Steptoe

International Conference

FOOD CONTACT COMPLIANCE

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Relationship between FCM and REACH compliance - What's up? -

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Content

- REACH and FCM compliance
- Further REACH obligations after May 2018
- How to ensure continued compliance in the supply chain?
- FCM under the BPR
- Brexit considerations

THE REACH REGULATION (Regulation (EC) No 1907/2006)

- Applies since June 2007
- Covers substances on their own, in preparations and in articles
- Requires registration of substances manufactured and/or marketed above 1 MT/year . **Last phase-in registration deadline (for > 1MT) was 31 May 2018**.
- Registration includes: a) a technical dossier; b) chemical safety report (CSR) when required
- Certain (very limited) exemptions: polymers; intermediates; Annex IV (minimum risk) and Annex V (registration deemed inappropriate or unnecessary) substances

THE REACH REGULATION – as amended

▶B ▶C1 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

(Text with EEA relevance) ◀

(OJ L 396, 30.12.2006, p. 1)

Amended by:

		Official Journal		
		No	page	date
▶M1	Council Regulation (EC) No 1354/2007 of 15 November 2007	L 304	1	22.11.2007
▶M2	Commission Regulation (EC) No 987/2008 of 8 October 2008	L 268	14	9.10.2008
▶M3	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008	L 353	1	31.12.2008
▶M4	Commission Regulation (EC) No 134/2009 of 16 February 2009	L 46	3	17.2.2009
▶M5	Commission Regulation (EC) No 552/2009 of 22 June 2009	L 164	7	26.6.2009
▶M6	Commission Regulation (EU) No 276/2010 of 31 March 2010	L 86	7	1.4.2010
▶M7	Commission Regulation (EU) No 453/2010 of 20 May 2010	L 133	1	31.5.2010
▶M8	Commission Regulation (EU) No 143/2011 of 17 February 2011	L 44	2	18.2.2011
▶M9	Commission Regulation (EU) No 207/2011 of 2 March 2011	L 58	27	3.3.2011
▶M10	Commission Regulation (EU) No 252/2011 of 15 March 2011	L 69	3	16.3.2011
▶M23	Council Regulation (EU) No 517/2013 of 13 May 2013	L 158	1	10.6.2013
▶M24	Commission Regulation (EU) No 1272/2013 of 6 December 2013	L 328	69	7.12.2013
▶M25	Commission Regulation (EU) No 301/2014 of 25 March 2014	L 90	1	26.3.2014
▶M26	Commission Regulation (EU) No 317/2014 of 27 March 2014	L 93	24	28.3.2014
▶M27	Commission Regulation (EU) No 474/2014 of 8 May 2014	L 136	19	9.5.2014
▶M28	Commission Regulation (EU) No 895/2014 of 14 August 2014	L 244	6	19.8.2014
▶M29	Commission Regulation (EU) 2015/282 of 20 February 2015	L 50	1	21.2.2015
▶M30	Commission Regulation (EU) 2015/326 of 2 March 2015	L 58	43	3.3.2015
▶M31	Commission Regulation (EU) 2015/628 of 22 April 2015	L 104	2	23.4.2015
▶M32	Commission Regulation (EU) 2015/830 of 28 May 2015	L 132	8	29.5.2015
▶M33	Commission Regulation (EU) 2015/1494 of 4 September 2015	L 233	2	5.9.2015
▶M34	Commission Regulation (EU) 2016/26 of 13 January 2016	L 9	1	14.1.2016
▶M35	Commission Regulation (EU) 2016/217 of 16 February 2016	L 40	5	17.2.2016
▶M36	Commission Regulation (EU) 2016/863 of 31 May 2016	L 144	27	1.6.2016
▶M37	Commission Regulation (EU) 2016/1005 of 22 June 2016	L 165	4	23.6.2016
▶M38	Commission Regulation (EU) 2016/1017 of 23 June 2016	L 166	1	24.6.2016
▶M39	Commission Regulation (EU) 2016/1688 of 20 September 2016	L 255	14	21.9.2016
▶M40	Commission Regulation (EU) 2016/2235 of 12 December 2016	L 337	3	13.12.2016
▶M41	Commission Regulation (EU) 2017/227 of 9 February 2017	L 35	6	10.2.2017
▶M42	Commission Regulation (EU) 2017/706 of 19 April 2017	L 104	8	20.4.2017
▶M43	Commission Regulation (EU) 2017/999 of 13 June 2017	L 150	7	14.6.2017
▶M44	Commission Regulation (EU) 2017/1000 of 13 June 2017	L 150	14	14.6.2017
▶M45	Commission Regulation (EU) 2017/1510 of 30 August 2017	L 224	110	31.8.2017
▶M46	Commission Regulation (EU) 2018/35 of 10 January 2018	L 6	45	11.1.2018

THE REACH REGULATION – main impact

- Article 5: No data, no market

  Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of

  this Title where this is required

- Registration is just the FIRST letter of REACH!
  - Scope updates (nanomaterials, polymers, endocrine disruptors, etc.?)
  - Dossier updates
  - Dossier evaluations
  - Substance evaluations (Authorisation and Restrictions)
  - Classification and labelling
  - Enforcement
- **ALL THESE ALSO COVER FCMs!**

THE REACH REGULATION – further impacts

CHEMICAL SAFETY ASSESSMENT (CSA)

- CSA should be performed for each substance subject to registration above 10 MT/y
- CSR should document the assessment
  - First step: hazard assessment
  - If classified dangerous: exposure assessment
  - Risk characterization: addressing all **identified uses** of the registrant
- Appropriate safety measures need to be communicated in **Safety Data Sheets** (SDS)
- **ALL THESE ALSO COVER FCMs!**

THE REACH REGULATION – further impacts

REQUIREMENTS FOR SDS

- Required when the substance meets the criteria for classification as dangerous
- Information in the SDS should be consistent with the information in the CSA
- The SDS should contain in an annex the relevant exposure scenarios (incl. use and exposure categories) for **all identified uses** as per the CSR

IDENTIFIED USES

- REACH Registration includes information on identified uses of the substance
- If the substance is classified as dangerous, the CSA for REACH includes exposure assessment addressing all identified uses

ALL THESE ALSO COVER FCMs!

THE REACH REGULATION – further impacts

Substances of Very High Concern (Article 57 REACH)

- Human health: Cat 1 or 2 CMR
- Environment: PBT; vPvB
- Or equivalent

Candidate List: different obligations also in articles to allow safe use

- notification: if content > 0.1% and volume > 1MT (Art 7(2) REACH)
- communication: if content >0.1% (Art 33 REACH)

ALL THESE ALSO COVER FCMs!

THE REACH REGULATION – further impacts

AUTHORISATION:

- **SVHC included in Annex XIV** cannot be used after their sunset date unless the use is authorised, exempt or other specific conditions apply (Article 56 REACH)
- Uses (or categories of uses) may be exempted if risk is properly controlled by other specific Community measure (Art. 58(2))

RESTRICTION:

- Substances listed in **Annex XVII** can only be manufactured, placed on the market or used in **compliance with the restrictions** therein.
- **ALL THESE ALSO COVER FCMs!**

Has REACH achieved its goals so far? – In Numbers from ECHA

- 21500 registered substances (vs. > 100 000 existing chemicals and cca. 40 000 estimated substances (for 2018: 6 824 vs. estimated 25000)
  - Minus non-phase-in and intermediates
- 89 750 registration dossiers for all tonnage bands
  - **In average 4 registrants per substance**
- 13 995 companies registered (vs. 28 329 existing companies in EU28 (data: CEFIC Landscape 2018)
- SMEs: only 17% → expected to be the largest number in 2018 (Ueapme)

Has REACH achieved its goal? - Compliance

- The number of registered substances is much lower than expected – are there many substances on the EU market > 1 MT without registration?
- The number of individual registrations for each registered substance is much lower than expected – are there manufacturers/importers on the EU market > 1 MT without registration?
- About half od EU companies have not submitted any registration – are they all only DUs?
- Large number of registration dossiers are non-compliant

ECHA: "it's a bit too early to say"

CEFIC: "we are convinced that the majority of substances … have been successfully registered"

Regulatory Compliance of FCM – a moving target

- **REACH**
- **BPR**
- **…and other regulatory requirements**

What is changing after 1 June 2018? – Legal effects

- No more reliance on pre-registration
  - Except: ECHA newsletter 6 June 2018: "If you have pre-registered or inquired about your phase-in substance, you can register it directly (until further notice, you can still use the pre-registration number)."
  - → pre-registration numbers may still allow you to register
- No more SIEFs
  - Recommendation of Directors Contact Group (COM, ECHA, industry): "co-registrants of phase-in substances to have a functional form of cooperation after 31 May 2018"
  - cooperation should remain in place for other obligations: updates, dossier and substance evaluation, data sharing obligations continue after 1 June 2018
- Registration of all substances only as new: Article 26 inquiry procedure + data sharing duties under Article 27 of REACH
- **ALL OTHER EFFECTS OF REACH CONTINUES ALSO for FCMs!**

What is changing after 1 June 2018? - Company events

- Changes in the supply chain
- Changes in identity/number of registrants
- Changes in volumes
- Changes in information on substance
- Changes in regulation of substance
  - Other REACH processes
  - Other pieces of legislation (BPR, POP, PIC, FCM…)

- ⇨ **Contractual agreements must provide for post-registration events**
- ⇨ **Continued communication in supply chain and "SIEF" is essential**

What should change after 1 June 2018? - ECHA/Commission/MS focus

- **Ensure genuine level playing field via ECHA: focusing on the most severe cases of non-compliance**
  - Empty dossiers
  - Poor quality dossiers
  - Leniency dossiers (exceptional scenarios and pending data sharing disputes)
- **Ensure genuine level playing field via MS Enforcement: focusing on the most severe cases of non-compliance**
  - Substances not registered at all; M/I has no valid registration
  - List of registered substances/registrants to be provided to customs authorities (as the Article 95 List under the Biocidal Product Regulation?)

What is changing after 1 June 2018? - the second Review actions (March 2018)

- Action 1: Encourage registration dossier updates
- Action 2: Improve evaluation procedures
- Action 3: Improve workability and quality of extended safety data sheets
- Action 4: Better tracking of substances of concern in the supply chain
- Action 5: Promote substitution of SVHCs
- Action 6: Simplify the authorisation process
- Action 7: Provide early socio-economic information for possible regulatory measures
- Action 8: Improve the restriction procedure
- Action 9: Further enhance member state involvement in the restriction procedure
- Action 10: Frame the application of the precautionary principle
- Action 11: Greater interplay between authorisation and restriction
- Action 12: Remove overlaps in REACH and Osh legislation interface
- Action 13: **Enhance enforcement**
- Action 14: Support SME compliance
- Action 15: Address fees and the future of Echa
- Action 16: Review registration requirements for low tonnage substances and polymers

FCMs under the BPR

- Products within the scope of Regulation 1935/2004 (the **Framework Regulation**) are no longer excluded from the scope of the BPR
- Scope of the Framework Regulation:
  - Materials and articles, including active and intelligent food contact materials and articles, which in their finished state:
    - are intended to be brought into contact with food; or
    - are already in contact with food and were intended for that purpose; or
    - can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.
- Annex I of Regulation 1935/2004 lists 17 groups of materials covered by its scope; including Plastics, Paper, Rubber, Glass, Ceramics, Silicones, Textiles, Wood; but also Printing inks, Adhesives, and Coatings

Food contact plastics under the BPR

- Plastics Regulation 10/2011 has a **positive list for all authorised additives** (with some important derogations) – the Union list
  - 'additives' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;
  - 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;
- **Surface biocides are considered additives**, so for plastics applications they should be listed on the Union list
- **Process biocides** may still be used as **Polymer Production Aids** (PPAs) are under derogation from the Union list
- **Food preservatives** are **excluded from the scope of the BPR**, as covered by Regulation (EC) No 1333/2008 on food additives

Regulatory analysis – What would be needed?

- Dual obligations:
  - Exclude surface biocides for use in food contact plastics materials and articles from the scope of the Union List under the Plastics Regulation and refer to their authorization under the BPR
  - Review derogation under Article 6 of the Plastics Regulation for Provisional list
  - Coordinate ECHA and EFSA for the active substance authorisation and restrictions in food contact use (SMLs)
- Specific legislative changes in national legislation for incorporating the biocides measures under the BPR – replacing potential binding national rules for biocides in food contact uses

And, if this isn't difficult enough - Brexit considerations – "what if"

- UK Only Representative: Article 8 of REACH "… established in the Community …"
  - → transfer of OR to EU; or
  - → EU Affiliate to act as "Super-importer"
- UK M/I: Article 3(11) of REACH " … established within the Community …"
  - → DUs become importers unless redirect import to an EU importer (tonnage!); or
  - → Nominates an EU OR
- UK will not act as leading authority at EU level
- The European Chemical Industry Council (CEFIC) has urged Brexit negotiators to secure a bilateral agreement between the EU and UK that allows continued British participation in the implementation of regulations administered by ECHA.
- CEFIC also supports the "grandfathering"of existing and approved registrations and authorisations; "minimising the regulatory barrier" for moving chemicals across Europe.

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Let's start:

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