REACH 30/30
BREXIT, Microplastics and other issues
13 February 2019

Marcus Navin-Jones, Partner
+32 2 645 5097
navin-jones@khlaw.com
Preliminary words

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual’s specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depend on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the author’s alone and not those of the author’s clients.
Introduction

- Marcus advises on all aspects of EU chemical law.
- REACH, CLP, ROHS2, BPR, PPPR, POPs, PIC etc.
- Particular focus on:
  - microplastics; polymers of concern; PBT/vPvB substances; endocrine disruptors; nanomaterials; chemical waste and other emerging issues.
- Assisted UK House of Lords EU Energy and Environment Sub-Committee on EU/UK REACH and BREXIT issues.
- Chemical defence and litigation:
  - Current case T-226/18 regarding a REACH Restriction
  - Current case C-471/18 P regarding an ECHA SONC
  - T-283/15 regarding an ECHA Statement of Non-Compliance
  - A-006-2016 regarding polymer data required from monomer REACH registrants
  - A-012-2017 regarding a multi-constituent and alleged PBT/vPvB properties
  - A-018-2015 regarding an annulment to carry out an EOGRTS study
  - A-017-2015 regarding a PNDT study using a corrosive substance
  - A-012-2014 regarding read-across data and a 2nd species PNDT study
  - A-005-2011 regarding vertebrate animal testing
  - Advocacy on proposals to list a substance on A, B or C of the Stockholm Convention.

Marcus Navin-Jones, Partner
Keller and Heckman LLP
Brussels Office
+32 2 645 5097
navin-jones@khlaw.com

https://www.khlaw.com/Marcus-Navin-Jones
Overview

▪ BREXIT: Background and updates
▪ Polymers, monomers and microplastics
▪ Other issues: Sustainable Finance Taxonomy
Acronyms

- EU – European Union
- EEA – European Economic Area (Norway, Iceland, Liechtenstein and 28 EU MSs)
- EFTA – European Free Trade Association (Norway, Iceland, Liechtenstein and Switzerland)
- EEC – European Economic Community - subsequently became the EU.
- Brexit – Withdrawal of the United Kingdom (Britain) and Gibraltar from the European Union
- United Kingdom – England (London), Scotland (Edinburgh), Wales (Cardiff), Northern Ireland (Belfast) – NB Gibraltar
- British PM – British Prime Minister (Ms Theresa May as of 13 July 2016, previously David Cameron)
- CLP – Regulation 1272/2008
- ECHA – European Chemical Agency
- MSCA – Member State Competent Authority
- COM – European Commission
- MS – Member State (i.e. a country) within the European Union. Currently 28. Will be 27 if the UK leaves.
BREXIT: History and background
Background

- 1957 – The European Economic Community formed
- 1961 – UK applies to join EEC - application vetoed
- 1973 – UK joins EEC
- 1975 – UK referendum on continued EEC membership, 67% approval
- 1993 – Maastricht Treaty establishes the European Union (EU), incorporating and later succeeding the EEC.
- 2009 – Lisbon Treaty
Background

- January 2013  British PM David Cameron promises a re-negotiation of UK membership of EU, followed by an In-Out referendum, if the Conservative Party wins the 2015 UK General Election.

- May 2013  Conservative Party publishes a draft EU Referendum Bill. Bill states that the referendum must be held before 31 December 2017.

- 2014  Cameron outlines changes he aims to negotiate in new UK membership of EU.

- May 2015  UK General Election. Conservative Party win small majority

- 9 June 2015  EU Referendum Bill goes before the House of Commons. [Only SNP vote against.]

- 17 Dec 2015  UK ‘European Union Referendum Act 2015’ receives Royal Assent
Background

- **February 2016**  Outcome of new UK membership of UK renegotiations announced. [Concessions regarded by UK electorate as modest]

- **7 June 2016**  Deadline for registration to vote in EU Referendum

- **23 June 2016**  EU Referendum in UK
  - Only British, Irish and Commonwealth citizens over 18, resident in UK/Gibraltar able to vote.
  - Conservative Party: Neutral
  - Labour and Liberal Democrats Parties: Remain

- **24 June 2016**  72.22% Turnout.
  - 51.89% vote to leave, 48.11% vote to remain part of the EU.
  - Scotland, N. Ireland, and Gibraltar; major cities (London, Leeds, etc); and youth - vote to remain.
  - Cameron announces resignation

- **13 July 2016**  Theresa May appointed British Prime Minister
Article 50

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 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.

4. For the purposes of paragraphs 2 and 3, the member of the European Council or of the Council representing the withdrawing Member State shall not participate in the discussions of the European Council or Council or in decisions concerning it.

A qualified majority shall be defined in accordance with Article 238(3)(b) of the Treaty on the Functioning of the European Union.

5. If a State which has withdrawn from the Union asks to rejoin, its request shall be subject to the procedure referred to in Article 49.
JUDGMENT OF THE COURT (Full Court)
10 December 2018 (*)

(Reference for a preliminary ruling — Article 50 TEU — Notification by a Member State of its intention to withdraw from the European Union — Consequences of the notification — Right of unilateral revocation of the notification — Conditions)

In Case C-621/18,
REQUEST for a preliminary ruling under Article 267 TFEU from the Court of Session, Inner House, First Division (Scotland, United Kingdom), made by decision of 3 October 2018, received at the Court on the same day, in the proceedings

Andy Wightman,
Ross Greer,
Alyn Smith,
David Martin,
Catherine Stihler,
Jolyon Maugham,
Joanna Cherry

v

Secretary of State for Exiting the European Union,

interveners:

Chris Leslie,
Tom Brake,

THE COURT (Full Court),


Advocate General: M. Campos Sánchez-Bordón,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 27 November 2018,

after considering the observations submitted on behalf of:

— Andy Wightman, Ross Greer, Alyn Smith, David Martin, Catherine Stihler, Jolyon Maugham and Joanna Cherry, by A. O’Neill QC, M. Lester QC, D. Welsh, Advocate, P. Eeckhout, Professor of Law, and E. Motion, Solicitor,

14 November 2018

TF50 (2018) 55 – Commission to EU27

Subject: Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, as agreed at negotiators’ level on 14 November 2018.

Origin: European Commission, Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU.

Objective: Sent to the EU27 Member States, to the Brexit Steering Group of the European Parliament and published on the TF50 website on 14 November 2018.
BREXIT: Chemical industry and supply-chains
UK’S NUMBER ONE MANUFACTURING EXPORTER SAYS THE UK SHOULD REMAIN A MEMBER OF THE EUROPEAN UNION

12 April 2016

In a recent survey, the leaders of chemical and pharmaceutical businesses from across the UK said that remaining in the EU is in the best interest of their businesses.

The survey carried out by the Chemical Industries Association (CIA) showed that 62% of companies voted to remain, with the remaining 38% declaring that their company had decided not to take a position. No business in the survey of CIA’s 93 member companies – representing approximately 70% of total UK chemical and pharmaceutical sales – said that leaving the EU would be in the best interests of their business.

Extract from UK Chemical Industries Association Press Release:

VERBAND DER CHEMISCHEN INDUSTRIE e.V.

PRESS RELEASE
14 June 2016

Referendum in Great Britain / Impacts on the chemical-pharmaceutical industry

Brexit – bad for the chemical industry on both sides of the Channel

➤ Leaving the EU would be a fatal signal for the economic development in Europe
➤ Consequence: a drop in chemical exports and direct investments
➤ Current trade volume in chemical goods with Great Britain: 18.5 billion euros
➤ Investments of well over 2 billion euros by British investors in the German chemical industry

Extract from VCI press release
REACH Registration

- EEA Countries / REACH Registration dossiers - Overview of all Countries

<table>
<thead>
<tr>
<th>Overview of all Countries</th>
<th>Registrations</th>
<th>Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>11,877</td>
<td>5,149</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>5,488</td>
<td>2,249</td>
</tr>
<tr>
<td>France</td>
<td>4,008</td>
<td>1,989</td>
</tr>
<tr>
<td>Netherlands</td>
<td>3,932</td>
<td>1,762</td>
</tr>
</tbody>
</table>

[Extract from ECHA Registration Statistics, Data as of: 13/05/2016]

- UK registrations - Breakdown by Role in Supply Chain

<table>
<thead>
<tr>
<th>Role</th>
<th># Registrations</th>
<th>% of EEA</th>
<th># Substances</th>
<th>% of EEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>1,213</td>
<td>7.06%</td>
<td>855</td>
<td>14.33%</td>
</tr>
<tr>
<td>Manufacturer and Importer</td>
<td>403</td>
<td>6.95%</td>
<td>318</td>
<td>11.58%</td>
</tr>
<tr>
<td>Importer</td>
<td>1,557</td>
<td>12.87%</td>
<td>733</td>
<td>20.92%</td>
</tr>
<tr>
<td>Only Representative of a non-EU manufacturer</td>
<td>2,315</td>
<td>22.51%</td>
<td>1,115</td>
<td>40.44%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>5,488</td>
<td>12.10%</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

[Extract from ECHA Registration Statistics, Data as of: 13/05/2016]
HOUSE OF LORDS

European Union Committee

23rd Report of Session 2017–19

Brexit: chemical regulation

Ordered to be printed 30 October 2018 and published 7 November 2018
BREXIT: ‘No deal’ Brexit?
Act now to stay on the EU market after the UK’s withdrawal

ECHA/NR/19/04

All companies placing chemical substances onto the markets of the European Union and European Economic Area need to prepare for the United Kingdom’s withdrawal from the EU. New instructions are now available on ECHA’s website.

Helsinki, 8 February 2019 – ECHA recommends companies to prepare for a ‘no deal’ scenario ahead of the UK’s withdrawal on 30 March 2019.

With continued political uncertainty and possible delays in the adaptation of existing systems, companies need to ensure they meet necessary requirements.

To keep substances that are ready for market and avoid potential disruption, companies will need to:

- Prepare for the possibility of a ‘no deal’脱欧 scenario
- Ensure they and their third parties are prepared to handle data and registrations in the UK
- Take measures to comply with the new legislation

The new instructions provide guidance on how to transfer REACH registrations, including information on the steps to take and the legal positions that need to be considered.

How to transfer your UK REACH registrations prior to the UK withdrawal from the EU

February 2019
This draft Statutory Instrument supersedes the draft of the same title which was laid before Parliament on 6th January 2018 and published on 6th January 2019 (ISBN 978-0-11-177606-4)
It is being issued free of charge to all known recipients of that draft Statutory Instrument.

Draft Regulations laid before Parliament under paragraphs 11(1) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2019 No. 000

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

ENVIRONMENTAL PROTECTION

HEALTH AND SAFETY

The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

Made

***

Coming into force in accordance with regulation 1(1)

CONTENTS

1. Citation, commencement and interpretation
2. Amendment of the REACH Regulation
3. Amendment of Titles 1 to 15
4. Transitional provision
5. Amendment of Annexes and Appendices
6. Amendment of the Test Methods Regulation
7. Amendment of the Data Regulation
8. Amendment of the Fees and Charges Regulation
9. Amendment of an authorisation under Article 60(k) of the REACH Regulation
10. Revocation of direct retained EU legislation
11. Amendment of the EEA agreement
12. Amendment of the REACH (Enforcement) Regulations 2006
13. Amendment and revocation of subordinate legislation

SCHEDULE 1 — Amendment of Titles 1 to 15

3
3
3
3
3
3
3
3
3
3
4
4
4
4
Microplastics
ECHA proposes to restrict intentionally added microplastics

ECHA/PR/19/03

ECHA has submitted a restriction proposal for microplastic particles that are intentionally added to mixtures used by consumers or professionals. If adopted, the restriction could reduce the amount of microplastics released to the environment in the EU by about 400 thousand tonnes over 20 years.

Helsinki, 30 January 2019 – ECHA has assessed the health and environmental risks posed by intentionally added microplastics and has concluded that an EU-wide restriction would be justified. If adopted, the restriction could result in a reduction in emissions of microplastics of about 400 thousand tonnes over 20 years.

ECHA’s assessment found that intentionally added microplastics are most likely to accumulate in terrestrial environments, as the particles concentrate in sewage sludge that is frequently applied as fertiliser. A much smaller proportion of these microplastics is released directly to the aquatic environment.

The persistence and the potential for adverse effects or bioaccumulation of microplastics is a cause for concern. Once released, they can be extremely persistent in the environment, lasting thousands of years, and practically impossible to remove. Currently it is not possible to determine the impact of such long-term exposure on the environment.

Data available on effects is limited, particularly for the terrestrial environment, which makes risk assessment difficult. Due to their small size, microplastics and nanoplastics – even smaller particles that are created from the further degradation of microplastics – may be readily ingested and thereby enter the food chain. The potential effects on human health are though still not well understood.
ANNEX XV RESTRICTION REPORT
PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): intentionally added microplastics
IUPAC NAME(S): n/a
EC NUMBER(S): n/a
CAS NUMBER(S): n/a

CONTACT DETAILS OF THE DOSSIER SUBMITTER:
European Chemicals Agency (ECHA)
Annankatu 18, PO BOX 400, FI-00121, Helsinki, Finland

VERSION NUMBER: 1
DATE: 11 January 2019
### Table 2: Brief titles restriction on the intentional use of 'microplastics'

| Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 | 1. Shall not, from [entry into force (EF)] be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.  
2. For the purposes of this entry:  
   a. 'microplastic' means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions ≤ 5 mm, or (ii), for fibres, a length of ≤ 3 mm x ≤ 1 mm and length to diameter ratio of ≥ 3.  
   b. 'microbead' means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.  
   c. 'particle' is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.  
   d. 'polymer-containing particle' means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w.  
   e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas.  
   f. 'gas' means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa.  
   g. 'liquid' means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (1 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa.  
3. Paragraph 2a and 2b shall not apply to:  
   a. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis).  
   b. Polymers that are (bio)degradable, as set out in the [interim] criteria in Appendix X.  
4. Paragraph 1 shall not apply to:  
   a. Mixtures containing microplastics used at industrial sites.  
   b. Medicinal products for human or veterinary use.  
   c. Mixtures that are regulated in the EU under Regulation (EC) No xxx/xxxx on Fertilising Products.  
5. Paragraph 1 shall not apply to:  
   a. Substances or mixtures where microplastics are contained by technical means throughout their use to prevent releases to the environment and incinerated or disposed as hazardous waste at the end of their life-cycle.  
   b. Substances or mixtures where the physical properties of microplastic are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).  
   c. Substances or mixtures where microplastics are permanently incorporated into a solid matrix at the point of use.  
6. Paragraph 1 shall not apply from: |
Proposed REACH Restriction

- Proposed REACH Restriction (ban) would: “Restrict the use of intentionally added microplastic particles to consumer or professional use products of any kind.”

- ‘microplastic’ means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3.

- Certain polymers are currently excluded in the proposal, including:
  - Polymers that occur in nature that have not been chemically modified (other than by hydrolysis).
  - Polymers that are (bio)degradable, as set out in the [interim] criteria in Appendix X.

- The proposal comprises three types of measures:
  - “a restriction on the placing on the market of microplastics on their own or in mixtures where their use will inevitably result in releases to the environment, irrespective of the conditions of use. For some of these uses, a transitional period is proposed to allow sufficient time for stakeholders to comply with the restriction.”
  - “a labelling requirement to minimise releases to the environment for uses of microplastics where they are not inevitably released to the environment but where residual releases could occur if they are not used or disposed of appropriately”
  - “a reporting requirement to improve the quality of information available to assess the potential for risks in the future.”
Proposed REACH Restriction

▪ “...considering the uncertainty associated with measured and/or modelled exposure concentrations of microplastics, [ECHA] has concluded that conventional threshold-based risk assessment cannot currently be carried out for microplastics with sufficient reliability, even with PNEC values derived using large assessment factors e.g. 1 000 to 10 000. In this respect, microplastics are considered to be similar to PBT/vPvB substances...”.

▪ “An important property of microplastics to also bear in mind...is their ‘extreme’, arguably permanent, persistence in the environment. This property results in a situation where any releases contribute to a progressively increasing environmental stock, which would eventually result in exposures exceeding safe thresholds in the future, assuming that sufficient information becomes available to reliably derive them for different compartments. In this respect, the relevant risk characterization could be considered in terms of when will safe thresholds be exceeded, rather than if safe thresholds will be exceeded”

▪ “Based on these two considerations, [ECHA] considers that microplastics should be treated as a non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH Regulation, with any release to the environment assumed to result in risk. Therefore, [ECHA] has concluded that the risks arising from intentional use of microplastics that result in releases to the environment are not adequately controlled”

▪ “[ECHA] considers that a restriction under REACH should minimize releases of intentionally added microplastics to the environment, as per PBT/vPvB substances under REACH, to minimise the likelihood of adverse effects arising as a consequence of the exposure concentrations arising today, or that would arise in the future based on continued use. Minimisation of release would also minimise the potential for cumulative effects arising from the presence of both primary (intentionally added) and secondary microplastics in the environment.”
Next steps?

▪ Title VIII REACH procedure.

▪ ECHA internal check of draft proposal

▪ Public consultations/call for evidence [March-May 2019] although:
  “Stakeholders are requested to provide relevant information to ECHA during the Annex XV Restriction Dossier process, either in any call for evidence or separately during the process.”
  “If a derogation is not proposed by the Dossier Submitter then it will be incumbent on the relevant stakeholders to do so during any public consultation process with a full risk and socio-economic justification accompanying it.”

▪ ECHA RAC and SEAC Opinions [End of 2019?]

▪ Referred to European Commission for adoption

▪ Current proposal contains transitional / phase-in periods.
Other issues
Sustainable Finance Taxonomy consultation
### Selected sectors and climate mitigation activities

**A provisional list of activities under consideration**

<table>
<thead>
<tr>
<th>NACE Macro sector</th>
<th>Status</th>
<th>Activities</th>
<th>Potential NACE Codes</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| C Manufacturing   | Work to begin Jan 2019 (2nd round) | Manufacturing of:  
  - Ferrous and non-ferrous metals  
  - Cement  
  - Chemicals | C 20 Manufacture of chemicals and chemical products  
C 23.51 Manufacture of cement  
C 24.1 Manufacture of basic iron and steel and of ferro-alloys  
C 24.4 Manufacture of basic precious and other non-ferrous metals | Manufacture of basic metals, chemicals and other non-metallic mineral products (including cement) contribute 14.7% of GHG emissions covered by NACE codes. Within these, aluminium, steel, cement and chemicals have been identified for further examination based on emissions intensity and/or importance as raw materials for the low carbon transition. |
## Do no significant harm assessment

<table>
<thead>
<tr>
<th>(5) Pollution</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chemical use: avoid active ingredients that are listed in the Stockholm Convention, the Rotterdam Convention or that are listed as classification la or lb in the WHO recommended Classification of Pesticides by Hazard;</td>
</tr>
<tr>
<td>• Minimise the use of pesticides and favour alternative approaches or techniques, such as non-chemical alternatives to pesticides, in line with the Directive 2009/128/EC on the sustainable use of pesticides;</td>
</tr>
<tr>
<td>• Maintain water and soil quality.</td>
</tr>
</tbody>
</table>
Technical Expert Group on Sustainable Finance: Taxonomy feedback and workshop invitation

- Written feedback
  - 1st Round mitigation activities
  - Usability of the Taxonomy
- Workshops gathering additional expertise
  - 2nd Round mitigation activities
  - Adaptation activities
  - Do no significant harm evaluation

Timeline:
- Dec 18
- 22 Feb 19
- April 19
- June 19
- Prepare Taxonomy report
Feedback on the first round climate mitigation activities

Introduction

Disclaimer:

This invitation for feedback is part of DG FISMA, DG ENV, DG CLIMA and DG ENER ongoing work to develop the taxonomy, for which the Commission has set up the TEG. The action plan on financing sustainable growth – action 1 – requests the group to develop the taxonomy on the basis of broad consultation of all relevant stakeholders. This feedback process is not an official Commission document nor an official Commission position. Nothing in this feedback process commits the Commission nor does it preclude any policy outcomes.

This feedback includes sectors and activities for which the TEG has been able to propose technical screening criteria from pre-existing, market-based taxonomies. The results of this work are provided for open comment.

To the extent possible, criteria for defining substantial contribution and the technical criteria for screening those activities for potential significant harm to other environmental objectives are included. This is in line with framework set out in the proposed taxonomy regulation.

The deadline for providing feedback is 22 February 2019.
THANK YOU

Marcus Navin-Jones

+32 2 645 5097
navin-jones@khlaw.com