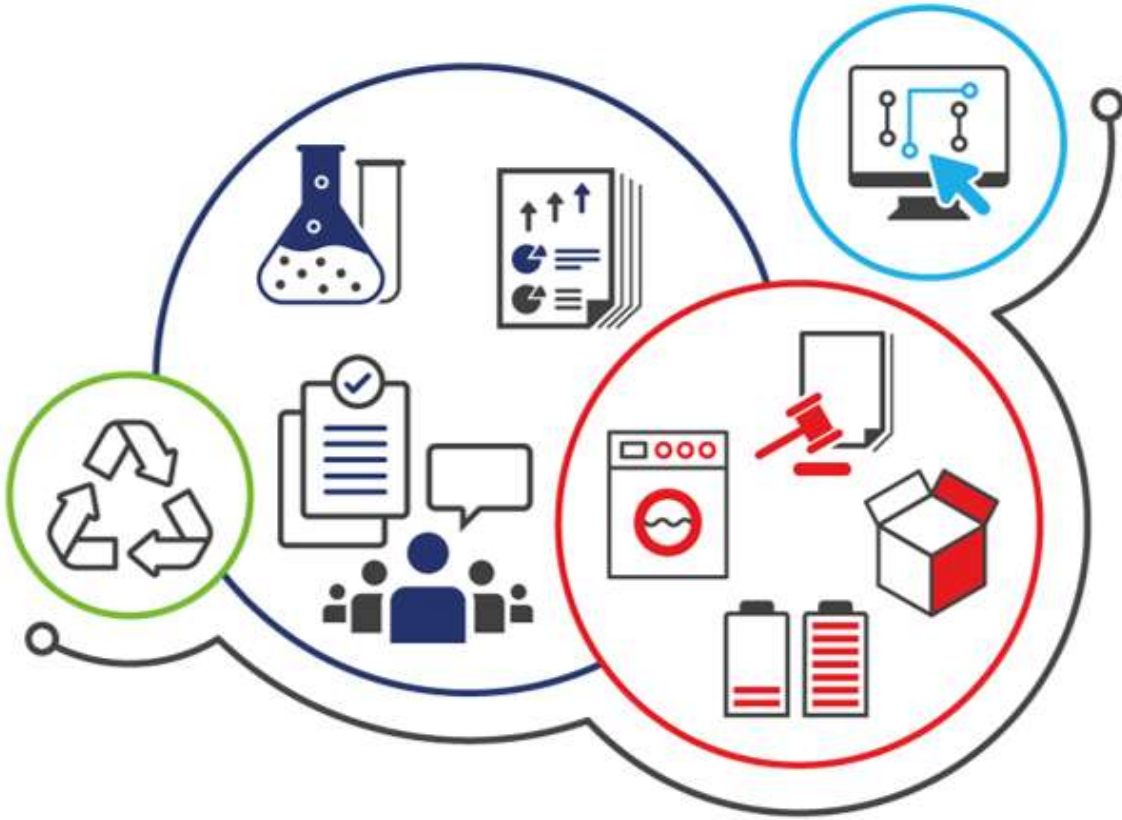


Overcoming Challenges with Substance Identity for REACH Registration

Ben Bruford

Consultant Chemistry at H2 Compliance

21st May, CHEMUK Stage 1, 13.15 – 13.30

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Wheel of Services



Checklist

- ❑ Understand what “Substance Identity” means in a REACH regulatory context
- ❑ Be able to distinguish between the general requirement by substance type *(mono-constituent, multi-constituent, UVCB, inorganic, organic)*
- ❑ Gain an appreciation of the specific challenges associated with substance identity for complex substances (UVCBs, recycled materials, inorganics)
- ❑ Learn practical strategies to address and justify substance identity for complex substances



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You’re at the airport…

What’s the one thing you must have to travel abroad?

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For REACH purposes chemicals need their own proof of identity too:

This is the chemical's Substance Identity.

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What is Substance Identity?

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- Structure
- Purity
- Composition
- Numerical Identifiers

Essential for:

- ✓ Determining if substances are the “same” to allow companies to join the correct REACH registration
- ✓ Data sharing
- ✓ Hazard/risk assessment

Carry out testing and produce a report

There are two main options:

- In house testing
- External testing by a laboratory with REACH experience

Using an external laboratory is often preferable to ensure a REACH compliant report is obtained.

Carry out testing and produce a report

What are the main components required in an analytical report?

Methodology

Results

Interpretation of the results

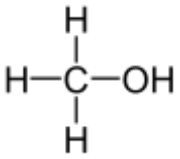
Conclusions

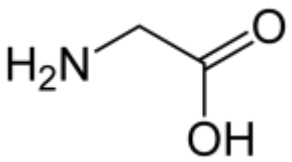
Determine appropriate Analytical Information

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Organic

Contain carbon, hydrogen, nitrogen and oxygen atoms.

e.g., methanol: 

glycine: 

Qualitative - structure

- FT-IR
- UV-Vis
- H NMR, C NMR
- MS

Minimum of 3 techniques required.

Quantitative - purity

- HPLC
- GC

Minimum of 1 technique required.

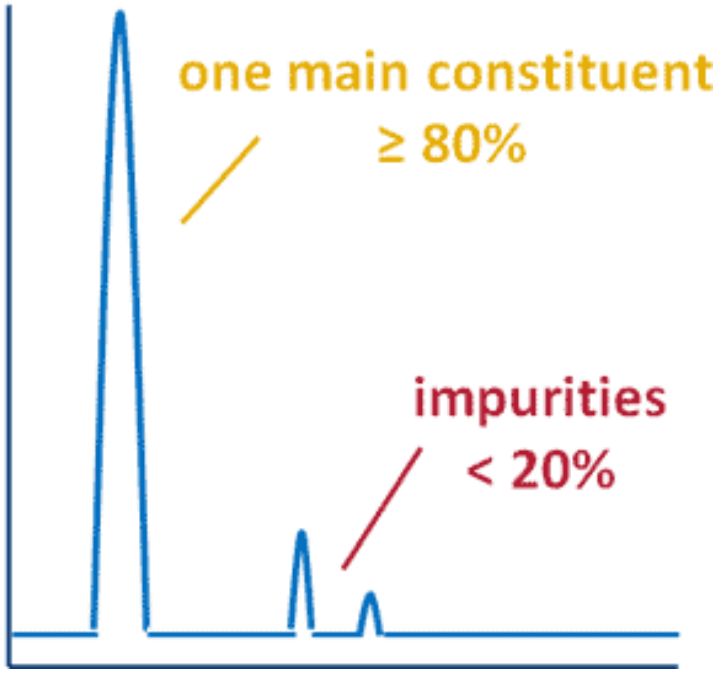
Inorganic

Determine appropriate Analytical Information

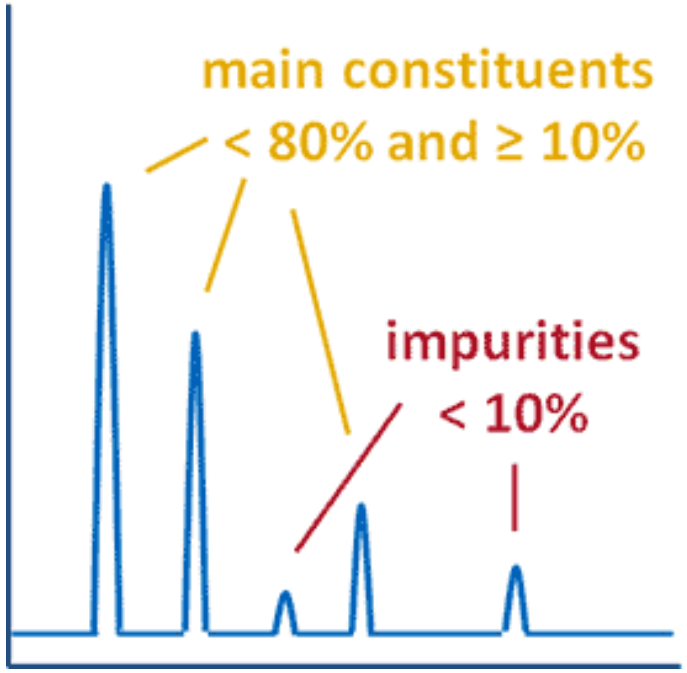
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Is your substance a:

Mono-Constituent

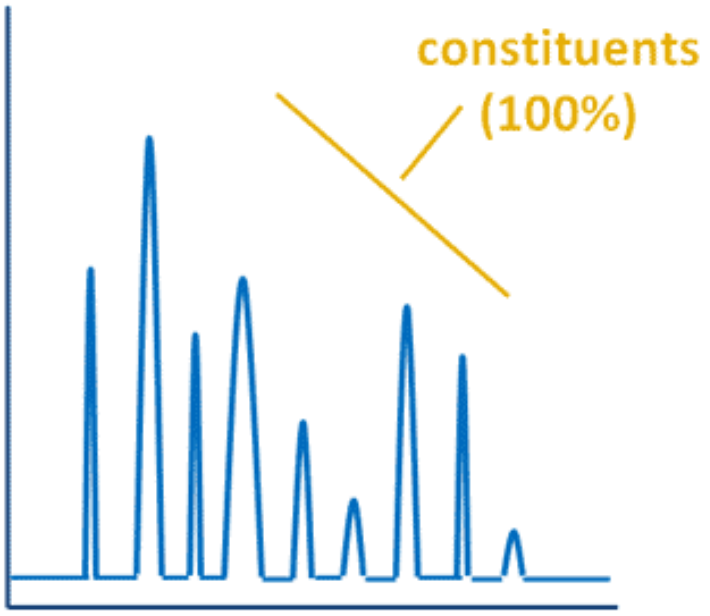


Multi-Constituent



UVCB

UVCB stands for **U**nknown or **V**ariable **C**omposition, complex reaction products or of **B**iological materials.

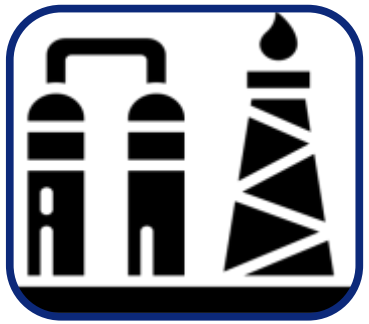


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Challenging Substances - UVCBs

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UVCB substances — **U**nknown or **V**ariable composition, **C**omplex reaction products, or **B**iological products



Often from natural sources or petroleum refining



Highly variable and/or unknown compositions.



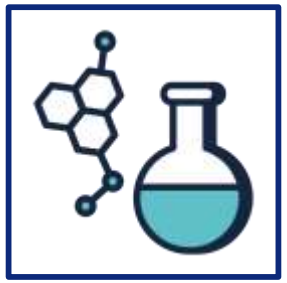
They cannot be fully defined by molecular composition

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Challenging Substances - UVCBs

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ECHACHEM
ECHA CHEMICALS DATABASE





For **existing** substances – check ECHA CHEM

Contact the Lead registrant - obtain the **Substance Identity Profile (SIP)**

Manufacturing process is important

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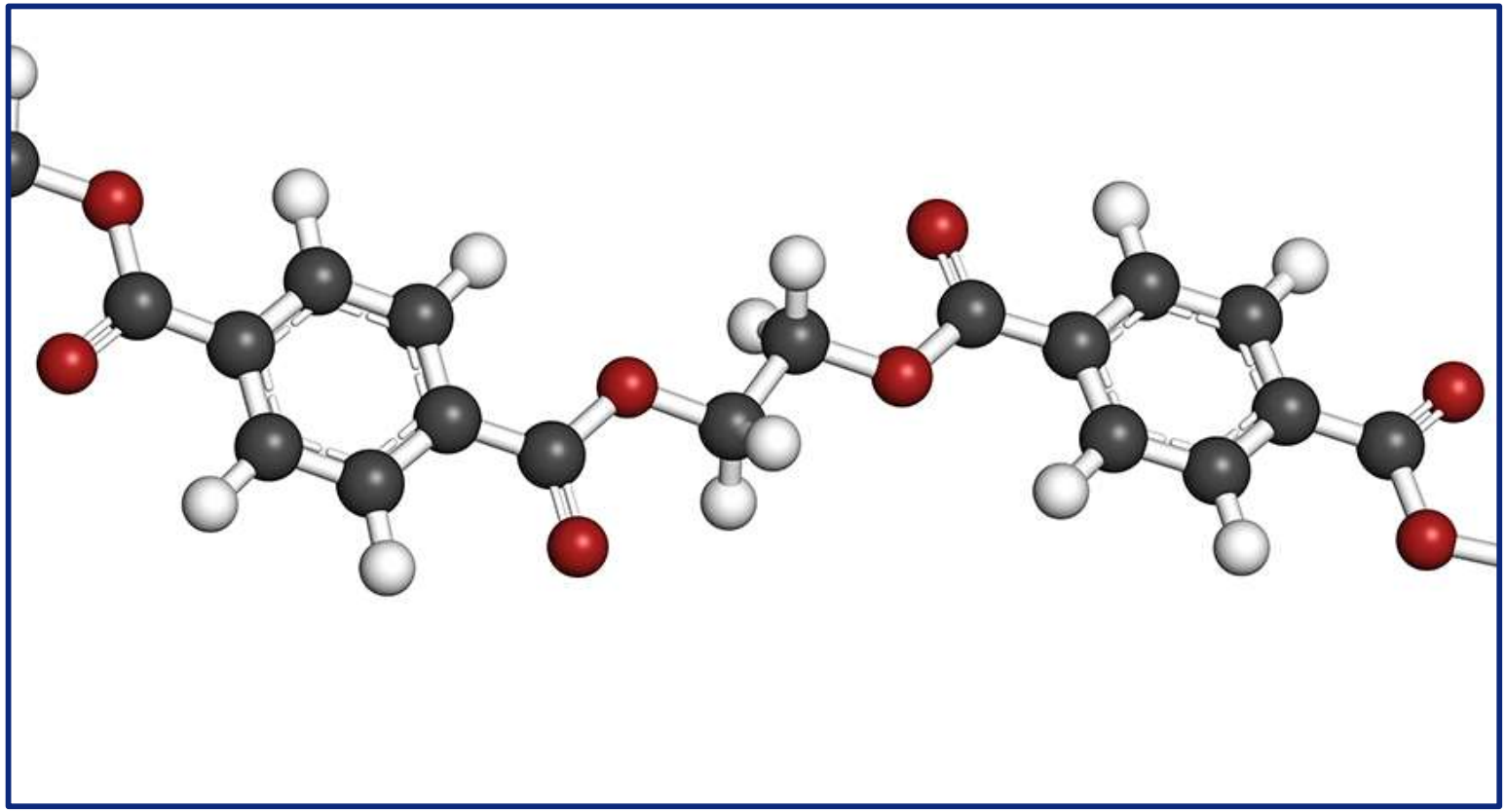
Challenging Substances - UVCBs

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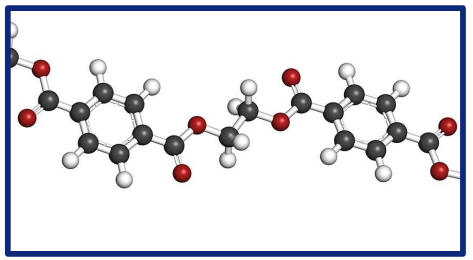
Things to consider

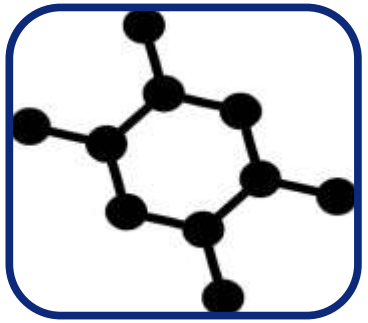
- Can the constituents be separated?
- Is the composition fully known, partially known, or inherently variable?
- Is significant variability expected or unavoidable?
- What does the manufacturing process actually do at a chemical level?
- Comparison to the SIP

Challenging Substances - Polymers



Challenging Substances - Polymers





Polymers are do not require registration under REACH

The monomers that make up the polymers do

Challenging Substances - Polymers

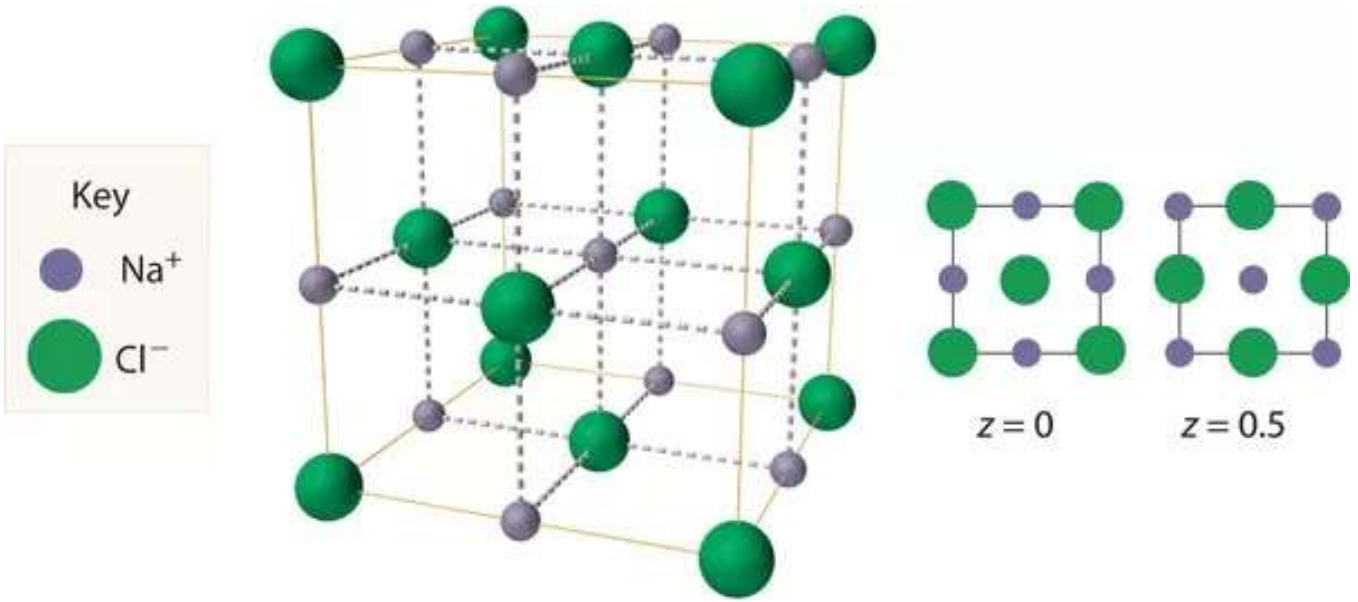
Importers of polymers can often not obtain the monomers themselves

Under UK REACH, data on the polymer can be accepted

Challenging Substances - Inorganics

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Question to consider: What phases or crystal structures exist?



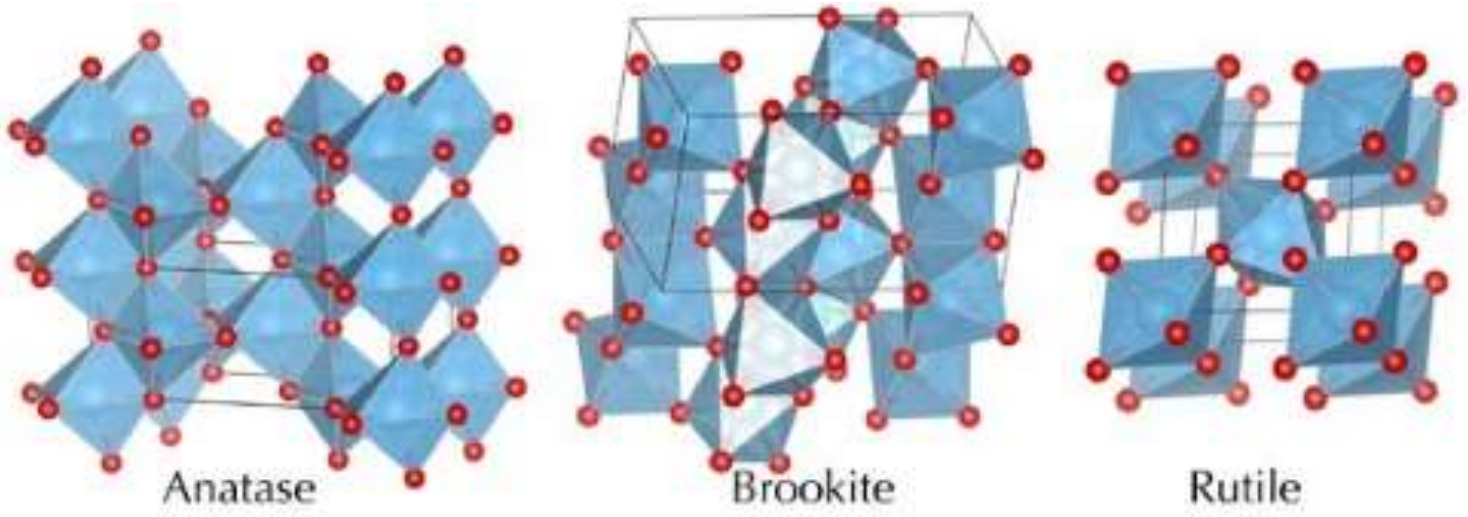
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Challenging Substances - Inorganics

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Question to consider: What phases or crystal structures exist?

Example: Titanium dioxide (TiO_2)



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Challenging Substances - Inorganics

Are the phases present in consistent, predictable proportions?

For example, an inorganic substance with multiple crystalline phases formed during synthesis

Phase	%
Fe_2O_3	40
TiO_2	35
ZnO	25

Challenging Substances - Inorganics

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Are the inorganic phases chemically distinct and identifiable?

- **If yes, the substance may be considered as a multi constituent.**
- **If no, it may be considered as a UVCB**

Can the phases be physically or chemically separated without breaking chemical bonds?



Challenging Substances

Recycled materials

Challenging Substances - Recycled materials

Waste is exempt from REACH registration

REACH obligations only begin once the material ceases to be waste



Challenging Substances - Recycled materials

For UVCB recycled materials, cannot join the registration for the virgin material

The origin is different (i.e., from recycled source).

A separate registration is required.

Challenging Substances - Recycled materials

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Feedstock

Impurities

Process conditions

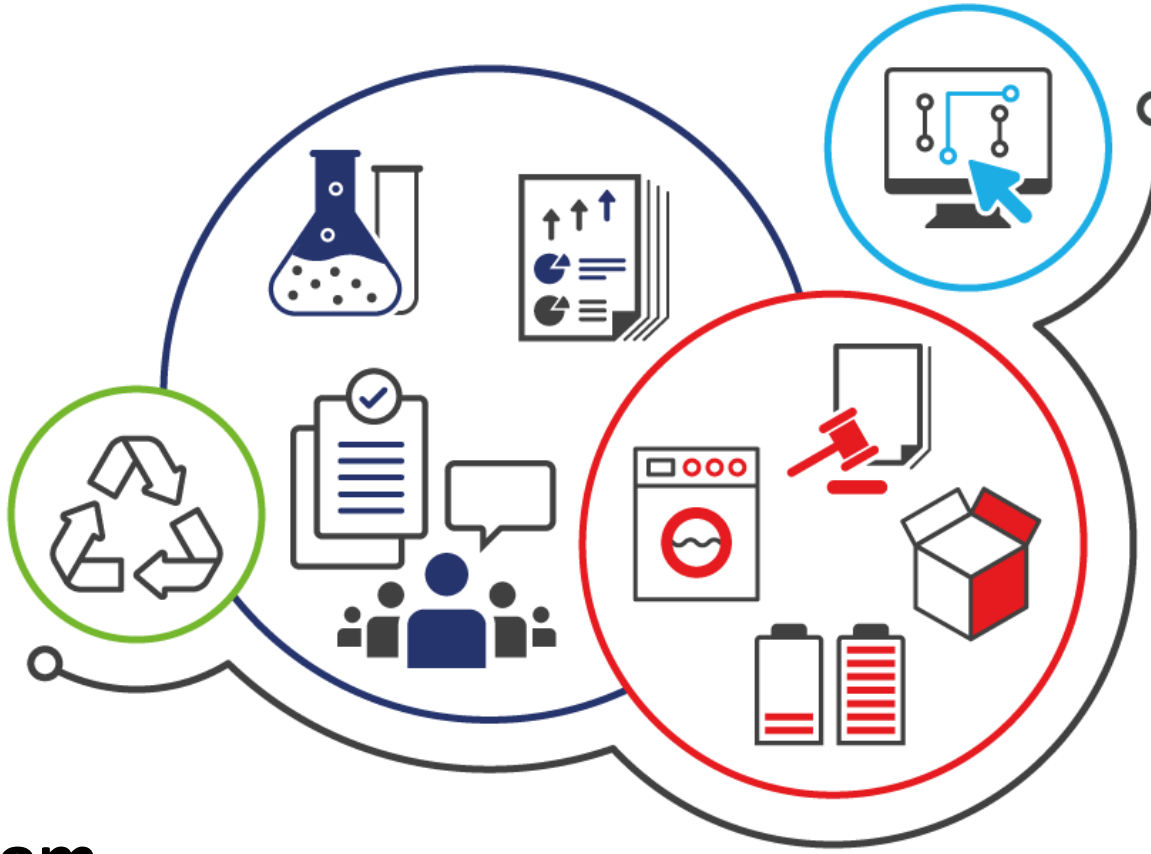
Summary

- Understand what your substance actually is
    - Inorganic/organic?
    - Mono, multi, UVCB?
- Determine the appropriate Analytical Information required
- Carry out the tests and produce a report
- For challenging substances (Recycled material / inorganics), ensure additional details are provided

Checklist

- ✓ Understand what “Substance Identity” means in a REACH regulatory context
- ✓ Be able to distinguish between the general requirement by substance type *(mono-constituent, multi-constituent, UVCB, inorganic, organic)*
- ✓ Understand the basic analytical information expected to support substance identity under REACH
- ✓ Gain an appreciation of the specific challenges associated with substance identity for complex substances (UVCBs, recycled materials, inorganics)
- ✓ Learn practical strategies to address and justify substance identity for complex substances

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