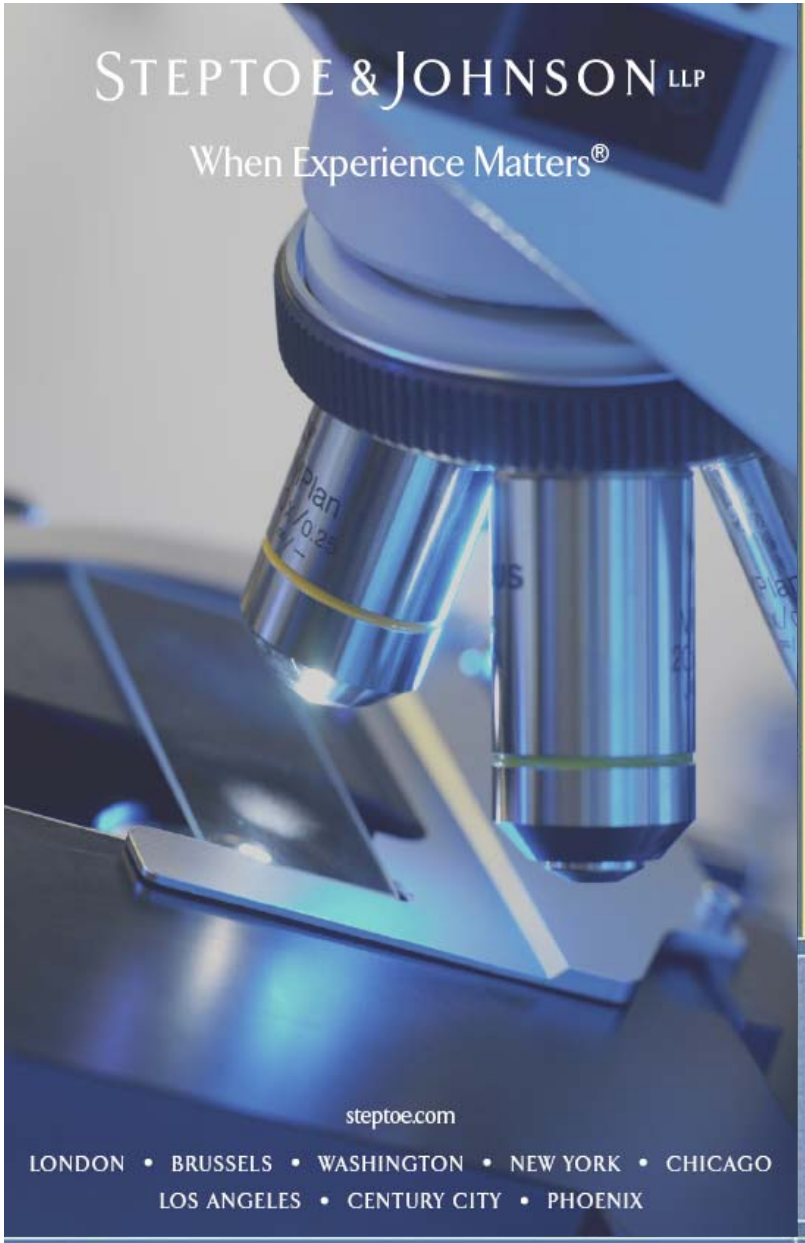

Articles

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OVERVIEW

REACH places specific duties and obligations on manufacturers, importers and downstream users of substances:

- **on their own**
- **in preparations**
- **and in articles (i.e. not articles *per se*)**

For substances which have not already been registered for the *specific* use in an article detailed rules apply.

KEY POINT: If importer (or manufacturer in EU) does not have to register a substance this removes a huge cost and administrative burden. Strong interest in having a product acknowledged as an article incorporating a substance which is exempt from registration requirement.

OVERVIEW

Substances in articles are subject to:

- **Registration ~ if *intentional* release (or possibly *unintentional* release if exposes humans or environment to risk)**
- **Notification ~ for SVHCs *unintentionally* released if exposes humans or environment to risk**
- **Information Requirements ~ on safe use**
- Restrictions
- Authorisation

WHAT IS AN ARTICLE?

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- **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**

Art. 3(3)

WHAT IS AN ARTICLE?

- **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**

***Shape*: its form (depth, width, height)**

***Surface*: outmost layer of the object**

***Design*: the way it is arranged to accomplish a particular purpose (e.g. twist of fibres in a textile)**

***Function*: "What is it used for?" (e.g. a pen to write, a battery to provide energy etc.)**

See *draft* RIP 3.8

WHAT IS AN ARTICLE?

- **Composed of one or more substances or preparations.**
- **May contain one or more materials: natural *(wood, wool etc.)* or processed *(PVC or steel etc.)*.**
- **Most products in private households and industries are articles (*furniture, clothes, vehicles, books, toys, kitchen equipment, electronic equipment etc.)*.**

WHAT IS AN ARTICLE?

Notion of "article" is not new to EU chemicals regulation but some *borderline cases* remain:

- **Substance/preparation in container (the container is an article in itself) *versus* substance/preparation which is part of an article**

- **Solids which are substances/preparations (e.g. metal bars, plates of alloys, plastic pellets) may be further processed *versus* them being part of an article)**

In September 2007 *draft* RIP 3.8 will be considered by Commission Sub-Group on Substances in Articles - may offer greater clarity but not legally binding. Possibility of living Annex to RIP 3.8 on borderline cases.

WHAT IS AN ARTICLE?

"FUNCTIONAL CONTAINERS" WITH SUB./PREP.

Art. 6: Register ***Intended release*** **Not part of an article just in a container or carrier material**	**Art. 7(1): Register** ***Intended release*** **Part of an article**	**Art. 7(2): Notify** ***Unintentional release & exposure of SHVC to humans or env.*** **Part of an article**
Chemical composition is most important for function	*Shape and design* most important for function	*Shape and design* most important for function
• S/P in spray can • Air Freshener with spray nozzle • Soap in pump flasks • Fire extinguisher • Ink/toner in printer cartridge • Pens • Firecracker • Car Battery • Correction Pen or Roller	Process of clarification is shifting products from Art 7(1) to Art. 6.	• Thermometer • Cooling Elements • Articles with decorative liquids

WHAT IS AN ARTICLE?

"MATRIX" WITH SUB. / PREP.

Art. 6: Register ***Intended release*** **Not part of an article just in a container or carrier material**	**Art. 7(1): Register** ***Intended release*** **Part of an article**	**Art. 7(2): Notify** ***Unintentional release & exposure of SHVC to humans or env.*** **Part of an article**
Chemical composition is most important for function	*Shape and design* most important for function	*Shape and design* most important for function
• Air freshener in a gel-matrix • Soap bar • Brake linings • Cleaning wipes/sponge	• Shoe polishing sponge • Adhesive tape (unless delaminates or applies a substance in which case Art. 6) • Scented candle	• Textiles with biocides, fungicides, flame retardants, water repellants, anti- wrinkle treatment etc. *and remain in the textile*. • Wood furniture treated with biocides. • Electronics treated with flame retardants. • Cars treated with flame retardants.

WHAT IS AN ARTICLE?

When does a preparation become an article?

Product Form	Preparation	Article
Steel Bar*	√	
Steel Coil	√	
Steel Foil	√	
Steel Sheet & Strip	√	
Cast, Seamless and Welded Steel Pipe & Tube		√
Polyethylene pellets	√	
Polyethylene packaging		√

* However, bar, coil foil, sheet, strip, wire rod and wire could be regarded as articles because their shape or surface finish is more important than their chemical composition and they will not undergo a change of molecular structure (i.e. they will not be remelted).

REGISTRATION

REGISTRATION

Any producer* or importer+ of articles shall submit a registration (general deadlines for pre-registration and registration apply) to the Agency for any *substance* contained in those articles, if it is:

(a) present in those articles in quantities totalling > 1 tonne per producer or importer per year; and

(b) intended to be released under *normal or reasonably foreseeable* conditions of use.

Art. 7(1)

* Makes or assembles an article within the Community

+ Established within the Community and responsible for import

REGISTRATION

However Agency has residual power to require registration of any *unintentionally* released substance if:

(a) present in article > 1 tonne per producer or importer per year; and

(b) the Agency has grounds for suspecting that:

(i) the substance is released from the articles, and

(ii) the release of the substance from the articles presents a risk to human health or the environment.

Art. 7(5)

REGISTRATION

"Intended to be released" means (*draft* RIP 3.8):

Release is *essential* for the *end use* function of the article without which it would not work sufficiently: ink released from pen or detergent from cleaning wipe etc. (Function should be determined by producer's intention (see label texts, advertisements etc.) not by the consumer's possible views on the issue.)

Release *contributes* to a *quality* or *minor* function of the article providing *added value* which is not directly connected with end use function: perfumed eraser or scented candle etc.

REGISTRATION

Intended to be released under *normal or reasonably foreseeable* conditions of use. Reasonably foreseeable conditions of use are those outside the normal use originally intended by the article producer but which may be foreseen because of the form, shape or function of the article.

Reasonably foreseeable	Not reasonably foreseeable
• accidents of high likelihood (e.g. fragile containers) • misuse (not in accordance with function but still predictable e.g. by child) • extremely intensive uses	• uses clearly excluded by producer/importer of article for profession/industrial use • uses clearly advised to avoid by product design or warning labels • clear misuses

REGISTRATION

Unintentional release (*draft* RIP 3.8):

- during removal of impurities from semi-finished or finished article during production process (before marketing as finished product)

- during use or maintenance *and* is meant to improve the product quality in a wide sense *or* the safety as a side effect but does not contribute to the function of the article (e.g. chemicals from processing washed out of clothes)

- of substances formed during chemical reactions (e.g. article catches fire or ozone released from copying machines)

NOTIFICATION

NOTIFICATION

Any producer or importer of articles shall notify the Agency if a substance is present in those articles which:

- meets the criteria in Article 57 (i.e. a SVHC which may be listed in Annex XIV and be subject to Authorisation);
- is identified in accordance with Article 59(1) (i.e. identification of Art. 57 candidate list substances); present in those articles >1 tonne per producer or importer per year; and
- present above a concentration of 0.1 % weight by weight (% of whole article or per homogenous part/component/material?).

Art. 7(2)

AND there is exposure to humans or the environment during normal or reasonably foreseeable conditions of use *including* disposal.

Notification requirement applies 6 months after a substance is identified, from 1 June 2011.

NOTIFICATION

Notification information must *include*:

- identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
- registration number(s) referred to in Article 20(1), if available;
- identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
- classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
- brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
- tonnage range of the substance(s)

NOTIFICATION

Notification not required if:

- producer or importer can *exclude* exposure to humans or the environment
- during *normal* or *reasonably foreseeable* conditions of use
- including disposal (implications for end of life treatment)

In such cases, the producer or importer shall supply "appropriate instructions" to the recipient of the article.

Art. 7(3)

INFORMATION REQUIREMENTS

INFORMATION REQUIREMENTS

Duty on "any supplier of an article" to communicate to the recipient (excluding consumer), "sufficient information" on substances in it if:

- meet the criteria in Article 57 (i.e. a SVHC which may be listed in Annex XIV and be subject to Authorisation);
- identified in accordance with Article 59(1) (i.e. identification of Art. 57 candidate list substances); and
- present in a concentration of 0.1 % weight by weight.

Article 33(1)

Freestanding obligation - no requirement that recipient asks for information.

Silent on fees - implies that these may be permitted.

INFORMATION REQUIREMENTS

Supplier of an article: any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market*.

Sufficient information: that which is available to the supplier, to allow *safe use* of the article including, as a minimum, the name of that substance.

* Placing on the market means: supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

INFORMATION REQUIREMENTS

If consumer *requests* information then same requirement to supply "sufficient information" applies (for substances which meet the same criteria):

- free of charge
- within 45 days of receipt of the request

Expect requests from consumer NGOs.

Article 33(2)

INFORMATION REQUIREMENTS

Information requirement provisions technically apply from 1 June 2007 but information requirement is linked to the existence of a candidate list so no effect until it is established (probably 2nd half of 2008/1st half 2009).

Should be no retrospective effect to cover interim period.

REACH is silent on practicalities of how/when information is required.

PRACTICAL STEPS

PRACTICAL STEPS

Questions to ask yourself:

- What products do I produce/import?
- Which products are articles under REACH?
- What substances are in the articles I produce/import?
- Is marketing/labelling material consistent with my classification of the product as an article?
- Have the substances already been registered for use in that article?
- If they have not been registered for that use, is there intentional release?

PRACTICAL STEPS

Questions to ask yourself:

- Is there exposure (but not intentional release)?
- Do the substances meet criteria for SVHCs (if so should I consider phase out)?
- What concentration levels?
- What total volumes?
- Am I prepared to provide information on the substances to recipients including consumers?

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