

# Substance ID and BPR

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# Your presenters



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# About us



Regulatory and science-based services for the chemical, biotechnology and related industries

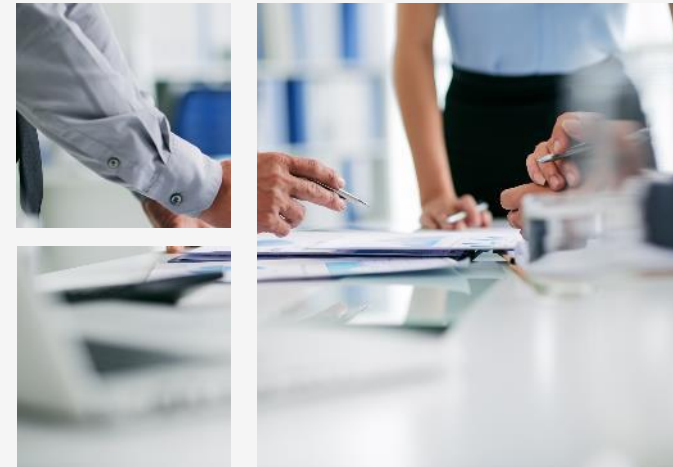
Experts in:

- Toxicology
- Chemistry
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To excel in the provision of scientific, regulatory and registration services to the chemical and related industries

14 offices:  
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Established in 1990  
100+ staff globally



Scientific and regulatory support





Core values:

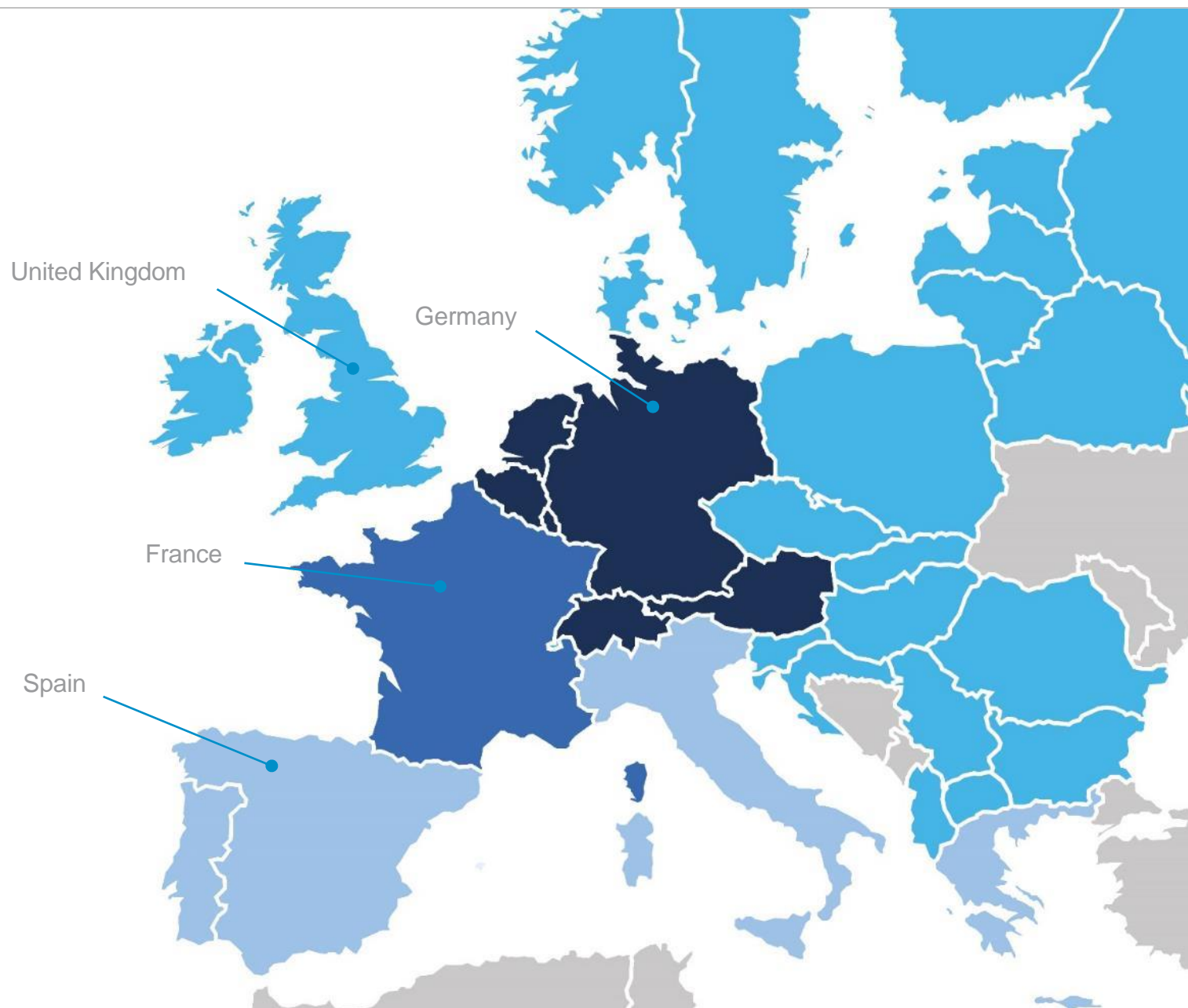
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- National approvals throughout the EU
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- |   |   |
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# Agenda

- Substance identification – the importance of getting it right
- Substance definition and ECHA guidance
- Learnings from REACH
- Consequences of incorrect substance identification
- Improving the substance identification process under REACH
- What does it mean for BPR
- Importance of consistency of approach between BPR, REACH and CLP
- Two compositions the same or not
- How to get your substance identity right!
- Key takeaways





## Substance identification – the importance of getting it right

- Defines the scope and basis for the BPR dossier
- Ensures that a single substance is covered
- Establishes the appropriateness of the hazard data
- Important for clear hazard and risk communication
- Establishes whether two (or more) compositions are the same (or not)
- Facilitates data sharing

# Substance definition

The Biocidal Products Regulation (BPR) – Article 3(2) – defers to the REACH definition

Article 3(1) of the REACH Regulation and Article 2(7) of the CLP Regulation state:

*“**substance**: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, **including any additive necessary to preserve the stability and impurity deriving from the process used**, but **excluding any solvent which may be separated without affecting the stability of the substance or changing its composition**”*



# ECHA guidance on substance identification

- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C)
  - Section 2.5.2 defers to REACH and CLP guidance
- Primary guidance is ECHA guidance for identification and naming of substances under REACH and CLP
- ECHA sector-specific support for substance identification is also available:
  - Not official guidance
  - Complementary to the official guidance
  - Consistent approach to identifying substances

## Essential oils

Oleochemicals	Essential oils	Petroleum products	Hydrocarbon solvents	Complex inorganic coloured pigments	Metals
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An essential oil is defined as a volatile part of a natural product, which can be obtained by distillation, steam distillation or expression in the case of citrus fruits. It contains mostly volatile hydrocarbons. Essential oils are derived from various sections of plants. The oil is "essential" in the sense that it carries a distinctive scent, or essence of the plant.

Further support can be found through the European Federation of Essential Oils (EFEO) and International Fragrance Association (IFRA).

### Sectoral guidance for essential oils

The European Federation of Essential Oils (EFEO) and the International Fragrance Association (IFRA) has published guidance for characterising essential oils. The limited number of language versions available on ECHA's website is due to the limited number of essential oil producing member states. Follow this guidance when you are identifying essential oils for REACH and CLP purposes.

### RELATED

- [Substance identity guidance on essential oils](#) (EFEO website)
- [Substance identity guidance on essential oils](#) (IFRA website)  
[bg](#) [de](#) [es](#) [fr](#) [hr](#) [it](#) [pt](#)
- [Environmental assessment guidance on essential oils](#) (EFEO website)
- [Environmental assessment guidance on essential oils](#) (IFRA website)  
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# Learning from REACH

- Importance of substance identification underestimated
  - Acknowledged by ECHA and Industry
- Over reliance on historic identifiers
  - Often inappropriate
- Substance identification assumed rather than assessed
  - Not always what it was thought to be
- UVCB substances present a significant challenge
  - Special attention needed
- ECHA and industry not always aligned in their thinking



# Consequences of incorrect substance identification

- Significant ECHA intervention required to:
  - Split and merge joint registrations
  - Adapt existing identifiers
- This often resulted in:
  - Consortia agreements having to be redefined
  - Letter of Access no longer appropriate
  - Data sharing agreements no longer legally sound
  - New testing required
  - Significant and unexpected cost
  - Supply chain consequences as a result of new identifiers



# Improving the substance identification process under REACH

- ECHA and industry more aligned as a result of increased collaboration
  - Sector specific guidance documents developed
  - Profile of substance identification raised
    - ❑ Workshops
    - ❑ Newsletter articles
    - ❑ Meetings
  - Early intervention as part of compliance check – informal call

# What does it mean for the BPR

- REACH, CLP and BPR share the same substance definition
- Consequently ECHA substance identification guidance is applicable to BPR
- Problems seen under REACH to a certain extent will surface under BPR
- However, REACH, CLP and BPR are different Regulations
  - They have different processes
  - The scale is different
  - The regulated industry is different
  - The regulatory administration is different
    - ❑ Different units in ECHA
    - ❑ Different level of Member State involvement





## Importance of consistency of approach between BPR, REACH and CLP

- Approved biocidal active substances are considered registered under REACH
- A biocidal substance can also be a general chemical
- CLP addresses substances whether regulated by REACH or BPR
- Principle of hazard assessment and data sharing are the same

# Two compositions the same or not


- REACH, CLP and BPR do not have a precise definition for substance sameness
- Balance between unnecessary animal testing and correct hazard assessment
- Two compositions that have been identified with the same name/identifier are often considered the same
  - Relies on the assumption that a common set of rules has been followed to establish this
- For well-defined substances this is often a straightforward task
- For UVCBs it is more complex
- In some cases UVCB substances that are effectively the same may have been identified differently



## Getting your substance identity right!

- Review the identity of your substance as soon as possible
- Ensure the rules in the guidance have been considered
- Discuss with parties who have the same substance
  - Same substance = same substance identity
  - Document/record discussions and agreements
- Engage with trade associations/industry bodies
- Engage ECHA/Member State Competent Authorities when appropriate
  - Inquiry
  - Chemical similarity check
  - Technical equivalence

# Key takeaways




Correct substance identification is a critical part of the regulatory submission



In building your submission, review your substance identity



Get support, particularly in the case of UVCB substances



Ensure you are up-to-date with relevant industry sector developments

Thank you for listening!

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