

Brexit and the Implications on Supply and Use of Chemicals, Machinery & Products in Irish Businesses

December 5th 2018



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Opening and Welcoming Remarks

Dr. Sharon McGuinness, HSA



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Health and Safety Authority Mandate

- To regulate and promote the safety, health and welfare of people at work and those affected by work activities
- To promote improvement in the safety, health and welfare of people at work and those affected by work activities
- **To regulate and promote the safe manufacture, use, placing on the market, trade and transport of chemicals**
- **To act as surveillance authority in relation to relevant single European market legislation**
- **To act as the National Accreditation Body for Ireland**

Timelines to Withdrawal

Today	30 March 2019 Withdrawal	31 December 2020
Acquis	Acquis + Full Alignment No decision making No trade agreements	Provisions of Agreement
Membership	Transition	Future Relations
<p>TEU</p> <p>Negotiation and ratification of Withdrawal Agreement by Council and EP</p>	<p>Withdrawal Agreement + transitional arrangements + outline of the framework for future relations</p> <p>Negotiations of future relations only possible with a "third country"</p>	<p>Agreement depends on ratification by EU-27 Member States (mixed agreement)</p>

Current Situation

- Draft Agreement published on 14 November
- Draft Agreement endorsed by European Council on Nov 25th
- UK Parliament to vote on December 11th
- Presentations today focus on a No Deal Brexit

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Brexit and the implications for REACH

Dr. Majella Cosgrave, HSA



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REACH

- Most elements of REACH will be impacted by Brexit
- Key areas for Irish companies will be **registration** and **authorisation**
- Non- EU companies and UK-based Only Representatives (ORs) also affected

REACH Registration

- Requirement that substance manufactured in EU, or imported into EU at greater than 1 tonne per annum, must be registered
- UK registration statistics (*as of 29th November 2018*):
 - 12,449 registrations
 - 5,749 substances
 - 1,773 companies

 - 30% importers
 - 15% manufacturers
 - 50% Only Representatives (ORs)
 - 5% manufacturers and importers
- Many Irish companies may be relying on these UK-based registrations for their own supply (or covered by the UK-based OR)

REACH Registrations after Brexit

- UK will be a third country
- UK REACH registrations will become non-existent
- UK authorities will also no longer:
 - Participate in EU regulatory and decision making processes
 - Have access to ECHA databases
 - Be part of, or send experts to, ECHA or Commission committees

Impacts on IE companies - registration

- Currently, if IE company buys chemicals from UK supplier, role under REACH is as a downstream user -> **no registration obligations**
- After Brexit, UK will become a third country
- If IE company continues to buy chemicals from that UK supplier, role under REACH changes to importer -> **registration obligations**
- Consideration also needs to be given to IE distributors that may supply IE companies – their source could be UK-based

Impacts on registration for IE companies (1)

Scenario: IE company purchasing substance from UK registrant

- Currently, IE company is downstream user; no registration obligation
- After Brexit, IE company can't rely on the UK registration

Options:

UK supplier:

- move operations related to registered substance to legal entity within EU-27/EEA; legal entity change, or
- if manufacturer or formulator, appoint OR and transfer the registration
- if importer, can't appoint OR; UK importer can't transfer registration to OR

IE company:

- sources another EU-27/EEA based supplier, or
- continues to source from UK-based supplier, becomes an importer; registers

If you are in this position, consider your options and talk to your UK supplier now about his intentions post-Brexit

Impacts on registration for IE companies (2)

Scenario: IE company registrant in joint submission with UK lead registrant

- Following Brexit, UK registration will cease to exist

Options to ensure functioning joint submission:

- Lead registrant moves to EU-27/EEA, or
- A new lead registrant is appointed and LR role transferred before Brexit

If you are in such a position, talk to your UK lead registrant now to determine his intentions post-Brexit

Impacts on registration for ORs

Scenario: UK-based Only Representative who has submitted registrations

- After Brexit, such an OR will no longer be 'legally established in the EU'

Options :

- OR moves to EU-27/EEA, or
- Non-EU manufacturer appoints new OR based in EU-27/EEA and OR changed in REACH IT, or
- EU-27/EEA company becomes an importer and registers

If you are dependent on a UK-based OR arrangement, speak to your OR and/or your non-EU supplier to determine their intentions post-Brexit

UK companies transferring registrations to EU-27/EEA

- Company cannot be set up 'on paper' only and registrations transferred
- Must be as a result of a legal entity change – e.g. the importing/manufacturing business is transferred to the EU-27/EEA legal entity
- Responsible staff and relevant documentation must be available for inspection by the IE enforcement authority at premises of registrant
- Also applies to ORs; must be in compliance with article 8(2) of REACH
- Changes must be notified to ECHA in REACH IT ahead of the UK withdrawal
- ECHA expected to provide more details of practical aspects of this

UK companies transferring registrations to EU-27/EEA

- UK based manufacturer/importer can transfer registrations to EU-27/EEA
- Must be result of a legal entity change and one of the following:
 - ✓ UK based company goes through acquisition/relocation to the EU-27/EEA
 - ✓ An intra-group transfer of the whole operations/ activity to the EU-27/EEA (e.g. transfer of manufacturing from UK-based mother company to EU-27/EEA-based daughter company)
- Must take place ahead of the UK withdrawal and be notified to ECHA (through REACH IT) without undue delay
- Following the legal entity change, the UK legal entity must cease manufacturing/importing until after the UK has exited the EU

REACH Authorisation

- A manufacturer, importer or downstream user may not place a substance on the market for a use, or use it himself, after a certain date (sunset date) if the substance is included in Annex XIV of REACH
- A company who applies for an authorisation can do so for his own use and the uses of his downstream users
- A M/I/DU can place a substance on the market for a use for which is immediate DU has been granted an authorisation

UK-based companies are authorisation holders and IE companies may be using substances under those UK authorisations

REACH Authorisations after Brexit

- After Brexit, authorisations held by UK-based companies will not be valid

Options for UK companies:

- transfer authorisation/pending application to EU-27/EEA OR (can only happen after UK withdrawal) - manufacturers and formulators only; not importers
- transfer authorisation/pending application to EU-27/EEA manufacturer/importer/downstream user of the substance, with uses covered by the application through a legal entity change. (must happen before UK withdrawal). (note: change of legal entity cannot extend the scope of original application)

Options for UK-based ORs:

- transfer authorisation/pending application to EU-27/EEA OR (must happen before UK withdrawal)

REACH Authorisations after Brexit

Options for IE relying on UK authorisation:

- Find EU-27/EEA supplier with valid authorisation, or
- apply for an authorisation himself if wishes to continue using the substance

If you are an IE DU covered by an authorisation of your UK supplier, speak to your UK supplier now to determine his intentions post-Brexit

Companies based outside of the EU

Scenario: Non EU manufacturer/formulator has appointed UK-based OR

Options:

- Can appoint a new OR in an EU-27 MS/EEA
- Requires collaboration between old and new OR to do legal entity change
- Must take place before the UK withdrawal
- Must be notified to ECHA through REACH IT

Companies based outside of the EU

Scenario: Non-EU company exports to a UK based importer who has completed the registrations ; substance further supplied in the EU-27/EEA by UK company

Options:

- Appoint an OR located within the EU-27/EEA, or
- Substance can be registered by the EU-27/EEA importers, or
- (The UK company moves operations related to registered substance to legal entity within EU-27/EEA; legal entity change)

From a UK perspective....

- If a transitional arrangement is agreed, EU law will continue to apply in the UK during that time (subject to terms set out in Withdrawal Agreement)
- But, HSE/DEFRA will no longer participate in EU committees or act as a 'lead authority'
- Limited/no participation by UK in EU institutions, agencies and bodies

UK: Future Economic Partnership

- White paper published July 2018; sets out UK Government proposal for future economic relationship with EU
- Close alignment on goods, including chemicals (but details to be sorted in negotiations)
- Participation by UK in work of EU agencies ‘that provide authorisations for goods in highly regulated sectors’ – includes ECHA

UK No Deal Contingency Planning

- The EU (Withdrawal) Act became law in June 2018
- Will convert EU chemicals regulations to UK domestic law
- Contingency Statutory Instruments (SIs) will correct deficiencies to ensure regulations are operable outside EU
- SIs ready to come into effect 29 March 2019
- A no deal outcome would mean companies wanting to operate in both UK and EU markets will need to deal with both regulatory systems

Preparing for Brexit - REACH

- Examine your current supply chain
- Do you source substances from a UK-based supplier?
- Are you a downstream user, relying on a UK-based only Representative?
- Are you reliant on an IE distributor who in turn sources from the UK?
- Are you reliant on a UK company granted authorisation?
- Can you change your supplier to an EU-27/EEA one?
- Are you in a position to take on the role of importer if you continue to source in the UK post-Brexit?
- Speak to your UK suppliers/ORs to determine their plans post-Brexit

REACH Supports

- HSA chemicals helpdesk: chemicals@hsa.ie
- HSA webpages www.hsa.ie/brexit
- ECHA webpages on UK withdrawal (Q&As)
<https://www.echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu>
- European Commission Notices https://ec.europa.eu/info/brexit_en
- UK Government Brexit Publications – no deal scenarios
<https://www.gov.uk/government/brexit>
- IE Government Departments and Agencies (especially Enterprise Ireland, InterTrade Ireland, Strategic Banking Corporation of Ireland, Revenue)
- Trade organisations

Thank you



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Supply and distribution of chemical products post-Brexit

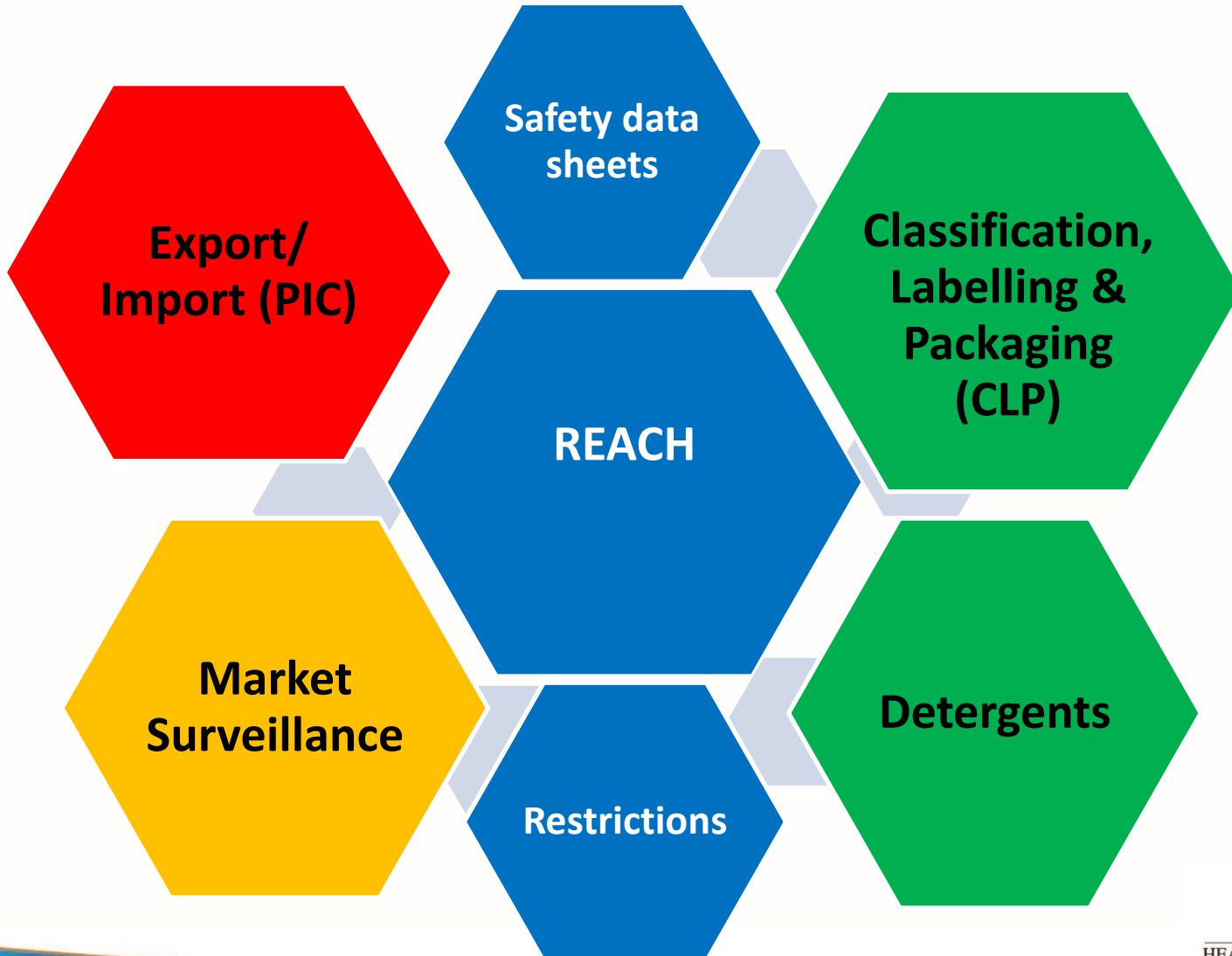
Yvonne Mullooly, HSA



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Supply & Distribution



Trade & Supply between Ireland & UK

- Majority of IE chemical products come from UK suppliers
- Most IE companies are currently “downstream users” under REACH/CLP/Detergents
- When UK leaves, IE companies role may change resulting in higher regulatory obligations and associated costs.
- Chemical Products imported from the UK need to be EU compliant.

Chemical Products

- **Substances**- Alcohols, acids, salts
- **Mixtures**- Paints, Degreasers, Pigments, Detergents, Silicone, Adhesives, Coatings
- **Articles**- Jewellery, Shoes, Furniture, Electronic Equipment, Construction panels

***DO THE CHEMICAL PRODUCTS YOU SUPPLY
or USE COME FROM THE UK ?***

Substances, Mixtures & Articles

- ➔ Substances, mixtures supplied into the EU market must comply with REACH, CLP & Detergents¹ (¹where applicable)
 - ➔ Articles supplied to EU market must comply with REACH
 - ➔ Substances, mixtures & articles supplied to UK market from EU (Ireland) must comply with UK standards
- **Legal responsibility of distributors and downstream users may change !**

Change in role

Distributor/Downstream users



EU Importer

What does it mean to be an EU Importer of Chemical Products?



MARKET SUPPLY & SAFE USE

- Legal Responsibility for safety of the product lies with the 1st EU Importer from the UK
- Chemical Product: Substance/mixture
 - **Classified, Labelled and Packaged (CLP)**
 - **Notified to the C&L Inventory**
 - **Supplied with an appropriate Safety Data Sheet (SDS)**
- Chemical Product: Substance/Mixture or Article
 - **Doesn't contain prohibited substances (Annex XVII REACH+)**

Detergent Products

- Detergent Regulations: Household & Industrial.
- Additional labelling & prohibition of certain substances
- **‘Placing on the market’** means the first making available on the Union market. Import into the Union customs territory shall be deemed to be placing on the market.
- **‘Making available on the market’** means any supply for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
- *Personnel hygiene products (shower gels, shampoos) **do not** fall within the scope of Detergents*

Market Surveillance

- Currently majority of “non compliant” chemical products found on the Irish market are referred to UK Authorities to enforce.
- Product Recall & EU RAPEX Alert
- Major impacts on business resources & reputation
- Major impact on Authority and Customs resources

Options

1. Source another EU supplier willing to supply the Irish market.

Remember labels & SDS's must be in English & SDS must contain relevant Irish standards!

2. Source/employ competent person familiar with REACH, CLP & Irish national standards to ensure you can supply compliant chemical products to the Irish/EU market

Important information to note

- No “Only Representative” provision in the CLP & Detergent Regulations.
- Existing UK C&L notification information will remain available unless it is removed via REACH IT account
- Irish companies may need to seek new suppliers of their chemicals within EU – may lead to shortages in supply. Look for business opportunities!

Exporting Chemical Products to the UK



Exporting Chemical Products to UK

- Rotterdam Regulation – Prior Informed Consent
- Only applies to banned or severely restricted Pesticides & Industrial Chemicals
- Customs requires a RIN for custom declaration
- Apply via electronic system ePIC- ECHA
- Exports < 10 kg/yr/country for R&D/Testing- Special RIN(SAD Box 44)
- Yearly notification of quantity shipped per country

Exporting to the UK

- Check if any substances listed in *PIC Part 1* are in any of your chemical products

NO DEAL

- EU Withdrawal starts earlier than March
- Export notifications must be submitted 35 days before export - **FEBRUARY 2019!**
- UK Export Notifications will cease to exist from March 2019

- As UK still a party to Rotterdam Convention UK companies still have obligations

Export Import

- UK Regulations will also apply to Irish products on the UK market
- If product requirements are different in the UK
 - Divergence may occur on the enforcement side if a non-compliance is observed for a UK product on the IE market.
 - Resolution of non compliant products could fall to the Irish Importer.
- http://www.hsa.ie/eng/Chemicals/Export_Import/

Parting advice

- Your company will experience change if your business supply chain is in any way linked to the UK
 - **Downstream users:** Do you know if your distributor will continue to source your product?
 - Start your market preparations now! Register in ePIC
1. **KNOW YOUR PRODUCT SOURCE**
 2. **TALK TO YOUR SUPPLY CHAIN**
 3. **DIVERSIFY**
- Follow the withdrawal negotiations to determine your future obligations

Information



CHEMICAL IMPORTERS

Information Sheet

October, 2013

Safety Data Sheets for Hazardous Chemicals

Information Sheet

Updated October, 2015

Exporters Duties under the Rotterdam Regulation (EU) No 649/2012 on the Export and Import of hazardous chemicals

Information Sheet

Updated May 2015

REACH - PRODUCTION, IMPORT AND SUPPLY OF ARTICLES

Information Sheet

April 2014



Labelling and Packaging requirements for Detergents & Biocidal Detergent Products

Information Sheet

July, 2014

Chemical Distributor Duties under REACH and CLP

Information Sheet

March 2011

Information for Retailers on Hazard Labelling & Packaging of Chemical Products

July, 2013

Relevant Publications

- Chemical a) Importers b) Exporters c) Distributors
- Retailers- Classification, Labelling and Packaging
- Classification, Labelling and Packaging of substances and mixtures
- Classification, Labelling and Packaging of Detergents
- Safety Data Sheets
- Import and Supply of Articles
- All available at www.hsa.ie/eng/publications/chemicalsandhazardoussubstances
- ECHA YouTube Videos
- <https://www.youtube.com/user/EUchemicals/videos>

Support

- We are here to help!
- HSA Chemicals helpdesk email chemicals@hsa.ie
- HSA: UK Withdrawal HSA webpage
- ECHA: <https://echa.europa.eu/uk-withdrawal-from-the-eu>
- ECHA How to notify to the C&L inventory:
<https://echa.europa.eu/support/dossier-submission-tools/reach-it/notification-to-the-cl-inventory>.
- DBEI: <https://dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit/>
- EU Commission: https://ec.europa.eu/commission/brexit-negotiations_en

Finally!

Take our **Chemical Usage Survey** and
be in with a chance to win an iPad

<https://www.surveymonkey.com/r/NBRWJFC>

***“Get Brexit Ready &
Know Your Source”***

Thank You



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**An Roinn Talmhaíochta,
Bia agus Mara**
Department of Agriculture,
Food and the Marine

Brexit

Impact on Biocides

Dr Finbar Brown
Pesticide Control Division
5th December 2018



What about Biocides

Regulation (EU) No 528/2012?





Impact – many questions

- Effect on active substances (a.s.)?
- Effect on products (b.p.)?
- Effect on a.s. suppliers?
- Effect on case owners?
- Effect on Authorisation Holders (A.H.)?
- Effect on Letters of Access (L.o.A.)?
- Effect on data protection?
- And so on.....





What is certain?

- What is certain come 29th March 2019?
- UK can no longer act as an eCA
- Applies to both active substances & products
- EU-27, EEA and CH have to carry more work
- eCAs have to increase capacity
- Inevitable delay in MS evaluations
- Potential loss of some products to IE market
- There is still time to act





Preparation

- 7 Brexit Technical Seminars
- Search for new eCA for a.s.
- Change to Review Programme – existing a.s.
- Search for new eCA for a.s. renewal
- Search for alternative eCAs for products
- First authorisations and renewals





Active substances



- Applicant is UK based? **Still OK.**
- Manufacturer is UK based? **OK.**
- Will ECHA refuse UK companies right to refer to vertebrate test/study? **No outright refusal.**
- Will a.s. studies retain data protection? **Yes.**
- Status of approved a.s. (UK refMS)? **OK.**
- Art.95 listed supplier is UK based? **Not OK.**
- L.o.A. to data from UK company? **OK.**
- UK a.s. evaluation ongoing? **Not OK.**



Product Notifications

- Registration under Article 89 transitional phase
- Brexit impact come 29/3/?
- Art.95 listed supplier is UK based? **Not OK.**
- Can the notification holder be UK based? **Yes***
- Can the label be an IE-UK dual label? **Yes***

* The understanding of the IE CA would be yes, but await confirmation from EU COM.



Product Authorisations

- Authorisation under the BPR
- Brexit impact come 29/3/?
- Art.95 listed supplier is UK based? **Not OK.**
- AH is UK based? **Not OK. EU-27, EEA AH base.**
- Can the label be an IE-UK dual label? **Yes***
- UK company information on the label? **Yes***
- L.o.A. to data from UK company? **OK.**
- UK evaluation ongoing? **Not OK.**



Specific type of BPR Authorisations



- Brexit impact come 29/3/?
- National Authorisations
- Mutual Recognitions (Sequence & Parallel)
- Union Authorisations
- Simplified Authorisations and notifications
- Same Biocidal Products
- Changes (minor/major/admin) to authorisations

National Authorisations



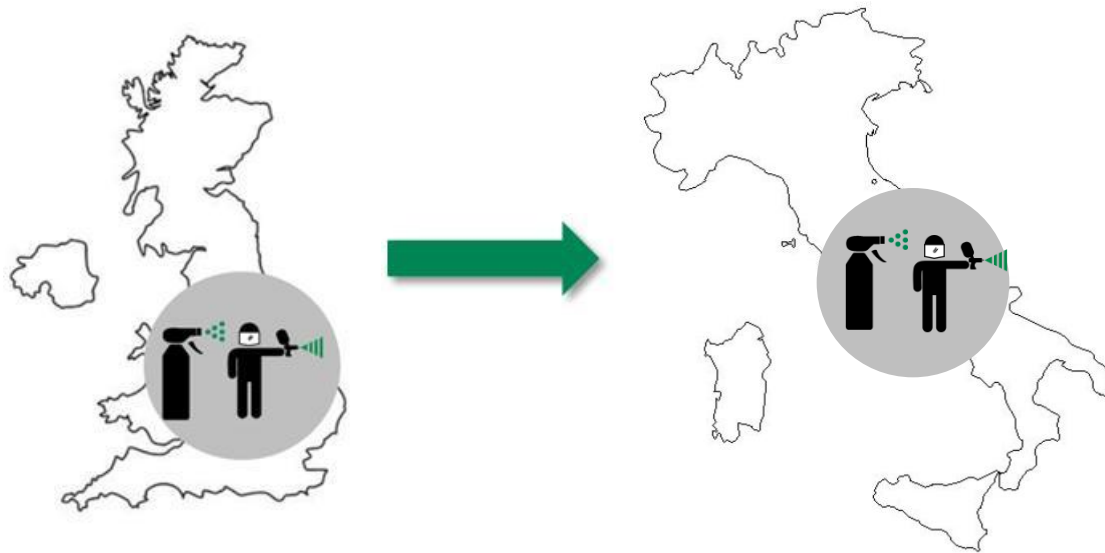
- Assets and ongoing cases in UK on 29/3/20



Mutual Recognitions - Parallel



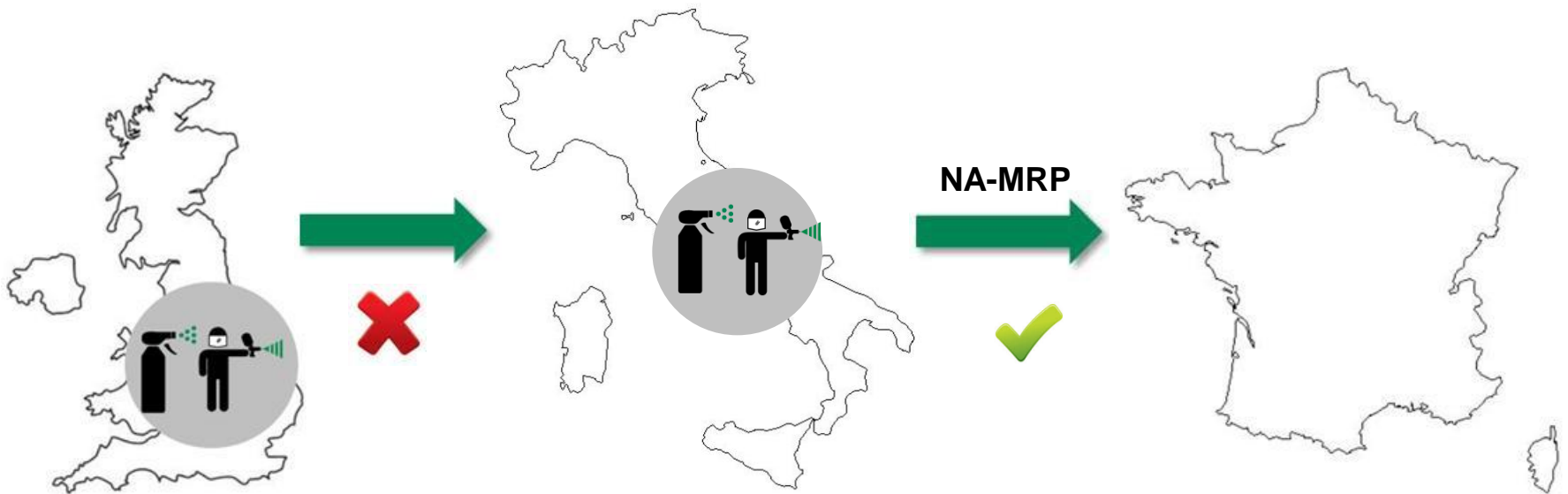
- Available agreed SPC/PAR or Authorised 29/3



Mutual Recognitions - Parallel



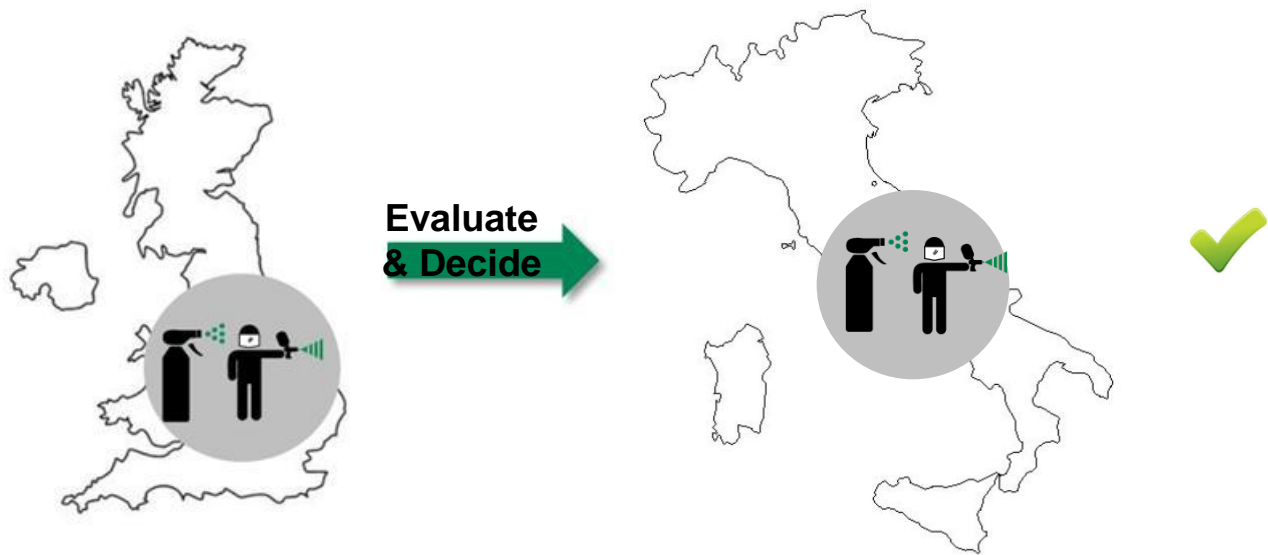
- SPC/PAR will not be agreed by 29/3. Need new refMS.



Mutual Recognitions - Sequence



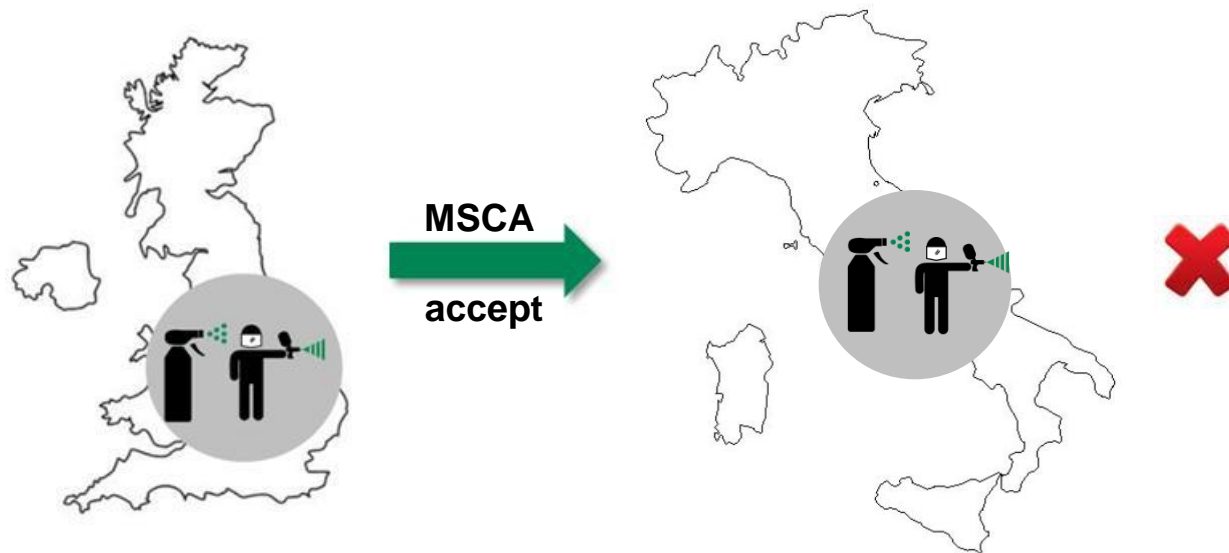
- Agreed SPC (Evaluate & Decide step) by 29/3?



Mutual Recognitions - Sequence



- No agreed SPC (in MSCA accept or Validate steps) by 29/3?



Union Authorisation



- Granted before 29/3, but need new eCA for RNL and Change



Union Authorisation



- Not likely to be granted before 29/3, need new eCA



Union Authorisation



- BPC Opinion adopted before 29/3 ✓



Renewal products



- UK reference will not be completed before 29/3. Need to find new refMS.



Simplified procedure



- If UK was the refMS, need new refMS to authorise before 29/3 and new notifications



Same Biocidal Products



- Remain unaffected by 29/3. Standalone auths.





IT Tools – R4BP3 & SPC

- Brexit impact come 29/3?
- Access to R4BP3 - UK CA? **Restrictions.**
- Access to their data – UK companies? **Yes.**
- UK company submit applications via R4BP3?
Yes, but note ‘case owner’ and ‘AH’ difference
- ECHA Dissemination website





Useful Resources

- ECHA Q & A

<https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu>

- EU COM Q & A

https://ec.europa.eu/info/sites/info/files/qa_biocides.pdf

- UK Gov. Biocide page

<https://www.gov.uk/government/publications/regulating-biocidal-products-if-theres-no-brexit-deal/regulating-biocidal-products-if-theres-no-brexit-deal>

Conclusions & take home message



- Making the uncomfortable comfortable
- Check status of your a.s./products
- Check AH location
- Check Art.95 supplier listing
- Consider a new refMS if necessary
- Consider market area for future submissions
- There is still time to act
- Contact your CA for further information



Thank you!



Contact:

Biocides@agriculture.gov.ie

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Questions and Answers

Session 1



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