

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blue background. The lenses are metallic and have some text on them, including "Plan" and "0.25".

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REACH Compliance for Polyolefin Additives

*Dr. Anna Gergely, Director EHS Regulatory
STEPTOE & JOHNSON LLP, Brussels*

agergely@steptoe.com

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OUTLINE

- REACH: Scope and Definitions
- Registration Exemptions
- Monomers and Additives in Polymers
- Intermediates
- Substances in Articles
- REACH requirements in the packaging supply chain

The REACH Regulation: Scope

- REACH (Regulation (EC) No 1907/2006) covers the manufacture, import, placing on market and use of chemical “substances” on their own, in preparations and in articles
- Few **exclusions** from overall scope of REACH, including:
 - ✓ Non-isolated intermediates
 - ✓ Waste
- Several **exemptions** from some REACH requirements, including:
 - ✓ Polymers
 - ✓ Intermediates
 - ✓ Annex IV and V

REACH: Definitions

- Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, **including any additive necessary to preserve its stability** and any **impurity** deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition
- Preparation means a mixture or solution **composed of** two or more substances
- Intermediate means a substance that is manufactured for and consumed in or used for chemical processing in order to be **transformed into** another substance
- Article means an object which during production is given a **special shape, surface or design** which determines its function to a greater degree than does its chemical composition

REACH: Definitions (cont.)

- Monomer means a **substance** which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process
- Polymer means a **substance** consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
 - (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
 - (b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a "monomer unit" means the **reacted form of a monomer** substance in a polymer

Polymers and Additives

- Polymers are **exempt** from Registration, but not from Authorization
- Exemption from Registration is **temporary** (until criteria are developed to subject some polymers to Registration)
- Polymer producers/importers must **register the non-registered monomers/substances** if contained in the finished polymer at $\geq 2\%$ w/w and ≥ 1 ton per year
- Additives, if needed to **stabilize** the polymer (antioxidants etc.) are included in the polymer definition
- Technical additives (colorants, flame retardants etc.) need to be considered for registration (unless otherwise exempt)
- Other substances (such as catalysts etc.) may be considered **intermediates**

Intermediates

- **Non-Isolated Intermediates** (not removed from synthesis equipment):
 - Excluded from the scope of REACH
- **On-site and Transported Isolated Intermediates:**
 - Subject to reduced registration (only if strictly controlled conditions are met)
 - Subject to Evaluation (including further testing)
 - Exempt from Authorization
- **Isolated Intermediates (not meeting the requirements above):**
 - Fully subject to REACH as other substances

Intermediates (cont.)

Monomers: A specific intermediate category

- Subject to “full” registration **by the monomer manufacturer/importer** even if used as on-site or transported isolated intermediates (no exemption)
- Subject to “full” registration **by the polymer manufacturer/importer** if:
 - Not already registered by an actor up the supply chain
 - The polymer consists of $>2\%$ w/w of the monomer
 - The total quantity are > 1 tonne per year

Other Reactants: intermediates

Exemptions from Registration

If otherwise conditions for registration are met;

- ✓ **Annex IV:** limited list of substances which present minimum risk
 - tallow, hydrogenated; starch; glycerides etc.
- ✓ **Annex V:** specific cases for substance categories for which registration is deemed inappropriate
 - Products of reactions incidental to exposure to environment (aging)
 - Products of unintended reactions (when additives function as intended and chemical reactions occur)
 - By-products (unless marketed themselves)

REACH Requirements related to Articles

- Substances in articles are differentiated from substances as such or in preparations
 - ✓ Obligation to register substances intended to be **released** from articles (lubricants, adhesives, etc.)
 - ✓ Obligation to notify Candidate List Substances of Very High Concern (**SVHC**) in articles
 - ✓ Obligation to obtain authorization to incorporate **SVHCs**
 - ✓ Obligation to communicate safety information for articles containing SVHCs on the Candidate List to professional users/distributors and in some conditions consumers
 - ✓ **Issue:** Effect of a Candidate List substance present as an **impurity** in an article

The Candidate List

- The above obligations are triggered by the establishment of a “Candidate List” of the substances that fulfil the criteria for eventual inclusion in the list of substances subject to Authorization (Annex XIV)
- This list contains CMRs (category 1 and 2); PBTs, vPvBs and potentially, substances of equivalent concern
- Today there are almost 30 substances on the Candidate List; triggers a series of requirements

The Candidate List (cont.)

- Brominated flame retardants (hexa-bromocyclododecane)
- Phthalates (BBP,DEHP,DBP, DIBP)
- PAHs (anthracenes)
- Arsenic; Cobalt; Lead derivatives
- Ceramic fibres (Aluminosilicates and Zirconia aluminosilicates)
- If present in any article > 0.1% w/w: Communication obligation
- If present > 0.1% and > 1MT/year: Notification obligation (after June 2011)

Communication of information on Articles

➤ Article 33: Communication down the supply chain

As soon as a substance of very high concern (SVHC) is identified and included in the candidate list, “suppliers of articles” (i.e. article producers/importers, professional users and distributors) shall:

- ✓ Provide “recipients” of articles with information allowing the safe use of articles containing a SVHC $> 0,1\%$ w/w, including, as a minimum, the name of the substance
- ✓ Communicate the same information to the consumers upon request (within **45 days** of receipt of the request)

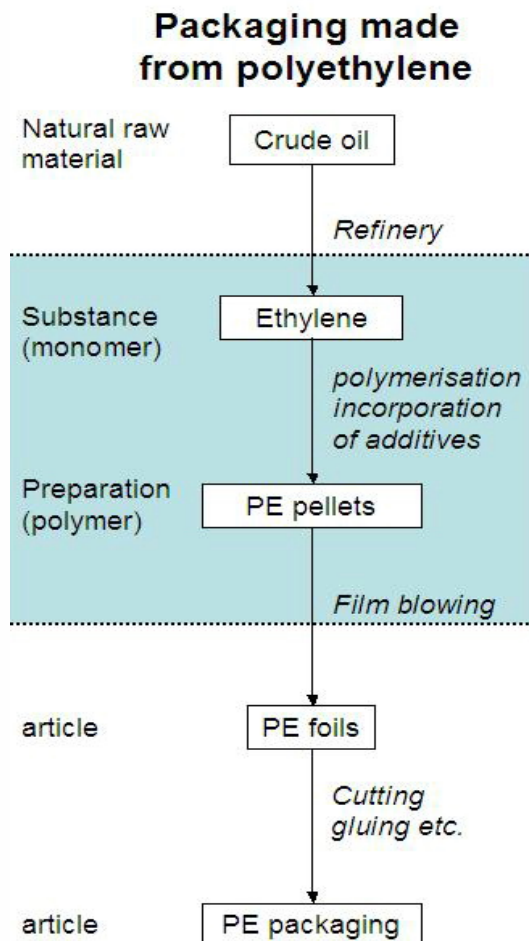
➤ Communication is required regardless of:

- ✓ Tonnage of SVHC in the article
- ✓ Whether the SVHC has been registered or notified

Some Uses for Plastics under REACH

- Food Contact applications:
 - ✓ Subject to Registration, Evaluation, Authorisation and Restrictions
 - ✓ Exempted from Human Health part of the CSR
 - ✓ Exempted from Authorisation for CMRs and substances of equivalent concern to human health
- Medical Devices applications:
 - ✓ Subject to Registration, Evaluation, Authorisation and Restrictions
 - ✓ Exempt from Authorisation for CMRs and substances of equivalent concern to human health
- Water Pipe applications
 - ✓ Fully subject to REACH requirements. No exemptions
- Drug Packaging
 - ✓ Fully subject to REACH requirements. No exemptions

Polymers as Articles



Considerations for Articles under REACH

- REACH provisions on articles are complex and several issues are still open for interpretation
- Borderline cases and unclear criteria with potentially serious consequences
- Even to establish what is an article may not be straightforward
- Practical difficulties to guarantee that an article does not contain Candidate List substances
- Blacklist effect: substitution even before a SVHC gets on the Candidate List

Impact of REACH on Polymer Manufacturers

- ✓ Administrative burdens (dedicated services)
- ✓ Testing and petitioning costs
- ✓ Need for reformulation due to:
 - Delisting of small volume, specialty chemicals
 - Delisting of substances of very high concern
- ✓ Need to revise the supply chain
 - Increased costs due to reduced availability of chemicals from reliable suppliers
 - Potential loss of export markets
 - Cheaper production of articles outside the EU

Impact of REACH on Additive Manufacturer

- Is the additive used to stabilize the polymer? - no registration
- Is the additive exempt (Annex IV or V)? - no registration
- Can the additive be considered an intermediate? – reduced requirements for registration
- Is the additive present in the final polymer as a component of a preparation? – registration as REACH requires
- Is the additive on the Candidate List?
 - ✓ Need to fulfil other obligations (notification, communication)
 - ✓ May need to get authorisation for the intended uses
- Issue: Candidate List substances present as impurities
 - ✓ Same obligations as for other CL substances?

To avoid...



THANK YOU

Happy to answer your questions now!

**Step toe & Johnson is ready to advise you
on all your REACH related issues**