The implications of REACH for plastics compounders in Asia

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1. Scope of the REACH Regulation - provisions specifically related to plastics materials
2. Specific measures for Food Contact Materials: Scope of Food Contact Framework Regulation (FR) and Plastics Regulation (PR) – links to REACH
3. Special classes of materials
4. Interactions and overlaps: potential conflicts and benefits
OUR EU ENVIRONMENT & LIFE SCIENCES TEAM

- **Depth in the chemicals regulatory space:** REACH (including nano), CLP, biocides, **food contact materials**, etc. - active since the respective EU regimes were first proposed and worked at all stages of their implementation.

- **Capacity:** the largest environment and life sciences regulatory practice of any law firm in Brussels – 10 full time professionals.

- **Recognition:** consistently ranked by legal directories in the top tier for Chemicals and Environment.

- **Unique litigation experience:** in proceedings related to EU chemicals legislation before the ECHA's Board of Appeal and before the European Courts.
  - Several appeals filed (and won!) in 2015 and four legal cases currently pending before the European Courts.
THE REACH REGULATION

- **REACH** (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals)
  - **Registration**: by 2018 all substances M/I above 1 MT will need registration - unless exempt
  - **Evaluation**: ongoing - may result in further requests or risk of non-compliance
  - **Authorization**: Annex XIV listing is ongoing - results in further data to support certain uses - risk of non-compliance and withdrawal from market
  - (and **Restriction** of): Annex XVII listing is ongoing – substances are banned unless meet the conditions
  - **Chemicals**: covers all substances above 1 MT, only few exemptions
SCOPE OF REACH REGULATION

– Covers substances on their own, in preparations and in articles (phase-in and new)
– Requires registration of substances manufactured and/or marketed above 1 MT/year
– Registration includes: a) a technical dossier; b) chemical safety report (CSR) when required
– Certain (limited) exemptions: polymers; intermediates; Annex IV (minimum risk) and Annex V (registration deemed inappropriate or unnecessary) substances
**RISK MANAGEMENT OPTION ANALYSIS (RMOA)**

- **Purpose**: to decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern on the basis of case-by-case analysis.

- **RMOA is a voluntary process**

- **RMOA can conclude that regulatory risk management is required for a substance (for example, harmonised classification and labelling, inclusion on the Candidate List, restriction, other EU legislation) or that regulatory action is not required.**

- **Public Activities Coordination Tool (PACT), allows stakeholders to predict which substances may be addressed by formal risk management actions in the future.**

- **Opportunity** to consider best business strategy to address substances of potential concern
THE SVHC ROADMAP

- Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020
- EU-wide commitment to include all relevant currently known substances of very high concern (SVHCs) in the Candidate List by 2020
- Groups of substances to be covered by the implementation plan:
  - Carcinogens, mutagens, reprotoxicants (Categories 1A/1B),
  - Sensitisers,
  - Persistent, bioaccumulative and toxic (PBTs) or very persistent, very bioaccumulative (vPvBs),
  - Endocrine disruptors (EDs), and
  - Petroleum/coal stream substances that are CMRs or PBTs.
**REACH: CANDIDATE LIST**

- **Candidate List**: different stakeholder obligations in articles to allow safe use
  - notification: if content > 0.1% and volume > 1MT
  - communication: if content > 0.1%

- Approved substances in regulated applications - such as substances *permitted in food contact applications* - may get identified on the Candidate List, triggering REACH obligations such as
  - **Authorisation** and/or
  - **Restriction** (no volume trigger!)
SVHC included in Annex XIV can’t be used after their sunset date unless the use is authorised; exempt or other specific conditions apply (Art. 56)

Uses (or categories of uses) may be exempted if risk is properly controlled by other specific Community measure (Art. 58(2))

As EU food contact legislation controls the human health hazards of substances, substances used in FCM can be considered exempt from authorisation if their SVHC properties relate to human health (Art. 56(2))

Question: If a Candidate List substance with environmental hazard properties is listed on the Union list, is it necessary to apply for the authorization of this use on Annex XIV?
REACH: RESTRICTION

- Substances listed in Annex XVII can only be manufactured, placed on the market or used in compliance with the restrictions therein. Food contact uses do not enjoy any specific exemptions.

- **Question**: Can a food contact substance listed on the Union list be proposed for Annex XVII listing restricting food contact use?

- **Question**: What is the interplay between REACH Authorisation/Restriction and Article 3 of the Framework Regulation?
REACH

- **Article 57(f):** “The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58: […] (f) substances — such as **those having endocrine disrupting properties** or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59” (emphasis added).

- **Article 138(7):** “By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals” (emphasis added).
SPECIAL CLASS: NANOMATERIALS

- Need for harmonized approach on nanomaterials between horizontal (REACH) and vertical (FCM) legislation
- Under Plastics Regulation 10/2011 substances in nanoform shall be explicitly authorised
- Under REACH the nanoform of a substance can be registered (“phased-in”) together with its bulk form
- Is nano “identifier” or “characteriser”? 
REGULATORY CHALLENGES: Specific measures for food contact materials


- Under **Article 5** of the FR **specific measures** may be adopted for the groups of materials covered by the FR - **Plastics are covered**

- Such a specific measure may include the **List of Substances authorized** for use in the manufacturing - **Union list of permitted monomers and additives in food contact plastics materials and articles**

- Importantly, **Article 8(2)** of the FR provides that **no substance shall be authorized unless it has been adequately and sufficiently demonstrated that, when used under the conditions to be set in the specific measures, the final material or article satisfies the requirements of Article 3 and, where they apply, Article 4 of the FR**

- **Main principle: Designed to be fit for purpose**
REFERENCES TO REACH IN THE FR

Whereas (12) of the FR:

- When specific measures include a list of substances authorised within the Community for use in the manufacture of materials and articles intended to come into contact with food, those substances should undergo a safety assessment prior to their authorisation. The safety assessment and authorisation of those substances should be without prejudice to the relevant requirements of the Community legislation concerning the registration, evaluation, authorisation and restriction of chemicals.

- Hence, REACH compliance is a prerequisite substances not properly (pre)-registered, or restricted or authorised under REACH can’t be used even if they comply with the food contact legislation.

- This overlap between the two regimes creates important supply chain obligations – still confusion in requirements
# DEFINITIONS

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<th>REACH</th>
<th>FOOD CONTACT</th>
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<td><strong>Substance</strong>: a chemical element and its compounds in the natural state or obtained by any manufacturing process [..] Article 3(1)</td>
<td><strong>Materials and articles</strong>: in their finished state are intended to be, expected to be or are already been brought into contact with food – covering all substances and articles</td>
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<td><strong>Article</strong>: an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition</td>
<td><strong>Monomer or other starting substance</strong>: a substance undergoing any type of polymerisation process to manufacture polymers and to modify existing natural or synthetic macromolecules</td>
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<td><strong>Monomer</strong>: a substance capable of forming covalent bonds with additional like or unlike molecules under relevant polymer forming conditions</td>
<td><strong>Polymer</strong>: any macromolecular substance obtained by a polymerisation process. Monomers are the repeating units in polymers forming its backbone.</td>
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<td><strong>Polymer</strong>: a substance consisting of a sequence of one or more types of – at least three - monomer units. Monomer units mean the reacted form of a monomer in the polymer</td>
<td><strong>NIAS</strong>: an impurity in the substance used or a reaction intermediate formed during the production process or a decomposition or reaction product</td>
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<td><strong>Impurities; By-products</strong>: No specific definition in the legal text</td>
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[neurodiversity, language, accessibility]
IMPACT OF DIFFERENCES IN DEFINITIONS

- What should be considered a “registered monomer”?
- What is the status of residual monomers in the polymer?
- What is considered an impurity?
- What is considered a nanomaterial?
GENERAL SAFETY REQUIREMENTS

Article 3 of the FR states:

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (a) endanger human health; or
- (b) bring about an unacceptable change in the composition of the food; or
- (c) bring about a deterioration in the organoleptic characteristics thereof.

► Manufacturing for food contact should comply with GMP (Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food)

► Compliance includes requirement on “designed to be fit for purpose” – food contact use is among identified uses under REACH
REACH: IDENTIFIED USES

- REACH Registration includes information on identified uses of the substance
- If food contact use is intended, REACH dossier refers to this use
- If the substance is classified as dangerous, the CSA for REACH includes exposure assessment addressing all identified uses
- For food contact end uses the CSR does not need to include human health risk considerations
REACH: 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)
REACH: 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
WHAT CAN BE EXPECTED

- **REACH:**
  - New inclusions in the SVHC list (a number of substances identified already)
  - New inclusions in Annex XIV - (most recently) DEHP was identified as an “endocrine disruptor” in Annex XIV to the REACH Regulation
  - Continued investigation of suspected ED under REACH Substance Evaluation procedure (initiated by CORAP listing)

- **FOOD CONTACT:**
  - Ban of already permitted substances if identified/potential ED??
CONCLUSIONS: CONFLICTS

- Conflict between REACH and FCM definitions
- Potential conflict between a proprietary REACH dossier (Registration and/or Authorisation) and a public Union list authorisation under the food contact legislation
- Potential conflict for imported active packaging materials with intended release of a substance. The substance might require REACH registration (Art. 7(1)), BUT if the released substance becomes a food additive, Art. 2(5)(b) exemption applies
- Potentially conflicting requirements for endocrine disruptors and nanomaterials
CONCLUSIONS: BENEFITS

- Data submitted for authorisation of a substance as a FCM can be used to support its REACH compliance.
- And vice versa: REACH registration can reduce data requirements for a food contact authorisation dossier.
- CSR can support FR Art.3 compliance requirements.
- The manufacturer of a substance on the Union list can’t advise against its use for food contact under REACH.
- The conflict between the listing of a substance on the Union list and its proprietary REACH registration should be resolved.
- Any potential liability issues related to the intentional or unintentional misuse of a substance, material or article for food contact could be prevented by fine-tuning their CSRs.
LET’S START

QUESTIONS?
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