Steptoe

Brexit and Chemicals

Practical Steps for Compliance

Darren Abrahams

CLEPA Materials and Substances WG,
29 March 2019

Darren Abrahams

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"exceptional expertise on EU regulations on chemical…and a great ability to understand the complexity of businesses."
Chambers & Partners Europe, 2019

- **English barrister, *Avocat* at the Brussels Bar**, partner resident in Brussels.
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market**.
- He focuses on **defence of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.

Firm Overview

- International law firm, particular strengths in regulatory issues and litigation
- Over 500 professionals in the US, Europe and China

Complex Litigation & Discovery Center

Chemical Regulation, Environment & Life Sciences Firm Overview

- Team includes approximately 30 people (in EU, US and China)
- Integrate legal, regulatory, policy, advocacy and scientific capabilities
- Focus on long term relationships and deep knowledge of regulated industries
- Work on a range of project types in clients' business, through lifecycle of support and problem solving: *idea to enforcement*.

Chemical Regulation, Environment & Life Sciences Firm Overview

- Practice group focuses on a range of substance-related regulatory programs
  - Biocides
  - Biotechnology
  - Chemicals
  - Consumer products
  - Cosmetics
  - Food & Food Contact Materials
  - Medical devices
  - Nanotechnology
  - Plant Protection Products

EU Team

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EU Team Strengths – Key Stats

+/- 50 consortia

+/- 50 current REACH files

+/- 50 current Biocides and PPPs files

9 pending actions before the European Courts

6 pending actions before the BoA of ECHA

12 appeals won before the BoA of ECHA

3 appeals before the BoA of ECHA won within 30 days of filing

1 successful complaint before the European Ombudsman

Over 100 food and food contact compliance opinions

Brexit & Chemicals: Today's Topics

1. Overview on Brexit status
2. REACH
3. BPR
4. CLP
5. Data sharing for chemicals regimes
6. Take away messages

1. OVERVIEW ON BREXIT STATUS

Article 50 - Treaty on the European Union (TEU)

"1. Any Member State may decide to withdraw from the Union ***in accordance with its own constitutional requirements****.*

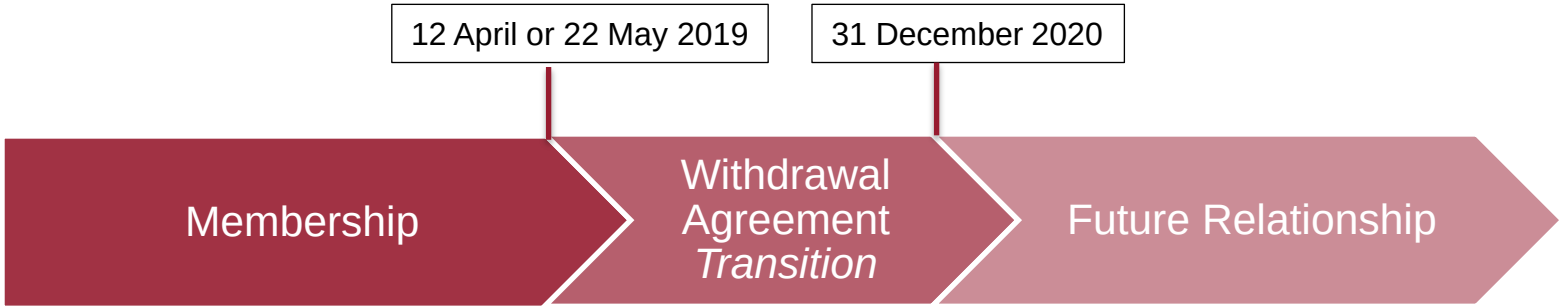
2. A Member State which decides to withdraw ***shall notify the European Council of its intention****. In the light of the guidelines provided by the European Council, the Union shall negotiate and conclude an agreement with that State, setting out the arrangements for its withdrawal, taking account of the framework for its future relationship with the Union. That agreement shall be negotiated in accordance with Article 218(3) of the Treaty on the Functioning of the European Union. It shall be concluded on behalf of the Union by the Council, acting by a* [strong] *qualified majority, after obtaining the consent of the European Parliament.*

3. ***The Treaties shall cease to apply to the State in question from the date of entry into force of the withdrawal agreement*** *or, failing that,* ***two years after the notification*** *referred to in paragraph 2, unless the European Council, in agreement with the Member State concerned, unanimously decides to extend this period. (…)"*

Timelines

- UK triggered Article 50 TEU on 29 March 2017
  → Established withdrawal date as 30 March 2019

- Brexit Day extended: UK becomes a third country



Hard Brexit

- No agreement reached by withdrawal date:

  "*All Union primary and secondary law **ceases to apply** to the United Kingdom" from withdrawal date*
  (EC Notice to Stakeholders)

- UK third country:
  - WTO tariffs will apply
  - No mutual recognition (certifications, authorizations, standards for circulation of goods)
  - Trade deals to be negotiated

- UK European Union (Withdrawal) Act 2018 applies:
  - Repeal of 1972 European Communities Act
  - Retention of existing EU law (plus mechanism to deal with "deficiencies" during a 2 year period
- UK must enact legislation covering areas formerly governed by EU law

2. REACH

A) EU REACH
UK Registered "Manufacturer/Formulator": OR Solution

A) EU REACH
UK Registered "Manufacturer/Formulator": OR Solution

- **Since UK entity is Manufacturer/Formulator (not just former EU importer) it <u>may appoint an OR:</u>**

Tasks:

- Appoint OR with suspensive clause agreement (tasks, responsibilities, annex of substances covered, and liabilities):
  - for Withdrawal Date 2300 BST
  - "notify change in REACH-IT immediately ahead of the UK withdrawal"
- Prepare 1 page confirmation of OR appointment for section 1.7 of dossier (not full agreement)
- Inform EU-27 importers
- If UK entity was LR, seek SIEF consent for new OR to take on role. Document consent of transfer of LR role

A) EU REACH
UK Registered "Manufacturer/Formulator": OR Solution

Concerns:

- Practicalities announced in ECHA's 8 February 2019 practical guidance for UK entities.
- Nothing in the guidance changes the core rules on the limited *circumstances in which registrations may be transferred*. In other words, Brexit does not create additional opportunities for transfers beyond what is currently permitted:
  - changes of ORs; and
  - corporate transfers of businesses from one entity to another - acquisition, relocation or intragroup transfer - with registration rights following the transaction).

Brexit does not create an unlimited right to transfer. In some circumstances, new registrations will need to be sought.

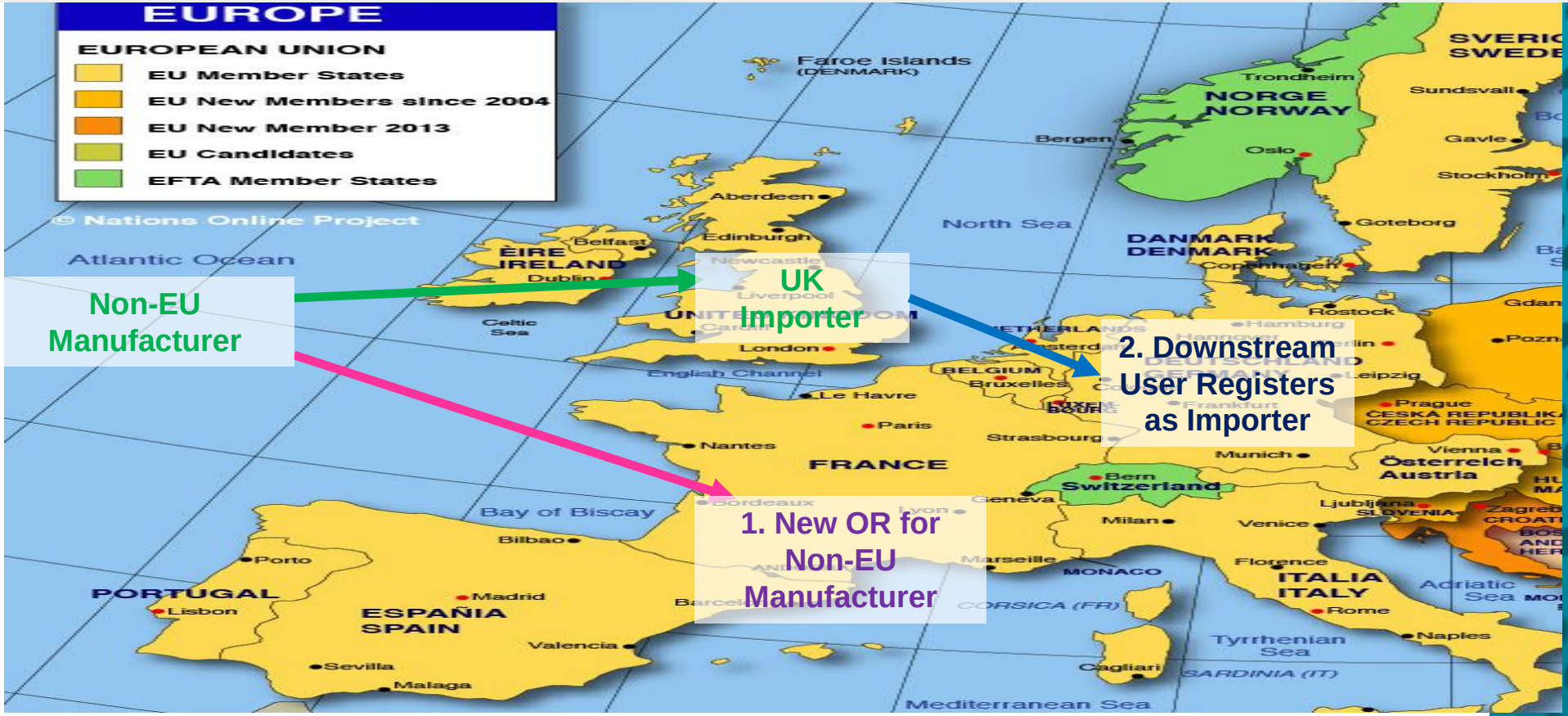
A) EU REACH
OR Solution: OR Appointment Essentials

- **Operational considerations**
  - OR responsibilities include: management systems (e.g. tonnage reports), SDS, supply chain communications, familiarity with REACH-IT, SIEF and consortia, data sharing etc.
  - The support to management of the registrations can easily be performed remotely UK but someone at OR needs to be responsible for responding to all REACH enquiries and coordinating with UK entity.
  - ECHA's Q&As on REACH state that "*paper companies*"/letterboxes are "*not sufficient*": "*Therefore, responsible staff and the relevant documentation must be available for inspection at the premises of every registrant*". This is not explicit in REACH, but is very likely to influence enforcement authorities in Member States.
  - Consider use of secure IT system accessible from that location.

A) EU REACH
OR Solution: LR Transfer Essentials

- **Transfer of LR role (by consent):**
  - Consent means:
    - Communication to SIEF with proposal
    - Documented agreement between current LR and future LR
    - Window for objections to be raised
    - Follow REACH-IT instructions and update joint registration to reflect transfer

B) EU REACH
UK Reg "Importer Only": 2 New Registration Solutions



B) EU REACH
UK Reg "Importer Only": 1. New OR Solution

- **Non-EU manufacturer may <u>appoint</u> EU-27 OR:**

Tasks:

- OR related tasks as in scenario A

Concerns:

- If non-EU manufacturer is not a related corp. entity → Centralization of commercial and regulatory control.
- Art. 26 inquiry + Art. 27 data sharing - but 4 month delay.
- EU importers must be notified of OR appointment:
  - Disclosure of customer lists?
  - Create black box mechanism?

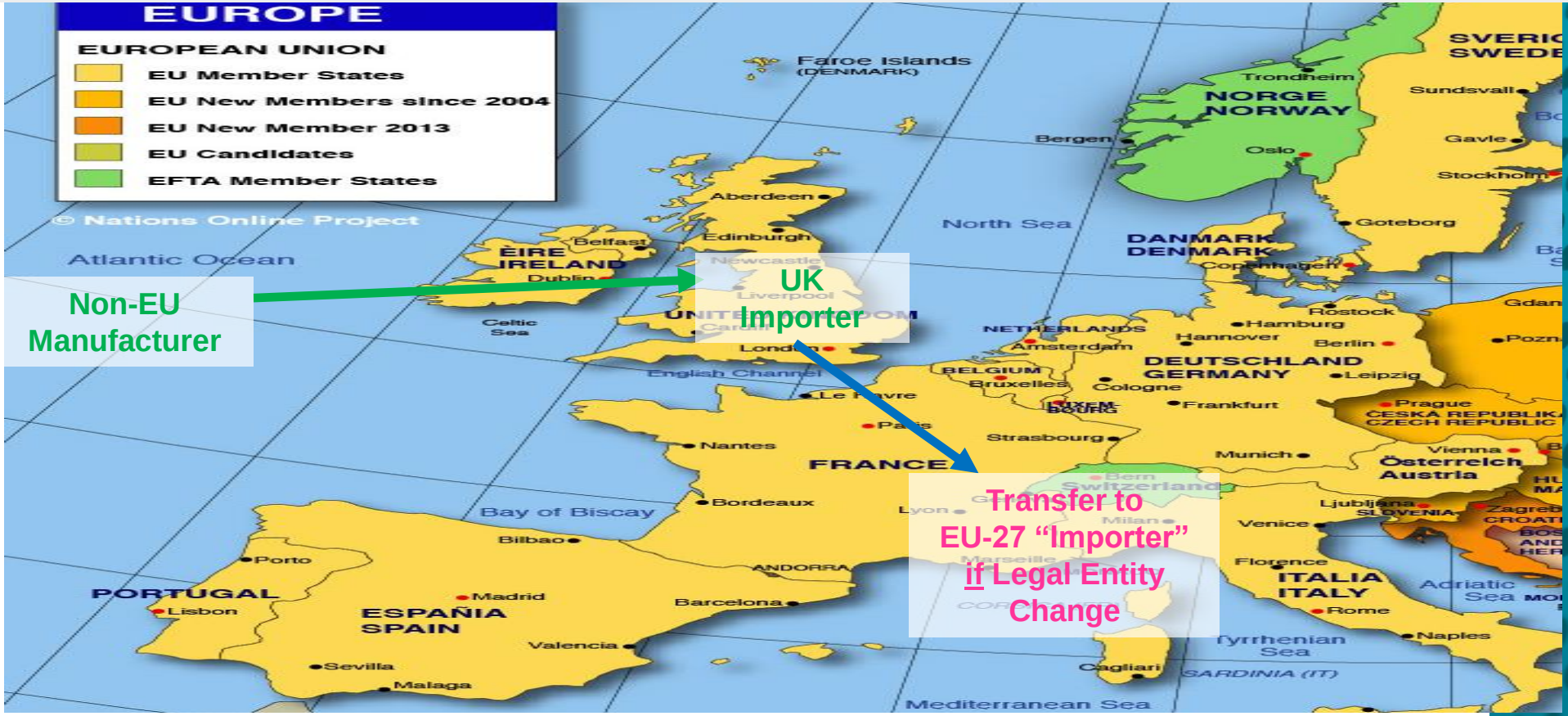
B) EU REACH
UK Reg "Importer Only": 2. DU Registers as Importer

- **Downstream User registers as Importer:**

  Tasks:
  - Dialogue with DUs to take on role
  - If UK Reg. was LR - same LR transfer tasks

  Concerns:
  - Will DUs bear cost of REACH registration or be able to have upstream UK supplier to cover/subsidize?
  - Will DU customers move to alternative suppliers offering REACH registration?
  - If DUs take on Reg. role → centralization of commercial and regulatory control (gives ability to access "spot market")
  - Same Art. 26 inquiry + Art. 27 delay issues

C) EU REACH
UK Registered "Importer Only": Transfers Registrations



C) EU REACH
UK Registered "Importer Only": Transfers Registrations

- **Transfer only possible in limited situations:**
  - ECHA Guidance on legal entity change
    - Mergers and takeovers
    - Asset sales (full or partial) and company splits
  - ECHA Brexit Q&As:
    - "acquisition or relocation" or
    - "intragroup transfer of the whole operations/manufacturing activity"

- **Alternatively – consider going to EU 27 already registered importer (no transfer and no delay) to cover compliance. Would need to be clearly documented.**

Tasks:
- Transfer via legal personality change in REACH-IT
- Same LR transfer tasks (if applicable)
- Same data rights issues as in scenario A)

Concerns:
- Will ECHA accept change of legal entity criteria are met?

Turning to the UK…

A) UK REACH
UK Registered "Manufacturer/Formulator"

A) UK REACH:
UK Registered "Manufacturer/Formulator"

Tasks:

- Automatic grandfathering into UK regime (applies even if registration was transferred to EU-27 entity in 2 years before Brexit) – No fees
- Timelines for subsequent action (kept under review):
  - Within 60 days: notification procedure to ensure grandfathering maintained (basic information) – UK registration number issued.
  - Within 2 years: Article 10 REACH dossier information.
- Map data agreements to see whether applicable to non-EU regimes and under what conditions.

Concerns:

- Data access to REACH dossier (not mandatory)
- If access granted – at what cost?
- Dossier preparation costs? IUCLID?

B) UK REACH
UK Registered "Importer"

B) UK REACH
UK Registered "Importer"

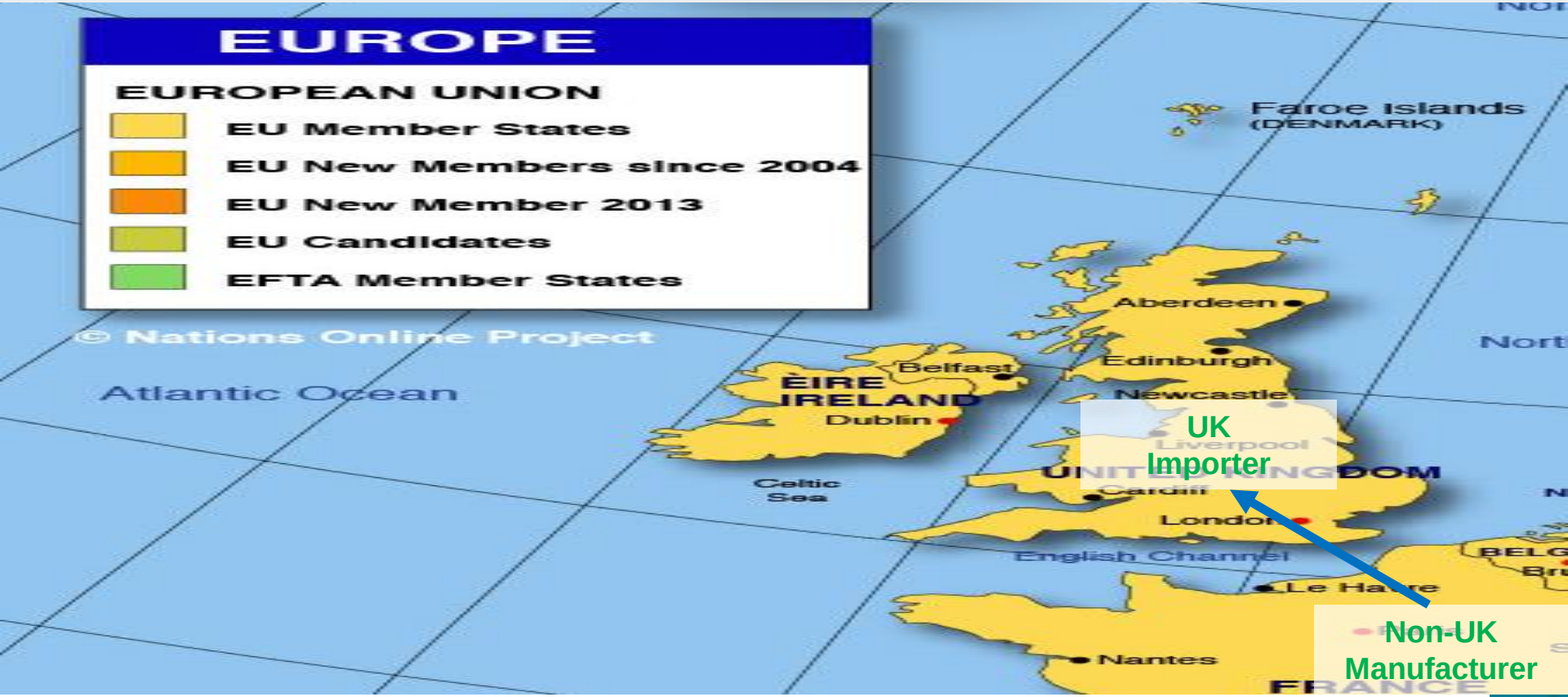
Tasks:

- See manufacturer

Concerns:

- See manufacturer

C) UK REACH
UK entity Not Registered "Importer"



C) UK REACH
UK entity Not Registered "Importer"

Tasks:

- Timelines for action (kept under review):
  - Notification – No fees
    - Within 180 days: "*some basic information*"
    - Appendix C: 1-10 t and 10t or more
  - Registration
    - "*within two years of the UK leaving the EU*"
    - Full data package and fees
    - Only mandatory "*if you wish to continue importing these chemicals*"
- Map data agreements to see whether applicable to non-EU regimes and under what conditions.

→ More favourable timelines than EU-27 manufacturer appointing UK OR

Concerns:

- Data access to REACH dossier (not mandatory)
- If access granted – at what cost?
- Dossier preparation costs? IUCLID?

3. BPR

Direct impacts on Biocides - EU

- HSE Role
- Pending Approvals (AS)
- Article 95 list
- Biocidal Product Authorisations

HSE Role: applications for approval/authorization

- Even if Soft Brexit (withdrawal agreement):
  - *"During the transition period, the United Kingdom shall not act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union or of Member States acting jointly referred to in [the BPR]"*
  - *"The United Kingdom shall transfer without delay to the competent authority of a Member State (…) all relevant files or documents in relation to assessments, approvals and authorisations ongoing on the day before the date of entry into force of this Agreement and led by a United Kingdom competent authority in accordance with Regulation (EU) No 528/2012 (…)"*

Pending approvals (AS)

- Evaluation of existing AS/PT combinations in the review programme is attributed by law to "a Member State"
- Delegated Regulation 2019/227 amending the Review Programme Regulation (Regulation (EU) No 1062/2014)
  - Transfer of 18 active substance dossiers
  - MS may request fees *"Notwithstanding the stage of evaluation of the application"*
    - Applicant informed at the latest by 30 April 2019
    - Application rejected if the participant fails to pay the fees
  - Deadline to submit conclusions and assessment reports: at the earliest 31 December 2020
- Application for renewal
  - No obligation for initial eCA to act as eCA for renewal
- New applications for approval, location of applicant not restricted

Article 95 list

- Article 95: "*unless either the substance supplier or the product supplier is included in the list*"
  - Substance supplier*: "A person established within the Union who manufactures or imports a relevant substance"*
  - Product supplier*: "A person established within the Union (…) who manufactures or makes available on the market a biocidal product "*
  - Need to transfer "in due time"
  - EU representative?

Biocidal product authorisations

- Authorisation Holder (AH)
  - *"the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorization"*
  - Need to transfer before withdrawal date
- Applications
  - New
  - Renewal
  - Pending
- "Orphan cases"

Biocidal product authorisations

- Mutual recognition
  - Recognition granted based on national authorisation delivered by the UK
    - Before the withdrawal date
    - After the withdrawal date
  - UK as reference MS
    - Pending
    - Change/renewal

Direct Biocides impacts – UK

- See HSE guidelines "*Regulating biocidal products if there's no Brexit deal*" (Dec 2018).
- HSE Guidance, "*Biocides: What you'll need to do in a no deal scenario*" (Jan 2019)

  - Grandfathering
    - Authorisations (products) : will remain valid until expiry date
    - Approvals (AS) : will remain valid until expiry date
    - UK Article 95 list
    - Treated Articles

Direct Biocides impacts – UK

Existing Authorisations

- Requirement to be UK established (transfer to UK entity if necessary): 29 March 2020
- If not listed on UK Article 95 list then ensure AS supplier is listed: 29 March 2021
- Any change to AS supplier requires application for Auth. Modification: 25 Sept 2021

Direct Biocides impacts – UK

Pending Authorisations

- with HSE
- with EU-27 eCA

- Duplication of authorization holders

- "*same information as was previously submitted*" – Data rights?

Direct Biocides impacts – UK

UK Article 95 list

- Requirement to be UK established.
- Transfer of EU Article 95 listings on exit day.
- 29 March 2021: submission deadline for supporting dossier
  - data rights
  - no HSE submission fees
  - HSE “may” refuse application “if it” does not hold the data – but what if data owner is not a UK data submitter?

Direct Biocides impacts – UK

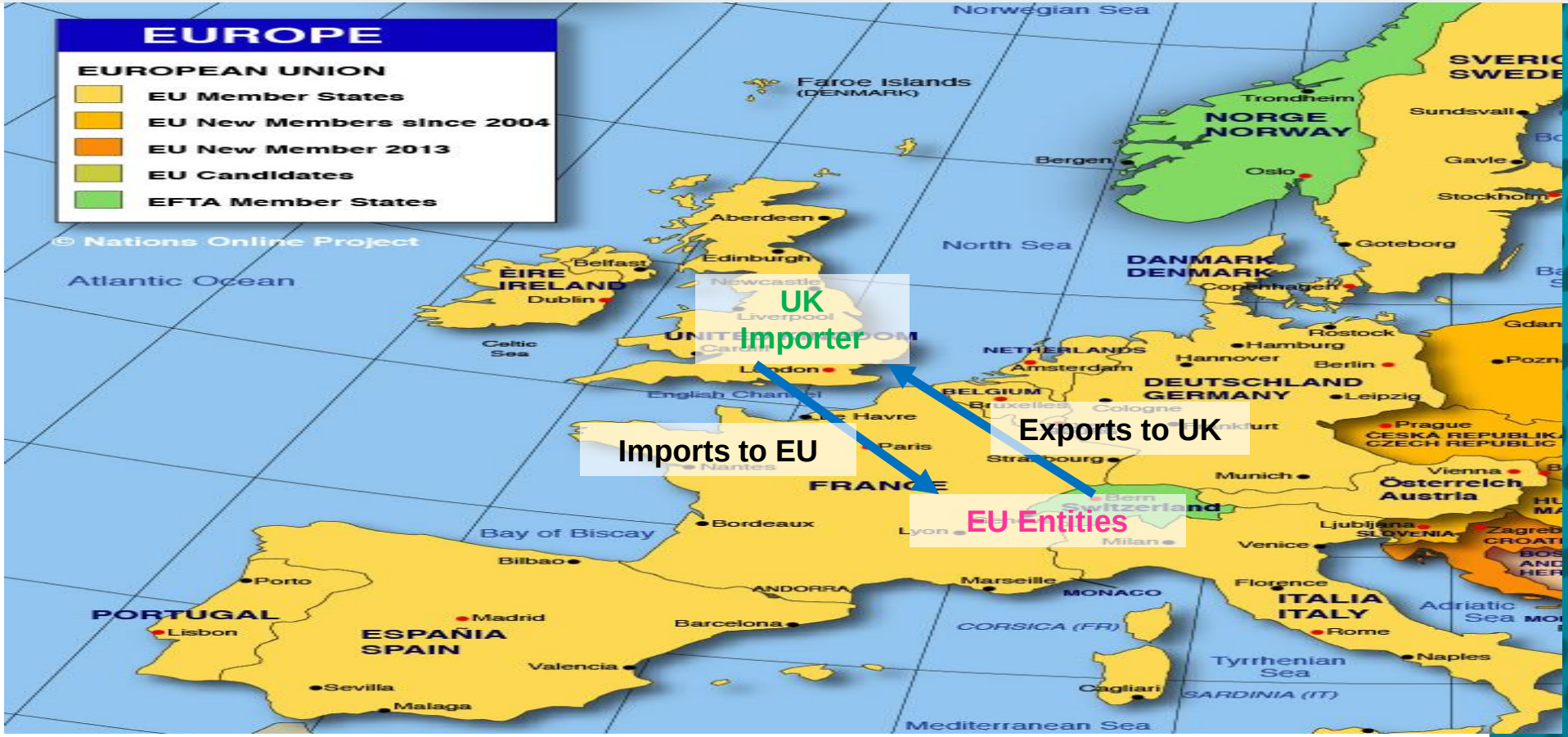
Treated Articles

- Art. 58 BPR will be mirrored.
- Will AS still be supported for UK market?

Indirect Impacts – Co-formulants (REACH)

- Impact on availability of compliant co-formulants
  - UK established entities no longer able to be:
    - Manufacturer
    - Only Representative
    - (Lead) Registrant
  - Compliance with UK-REACH?
- Data sharing
  - Article 10(a)
    "*(…) the registrant shall be in legitimate possession of or have permission to refer to the full study report summarized under (vi) and (vii) for the purpose of registration*"
  - Access for UK purposes ("UK-REACH") - No data sharing obligation

4. CLP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EUROPEAN UNION
EU Member States
EU New Members since 2004
EU New Member 2013
EU Candidates
EFTA Member States
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UK
Importer
Imports to EU
Exports to UK
EU Entities
Norwegian Sea
Faroe Islands (DENMARK)
Atlantic Ocean
North Sea
Bay of Biscay
Celtic Sea
English Channel
Mediterranean Sea
Tyrrhenian Sea
Adriatic Sea
NORGE NORWAY
DANMARK DENMARK
EIRE IRELAND
NETHERLANDS
BELGIUM
DEUTSCHLAND GERMANY
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Bergen
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Stockholm
Goteborg
Aberdeen
Edinburgh
Belfast
Dublin
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Liverpool
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Rostock
Hamburg
Hannover
Berlin
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Rome
Naples
Cologne
Paris
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Bordeaux
Lyon
Milan
Marseille
Barcelona
Madrid
Lisbon
Porto
Bilbao
Valencia
Sevilla
Malaga
Cagliari

EU and UK CLP

- EU
  - Imports need to comply with EU-27 CLP – ATP
  - EU-27 importer (from UK entity) will need to notify
  - No express role for ORs but
    - may submit the information needed for notification to the Inventory as part of a REACH registration dossier.
    - may also submit separate notifications to the Inventory where they are notifying on behalf of a group of importers. (Must act on a mandate.)
- UK
  - GHS labelling (pictograms) untouched – "*UK would effectively adopt the GHS in the same way as the EU*"
  - HSE competent authority with power to establish "*new arrangements*" for classification
- Tasks: As above
- Concerns:
  - Divergence of classifications

5. DATA SHARING FOR CHEMICALS REGIMES

EU REACH: Data Rights Essentials

- Data agreements typically split into three categories based on *position* entity:
  - Data holder
  - Data accessor
  - Part of task force/consortium

- Companies should <u>not</u> need to ask for permission to use *all* data rights – categorize/map agreements (drilling down for each data category):

USE	Clearly allowing for use	Clearly excluding use:	Ambiguous
in EU by affiliates (or OR) for REACH	No further action	Negotiate terms	Case by case assessment
outside EU by affiliates for other purposes (e.g. UK REACH)	No further action	Negotiate terms	Case by case assessment

EU REACH: Data Rights Essentials – Negotiations

- **For use of EU access rights in the EU27 – no changes:**
  - Same rules on mandatory sharing and compensation: scope and fair, transparent and non-discriminatory test
  - Same remedies – ECHA data sharing disputes
  - Non-duplication vertebrate animal studies
  - Contractual rules (may benefit related entities)

EU REACH: Data Rights Essentials – Negotiations

- **For use of EU access rights in the UK…**
  - EU (Withdrawal) Act indicates - same rules (generally) + mechanism to deal with "deficiencies" up to 29 March 2021.
  - Could mean very similar *system* but:
    - Extraterritoriality (when data owner not in UK market)
    - Will payments already made under REACH be discounted?

For all regimes: Impacts on contracts – EU and UK

- Scope of data rights
  - Transfer / Affiliates
  - Limitations on assignability
  - Scope limited to (EU) BPR
  - Geographical scope (“European Union”)
  - Required establishment in EU
  - Use limitations (specific concern for “existing data”)

- Other types of agreements
  - Sale, supply, services,…
  - New agreements with Brexit clause

6. TAKE AWAY MESSAGES