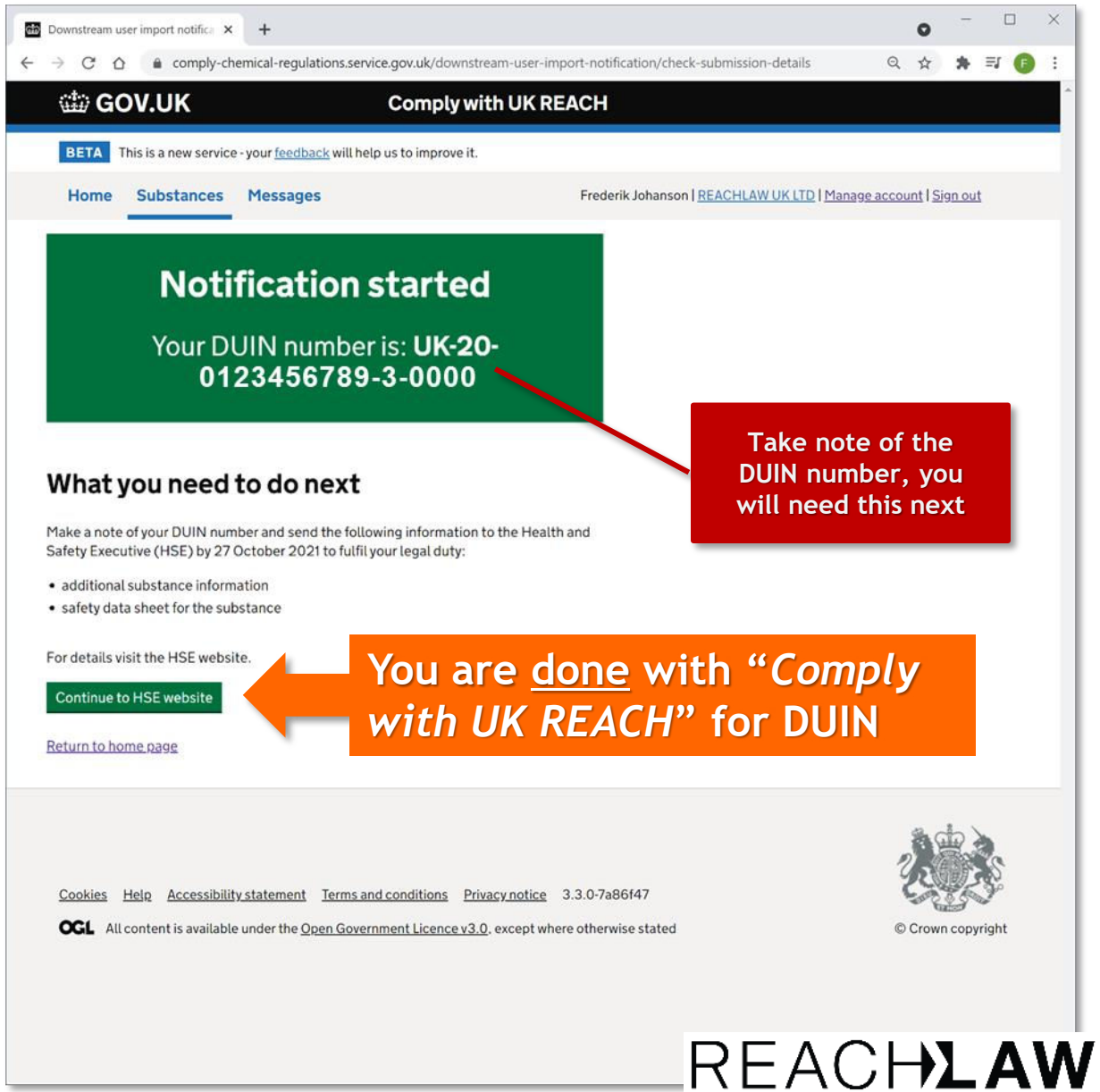
Late DUIN and Inquiry

Step 1: Get your DUIN number from Comply with UK REACH (2 / 2)





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Late DUIN and Inquiry

STEP 2: Submit detailed DUIN information by email

- Once Part 1 of the DUIN notification process is done, you need to **populate the HSE DUIN Excel template** available at HSE at:
  - https://www.hse.gov.uk/reach/duin-additional-information.xlsx
  - View the following page for information on the content of the Excel file to be populated

- **Notes on populating the HSE DUIN Excel template:**
  - Include only substances
  - Per substances, at least **one** of the following identifiers **must** be declared in the Excel:
    1. Substance name
    2. CAS number
    3. EC number.
  - Other information must only be included **if it is available to you**.

Late DUIN and Inquiry | The HSE DUIN Excel template

IMPORTANT:(1) Ensure you use your Legal Entity (LE) name from the 'Comply with UK REACH' service as the name of this Excel file before you submit it to HSE. When naming the file do not alter your LE name as it appears on the 'Comply with REACH' service. (2) If you have relevant spectral data (UV-Vis, FT-IR, NMR, MS) and HPLC/GC, these should be attached together with this spreadsheet. Also attach a description of the analytical methods or the appropriate references for the identification of the substance and, where appropriate, for the identification of impurities and additives (if these are available). (3) Use a separate line for each substance you are making a notification for; (4) the first line is an example only and should not be removed. (4) Please input at least one of the following in each row: Substance Name, EC number or CAS number.

Mandatory Information		Information to be provided to the extent it is available											
DUIN number	Your Legal Entity Name	Substance Name	ECHA Registration Number	IUPAC name (If different from the substance name)	Other names (usual name, trade name, abbreviation)	EC number	CAS number	CAS name	Other identity codes	Classification & Labelling	Is this substance subject to authorisation?	Is this substance subject to restriction?	Additional information relevant to appropriate risk management
Example number	Example company	propan-2-ol	01-2119457558-25-0000	propan-2-ol	iso-propanol	200-661-7	67-63-0	propan-2-ol	n/a	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	No-not on Annex XIV	No-not restricted	none
Enter the DUIN number allocated by the Comply with UK REACH service to your Legal Entity when you notified us of your status as a company importing from the EU/EEA or covered by an EU/EEA based Only Representative.	Enter your company name		The Registration number can be found on your Safety Data Sheet (SDS) where you have one, otherwise your supplier might have provided it separately. You may not have the final four digits.										

DUIN number given here

											Other Information
Molecular formula	Structural formula (including SMILES or InChi notation, if available)	Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	Molecular weight or molecular weight range	Degree of purity (%)	Nature of impurities, including isomers and by-products	Percentage of (significant) main impurities	Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)	Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)	High-pressure liquid chromatogram, gas chromatogram	Description of the analytical methods for the identification of the substance, impurities and additives.	Tonnage band
C3H8O	CC(C)O see Attachment 1	not relevant	61,09	97	propan-1-ol, ethanol, methanol	1, 1.5, 0.5	none	Attachment 2	Attachment 3	Attachment 4	1-10 tonnes/year

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Late DUIN
Mandatory Information and Information Available

Mandatory Information:

1. DUIN number (*one number per submitting legal entity*)
2. Legal Entity Name
3. And at least one of the following:
   - Substance name, ***or***;
   - CAS number, ***or***;
   - EC number

Information to be provided to the extent it is available to you, the DUIN submitter:

1. ECHA Registration Number
2. IUPAC name (if different from the substance name)
3. Other names (usual name, trade name, abbreviation)
4. CAS name
5. Other identity codes
6. Classification & Labelling
7. Is this substance subject to authorisation?
8. Is this substance subject to restriction?
9. Additional information relevant to appropriate risk management
10. Molecular formula
11. Structural formula (including SMILES or InChi notation, if available)
12. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
13. Molecular weight or molecular weight range
14. Degree of purity (%)
15. Nature of impurities, including isomers and by-products
16. Percentage of (significant) main impurities
17. Nature and order of magnitude (… ppm, … %) of any additives (e.g., stabilising agents or inhibitors)
18. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
19. High-pressure liquid chromatogram, gas chromatogram
20. Description of the analytical methods for the identification of the substance, impurities, and additives
21. Tonnage band

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UK REACH Inquiry: Why is it Important and How to Prepare
Inquiry First, then Registration

- **Before a Registration can be submitted, an inquiry must be submitted and accepted by the HSE → This will place you in the correct Substance Group**



Without an Inquiry you will <u>NOT</u> be able to UK REACH register

Unless you grandfathered your existing registration

UK REACH Inquiry: Why is it Important and How to Prepare

Inquiry First, then Registration

- Submitting an inquiry (*UK REACH Article 26*) is mandatory and the **first step of any new registration.**
  - An Inquiry must be concluded **before** the registration work can proceed
- The purpose of the inquiry is to **verify the substance identity** as a precursor for the Registration process of "new" substances (non-Grandfathered substances)
  - The inquiry dossier must include **enough information to allow the correct identification** of the substance
  - This allows the HSE to determine whether **the same substance is to be registered by someone else**
- Only once **HSE has accepted the inquiry**, the submitting company and substance will be placed in a ***Substance Group*** and the registration process can continue

UK REACH Inquiry: Why is it Important and How to Prepare

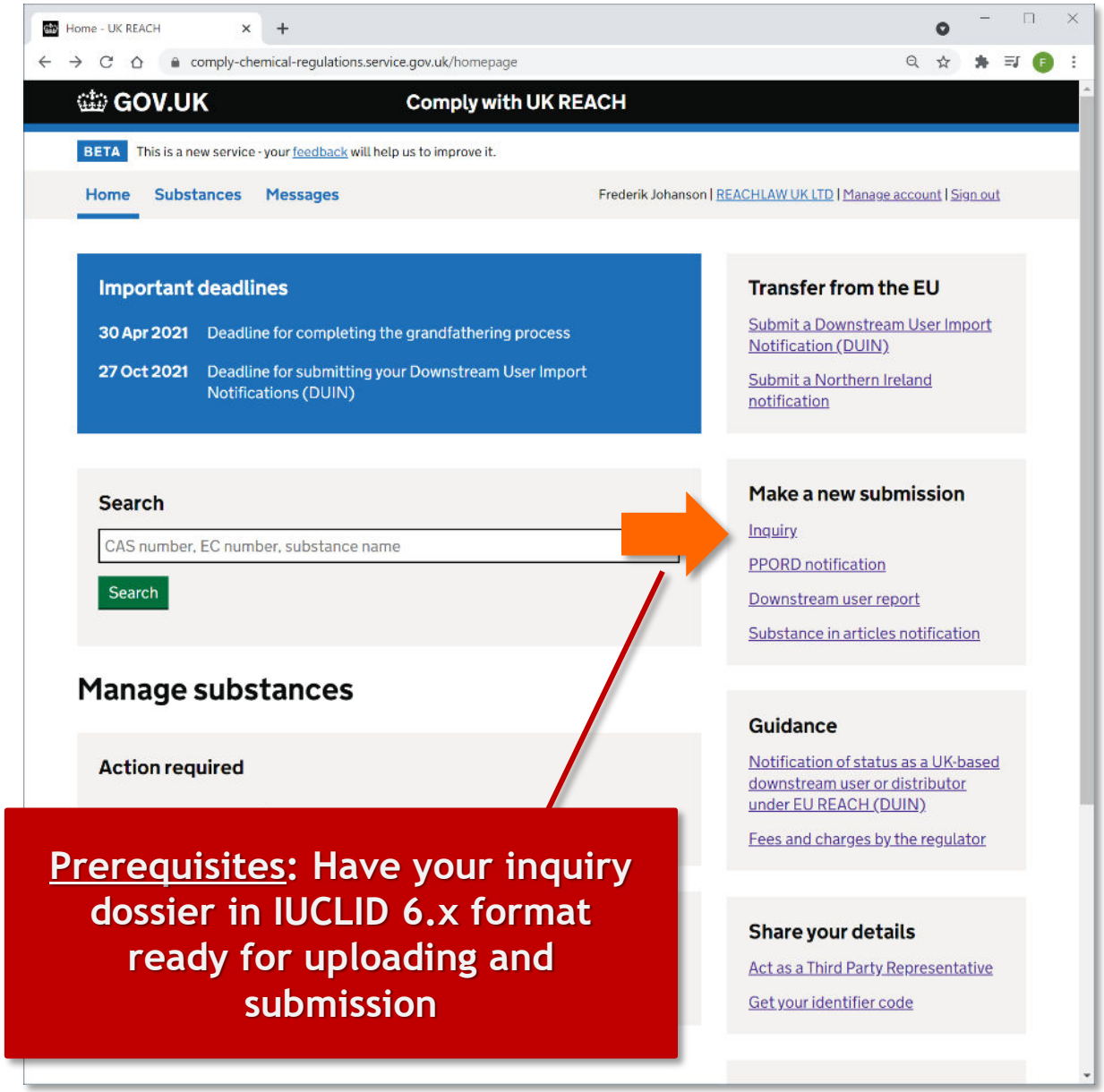
Preparing the Inquiry Dossier in IUCLID

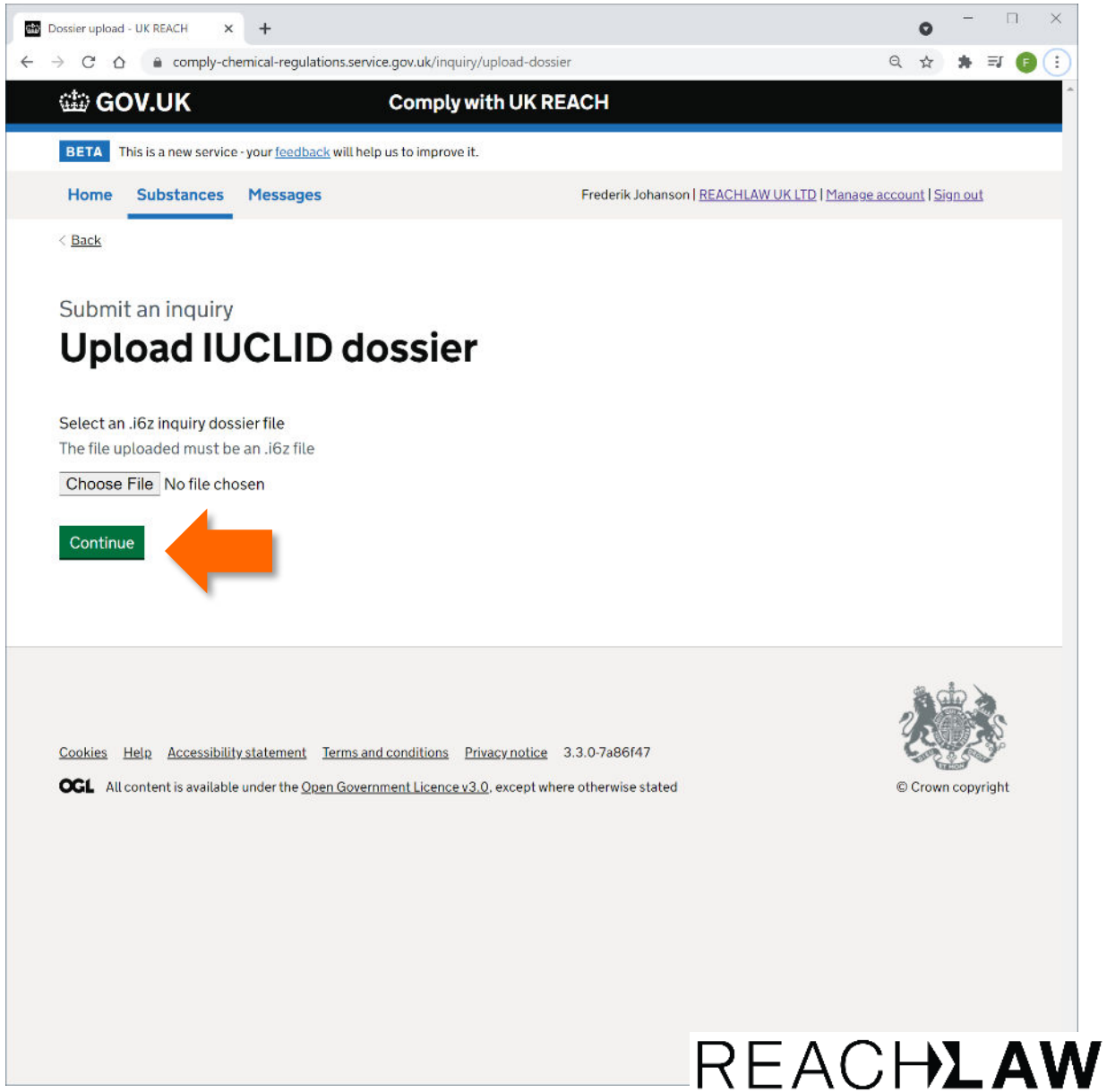


- The inquiry dossier is prepared in the **IUCLID software** that is freely available
  - IUCLID (*International Uniform Chemical Information Database*) is a key software application for both regulatory bodies and the chemical industry
- For Inquiry, the following sections of the dossier need to be prepared:
  - **Section 1.1** - Identification
  - **Section 1.2** - Composition
  - **Section 1.4** - Analytical information
  - + Appropriate dossier header when creating the dossier
- Once the required information has been populated in the dataset, the **Inquiry dossier is created and exported** for submission to the HSE via ***Comply with UK REACH*** system

UK REACH Inquiry: Why is it Important and How to Prepare

Submitting Your Inquiry in Comply with UK REACH (1 / 5)





Prerequisites: Have your inquiry dossier in IUCLID 6.x format ready for uploading and submission

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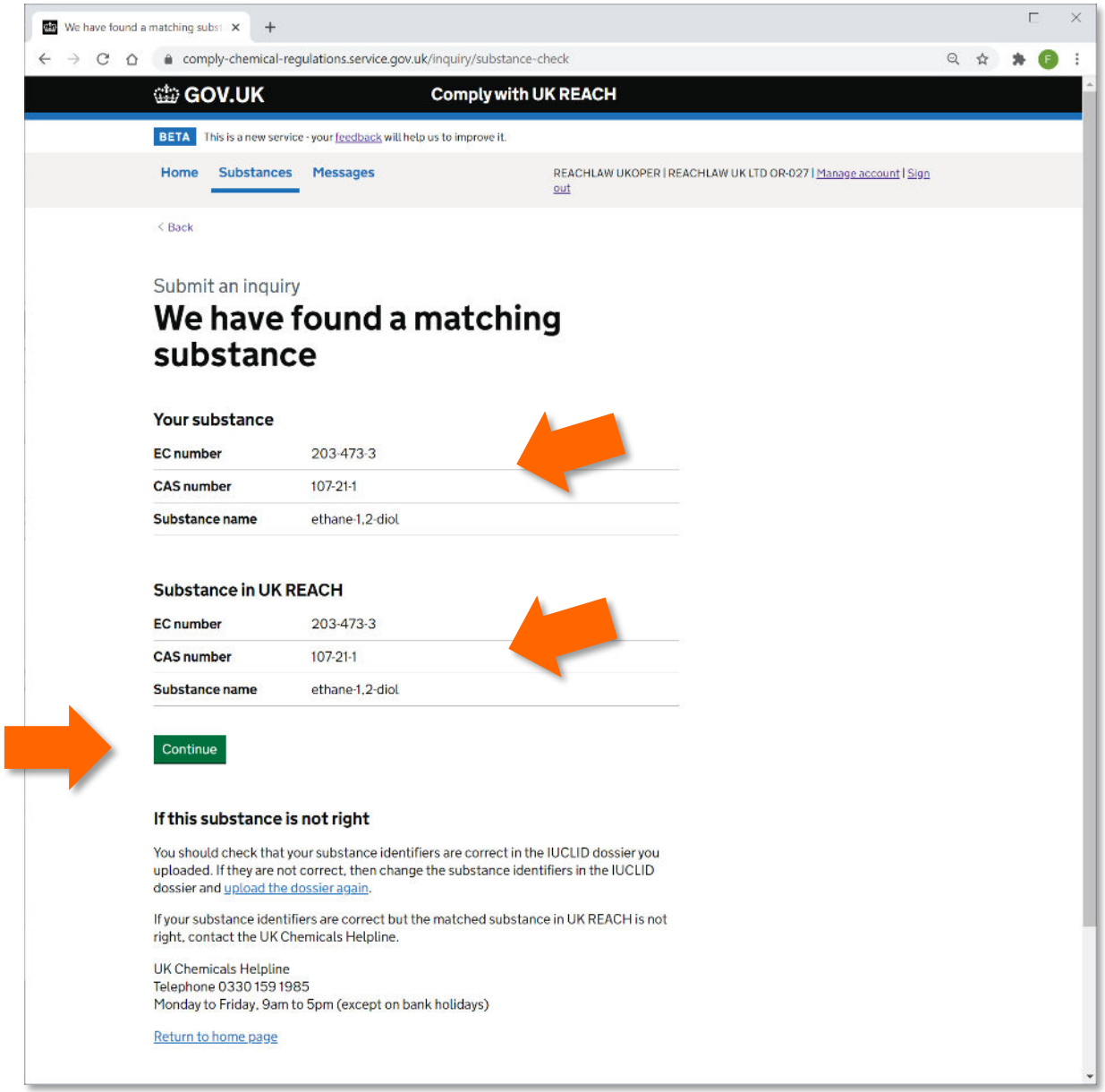
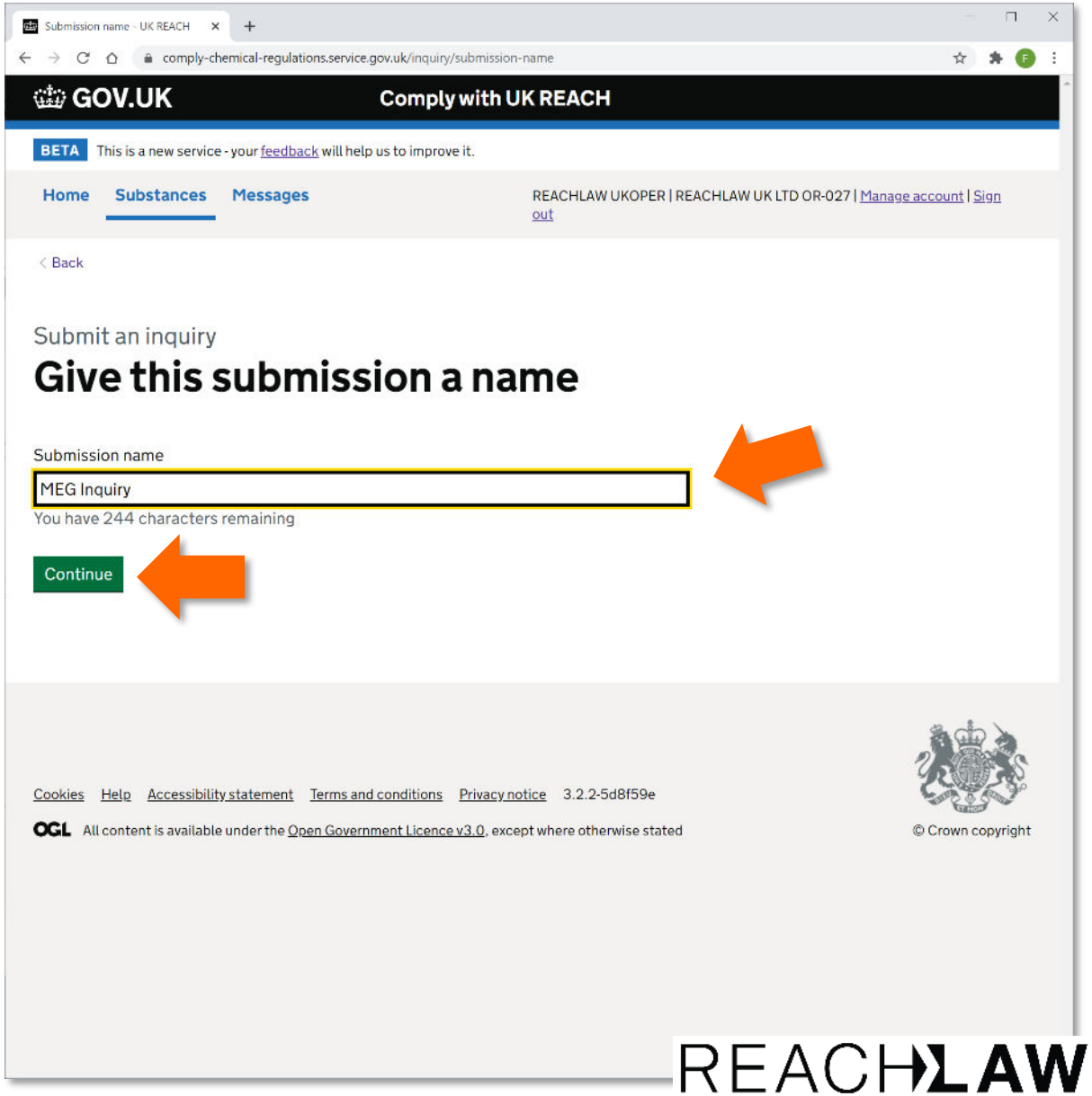
UK REACH Inquiry: Why is it Important and How to Prepare

Submitting Your Inquiry in Comply with UK REACH (2 / 5)





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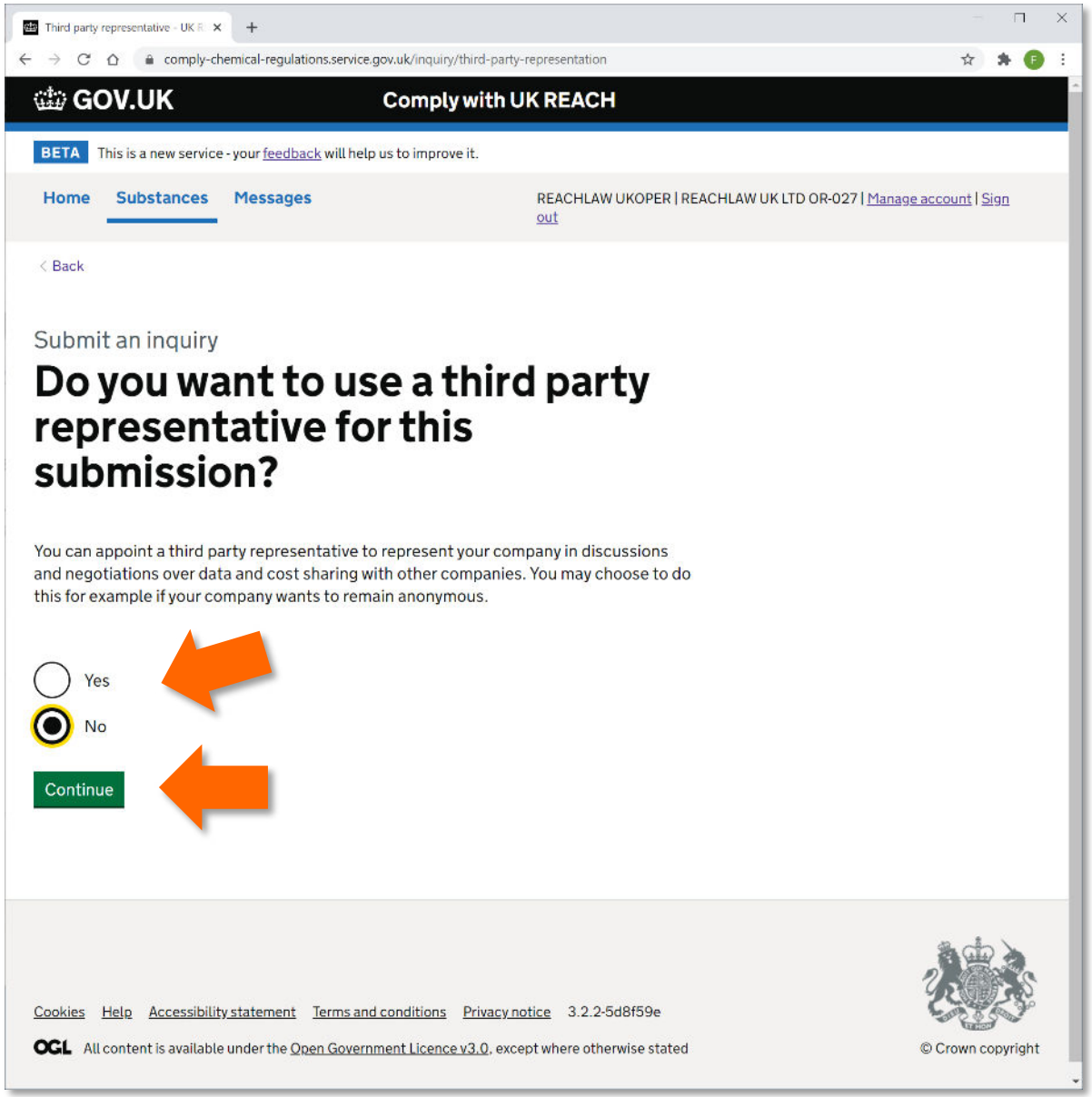
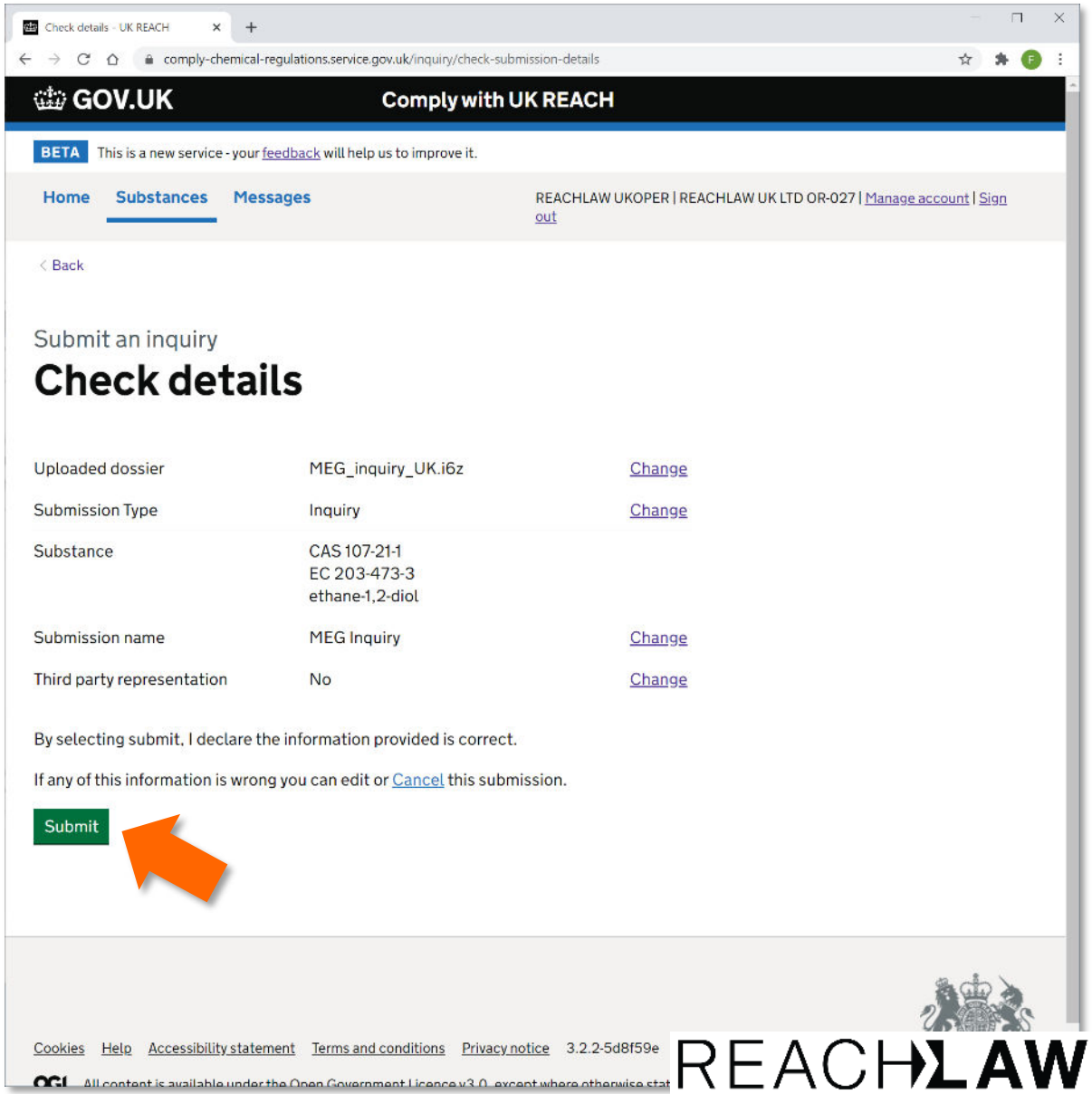
UK REACH Inquiry: Why is it Important and How to Prepare

Submitting Your Inquiry in Comply with UK REACH (3 / 5)





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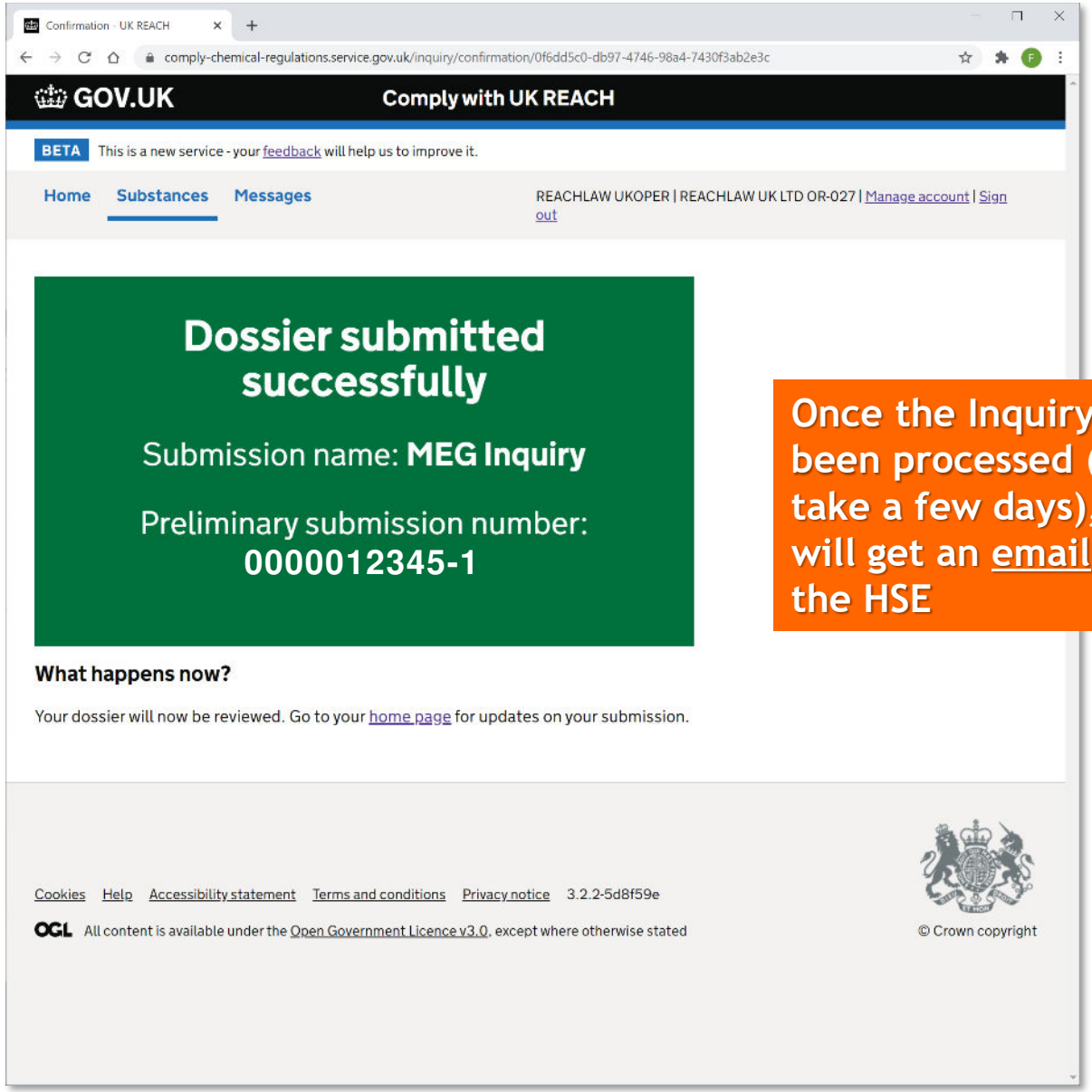
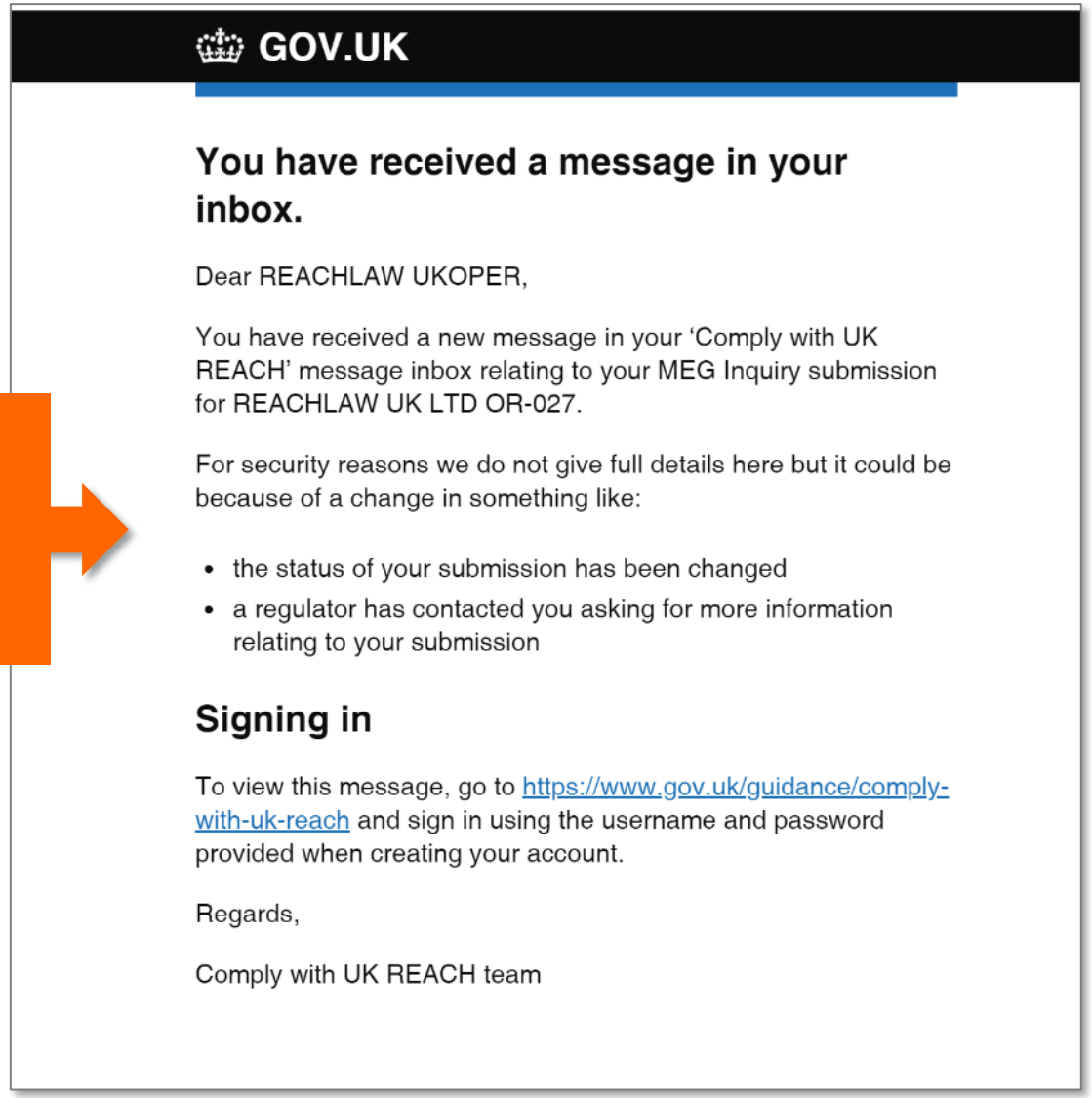
UK REACH Inquiry: Why is it Important and How to Prepare

Submitting Your Inquiry in Comply with UK REACH (4 / 5)



Once the Inquiry has been processed (may take a few days), you will get an email from the HSE



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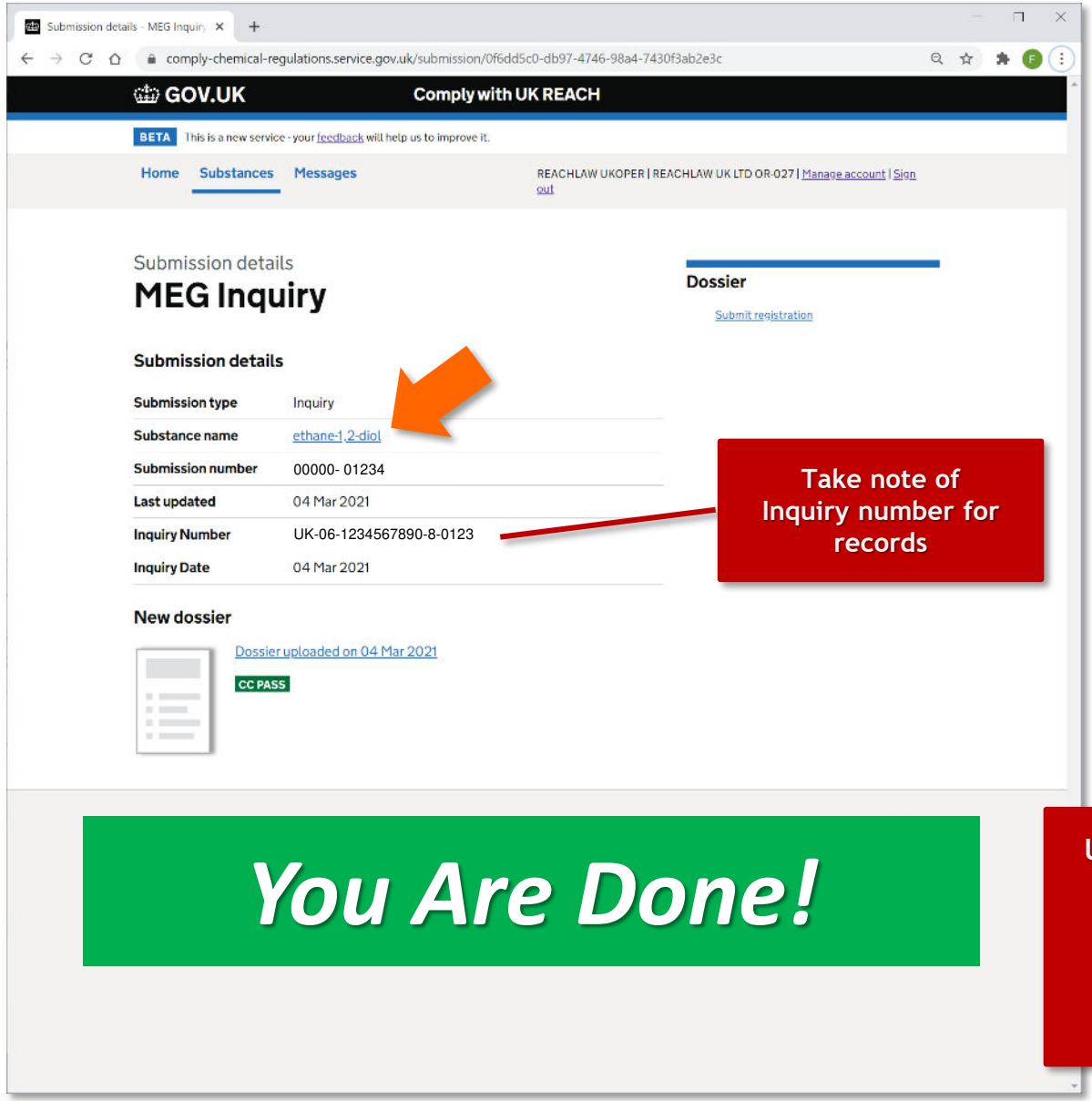
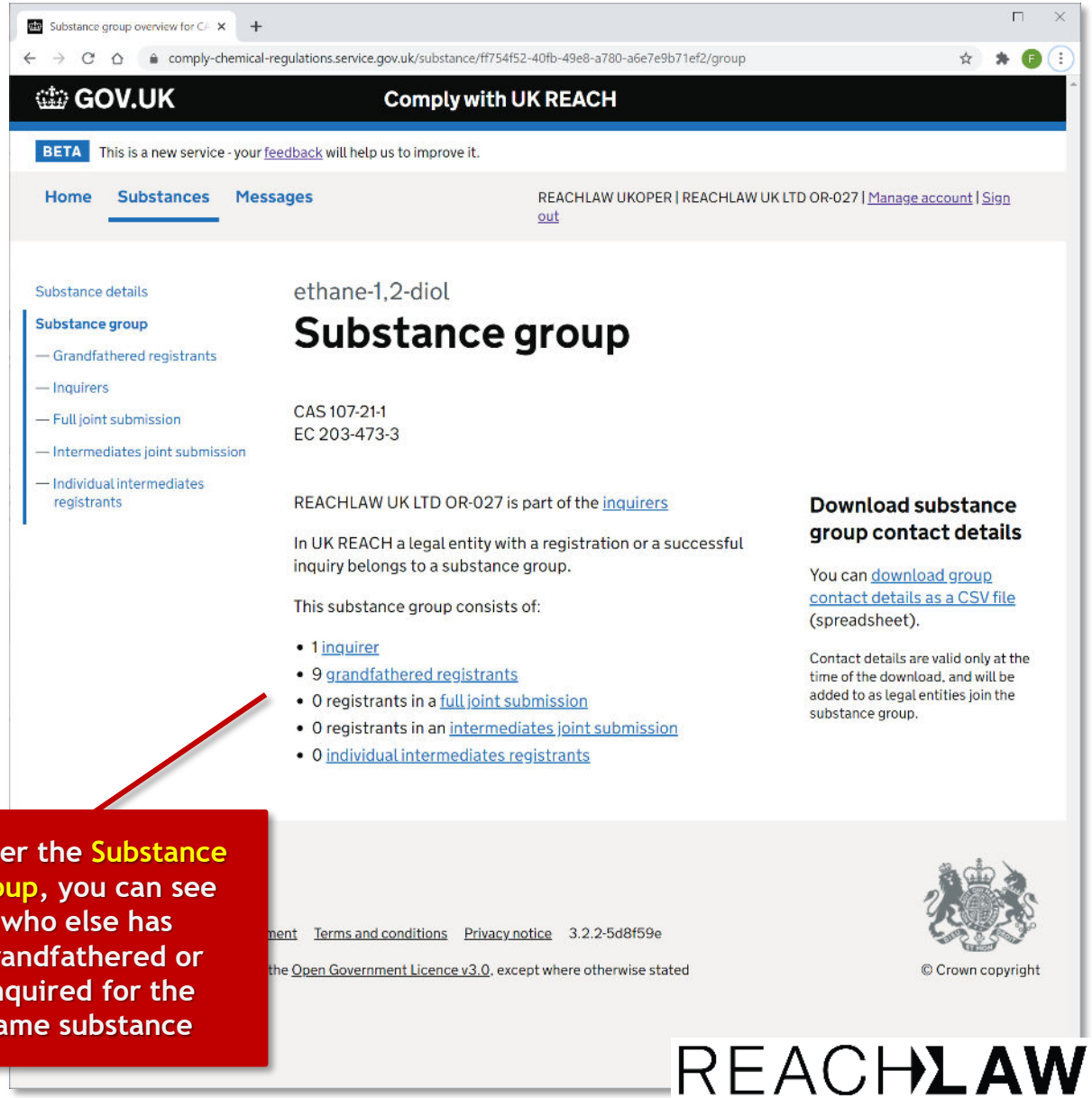
UK REACH Inquiry: Why is it Important and How to Prepare

Submitting Your Inquiry in Comply with UK REACH (5 / 5)





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Only once your Inquiry has been accepted and you are a member of the Substance Group, the Registration dialogue will be available in Comply with UK REACH

UK REACH Inquiry: Why is it Important and How to Prepare

From Inquiry to Registration

A successful inquiry of a substance will place the substance in a Substance Group including all other inquirers and companies that Grandfathered the same substance.

…no deadline but must be completed before starting registration work

In the Substance Group, members need to select / elect the Lead Registrant and choose how to cooperate for development of the Joint Registration

No deadline / the sooner the better

Prepare the Joint registration dossier (*Lead Dossier*) and share data for this purpose.

Lead Registrant to submit Joint Registration after which Co-registrants can submit their registrations.

Deadline 27.10.2026 / 27.10.2028 / 27.10.2030

Substance Group → **Joint Submission**

The substance group is for the purpose facilitating the Joint Registration process

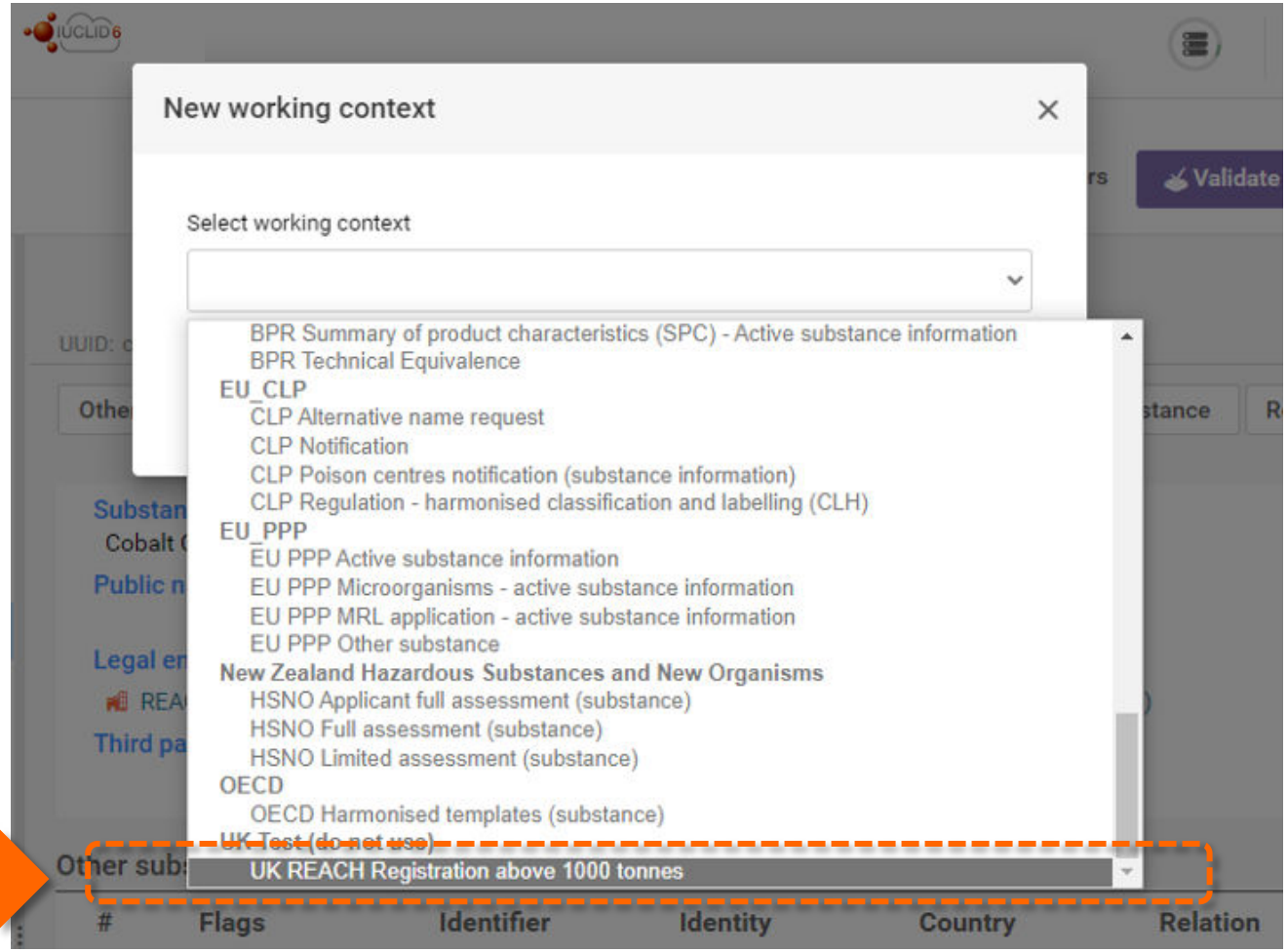
REACHLAW

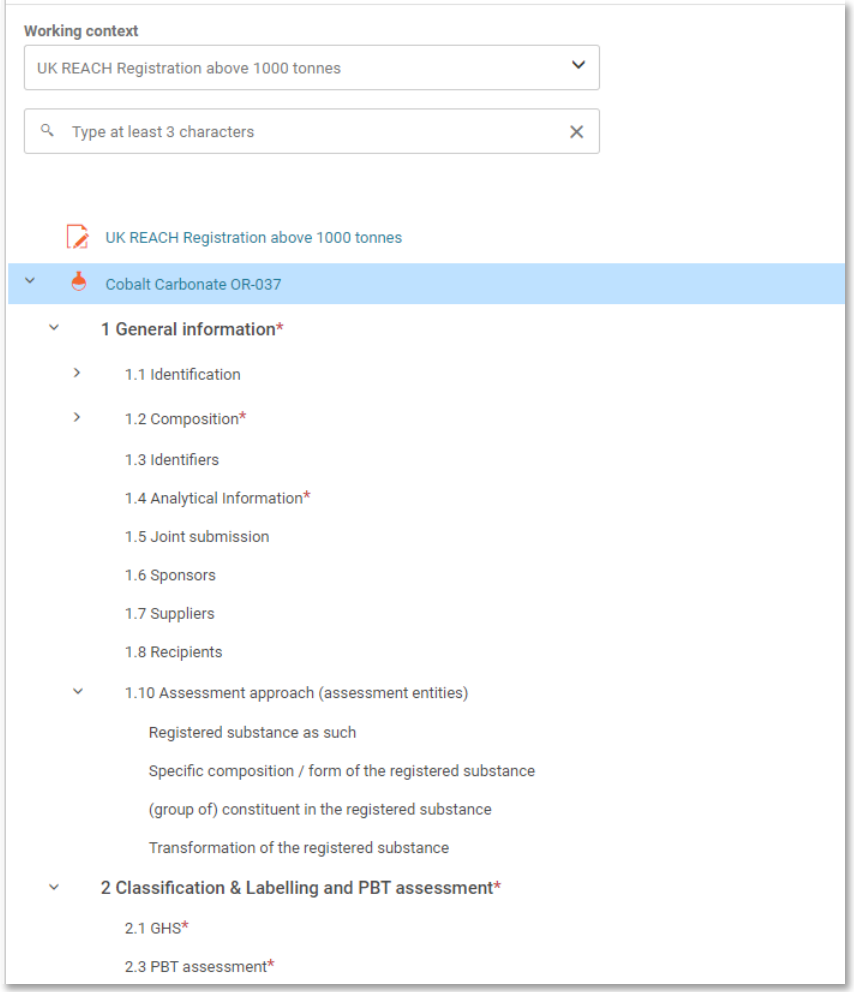
Defra Recommends inquiring early (according to UK REACH Art.26) in order to be able to follow what is going on in the substance groups and participate in the discussion on data sharing and more regardless of the registration model

1. UK REACH: The journey so far
2. The operating platform: The “Comply with UK REACH” Service
3. Late DUIN
4. UK REACH Inquiry
5. IUCLID Note
6. CONCLUSIONS
7. QUESTIONS & ANSWERS

IUCLID Note

IUCLID Starting to Contain UK REACH Dossier Templates





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UK REACH Registration Update

Conclusions

- UK REACH entered into force 1st January 2021 and transitional registration deadlines apply for substances subject to **Grandfathering with Late DUIN still possible**
- 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, which came into force on 19th July 2023
- Defra Recommends to inquire early (according to UK REACH Art.26) in order to be able to follow the development and conversation with the applicable substance groups

BE PROACTIVE WITH YOUR REGISTRATION

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Questions & Answers

Thank You for Your Attention!

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REACHLAW

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