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BARBOUR CPD SEMINAR REACH - INTERPRETATION

PLASTIC
COMPONENTS
ARTICLES
EXEMPT

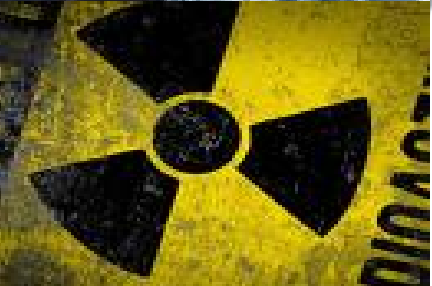


BOAT
One article or lots
of articles?





STEEL TUBES
ARTICLE
EXEMPT





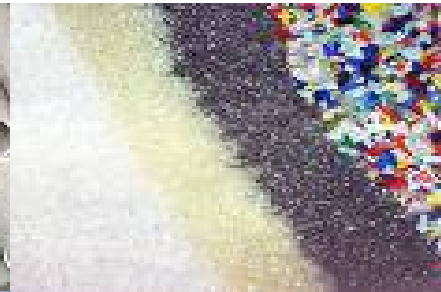
PLASTIC PELLETS
PREPARATION
IN SCOPE





COPPER INGOTS
SUBSTANCE -
inscope





CANDLES
ARTICLE CONTAINING
SUBSTANCES
DESIGNED FOR
RELEASE





RECYCLED PAPER





WATER
EXEMPT





ROAD SALT
Natural substance -
exempt





BIOCIDE
Active ingredient
considered to be
registered







RADIOACTIVE
SUBSTANCE
exempt





COSMETICS
In scope





PAINT
preparation –
constituents in
scope





PHARMACEUTICALS
Ingredients exempt





INK CARTERIDGE –
container of a
preparation

REGISTRATION OF SUBSTANCES IN ARTICLES

- An **Article** is defined as:
‘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.’
- An importer or producer of articles needs to **register** a substance in an article if
 - *The substance is present in those articles in quantities of 1 tonne or more per year per producer/importer and*
 - *The substance is intended to be released under normal or foreseeable conditions of use*
- **The above does not apply if the use in the article has been covered in a registration by an actor up the supply chain**

REGISTRATION OF ARTICLES

- ‘an **article** is an object which during its production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition’
- Paper
- Fibres
- Polymer pellets
- Metal wire
- Wet wipe
- Adhesive tapes
- Printer cartridge
- Felt tipped pens

REGISTRATION OF ARTICLES

- ***Intended release*** under normal or foreseeable conditions of use
 - Car tyres
 - Brake pads
 - Perfumed candle
 - Fabric treatments

SUBSTANCES OF VERY HIGH CONCERN (SVHC)

- SVHC will be those substances that are placed in the candidate list for authorisation
- Types of substances considered as SVHC
 - Class 1&2 carcinogens
 - Class 1&2 mutagens
 - Class 1&2 toxic to reproductive systems
 - PBT's (persistent, bio-accumulative and toxic)
 - vPvB (very persistent and very toxic)
- Initial candidate list will have only 12-16 substances
- Final list will have around 150 substances
- **SVHC may require to be notified by article producers/importers**

NOTIFICATION OF SUBSTANCES IN ARTICLES

- For articles that contain ***substances of very high concern*** the producer/importer of the article will need to **notify** the Agency and customers if:
 - the substance is present in a total of 1 tonne per year or more
 - and in a concentration above 0.1% (w/w).
- The Agency may then request registration.

REGISTRATION - INTERMEDIATES

- *An intermediate is a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another chemical substance (synthesis)*
- *Non-isolated intermediates – exempt*
- *Isolated intermediates (production and synthesis take place on the same site) – reduced hazard data set requirements*
- *Transported intermediate (manufacture and synthesis take place on different sites) – reduced hazard data set requirements*

To qualify as intermediates full technical control and containment must be guaranteed

REGISTRATION - POLYMERS

- A manufacturer or importer of a polymer shall submit a registration for monomer substance(s) or any other substance(s), ***that have not already been registered by an actor up the supply chain***, if both of the following conditions are met:
 - The polymer consists of 2% (w/w) or more of such monomer or other substance in the form of monomeric units and chemically bound substance(s)
 - The total quantity of such monomer substance(s) or other substances(s) makes up 1 tonne or more per year

ONLY REPRESENTATIVE

- Non EU manufacturers wishing to import into the EU can appoint an '*only representative*' who for purposes of REACH acts as an importer and registers the substance(s) with the ECHA
- The '*only representative*' is not an agent
- Customers of the non EU manufacturer are classed as DSUs and thus avoid registration
- The '*only representative*' needs to be a legal person or entity within the EU. They make the pre-registration/registration and maintain records of annual tonnages to all EU customers of the non-EU manufacturer for the substance(s). They also are the communication link with the ECHA and with customers (in respect of REACH issues e.g. SDS)

DOWNSTREAM USERS – BUSINESS MANAGEMENT

- It is anticipated that REACH will result in a significant reduction in the number of chemicals in the marketplace (15-20%) therefore it is important that DSUs take steps to manage their supply chain
- DSUs should undertake a ***raw material vulnerability assessment*** to identify those substances at risk of supply disruption and put in place plans to manage any changes of supplier or substances that may result from implementation of REACH. This may include pre-registration
- DSUs should be seeking assurance that their suppliers plan/have pre-registered the substances they use (and subsequently register them).

BUSINESS IMPACT OF REACH

- Compliance management
- Management of Data sharing/SIEF's/Consortia
- Confidentiality (protection of/ lack of, competitors/general public)
- Data management
- Costs/financial management
 - Registration fees
 - Testing and dossier preparation costs
 - Reformulation
 - SIEF/Consortia

BUSINESS IMPACT OF REACH

- Product/substance rationalisation (15-20% reduction in substances available)
- Manufacturer/Importer/DSU portfolio rationalisation
- Sourcing strategy
- Product viability
- Product integrity/quality/validation
- Managing customer expectations
- Opportunities

SUMMARY

- REACH is the biggest change to the management and control of chemicals in the EU since the first Dangerous Substances Directive in 1967.
- It will impact not only on chemical producers but also users of chemicals, article producers and their supply chains.
- REACH needs to be managed at a strategic level – it is not the sole province of the SHE or regulatory manager.
- REACH is here now and the work of managing for it starts now!

SOURCES OF INFORMATION & ASSISTANCE

- European Chemicals Agency
 - <http://echa.europa.eu>
- UK Competent Authority
 - www.hse.gov.uk/reach/index.htm
- Defra
 - www.defra.gov.uk/environment/chemicals/reach
- The REACH Centre Ltd.
 - www.thereachcentre.com
- REACH Ready
 - www.reachready.com
- ReFac
 - www.refac.eu
- REACHCentrum
 - www.reachcentrum.org