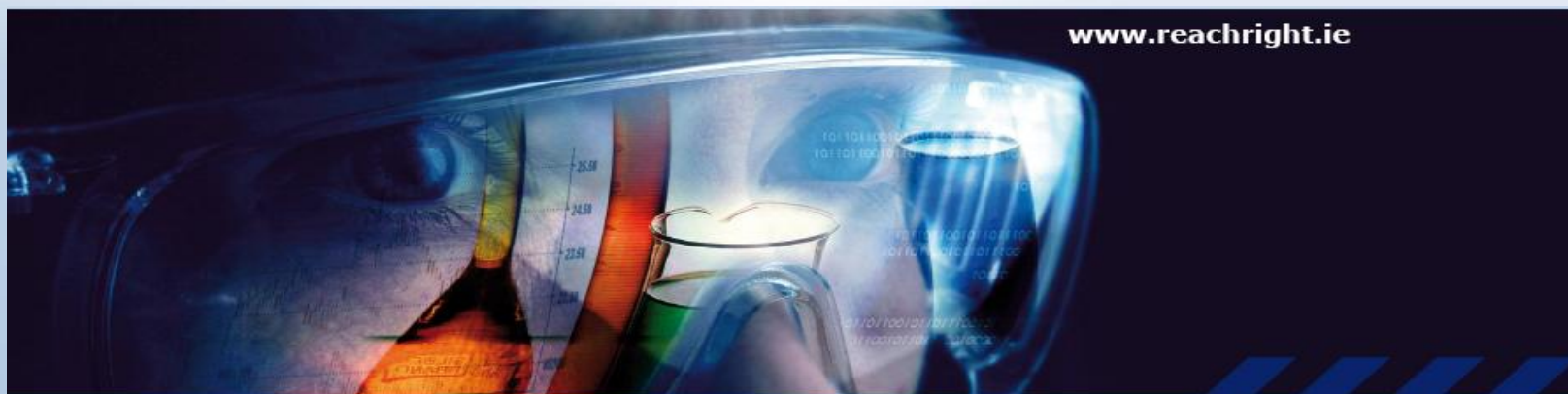


REACH/CLP Update



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IMFI 12th May 2011



HEALTH AND SAFETY
AUTHORITY

REACH

REGISTRATION, EVALUATION AND
AUTHORISATION OF CHEMICALS



Overview

- Update on REACH Registration
- Duties for Article producers and Importers
- Substances of Very High Concern and the Candidate List
- Authorisation
- SDS & CLP
- Role of HSA & ECHA
- Guidance Available

REACH Registration

- Registration applies to all substances Manufactured or Imported at 1 t/yr
- M/I of substances required to submit a Registration Dossier to European Chemicals Agency (ECHA) prior to any Manufacture or Import
- Allowed for a staggered Registration of phase-in substances



Registration Update

- Pre-registration June to Dec 2008
1M pre-registrations submitted to ECHA
> 95,000 from Ireland
- First REACH Registration deadline 1st Dec 2010
24,675 Registration Dossiers submitted for 5,000 substances
- Ireland submitted 235 Dossier before 1st Dec

Duties for Article Producers/Importers





Articles and REACH

“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”

- Examples include Furniture, components, etc

REACH duties in relation to articles

1. Article 7(1) Duty to register
2. Article 7(2) Duty to notify
3. Article 33 Duty to Communicate

1. Duty to register Substances in Articles

- Article 7(1) of REACH
- Producers and importers of articles shall submit registration to ECHA if substance is:
 - present in articles > 1t/a per producer/importer
and
 - Intended to be released under normal conditions
of use

SVHCs and Candidate List

- Substances of Very High Concern
 - CMRs
 - PBTs
 - vPvBs
 - Substances of Equivalent Concern
- Scientific Evidence that substance meets one of these criteria
- Included on ECHAs Candidate List of SVHCs



2. Duty to notify Substances in Articles

- Article 7(2) of REACH
- Producers and importers of articles shall notify substance on the candidate list to ECHA if the substance is:
 - present in articles $> 1\text{t/a}$ per producer/importer
 - (relates to the Calendar Year)
 - present in article above concentration of $0.1\%w/w$ (applies to the article as a whole)

Exemptions from the Duty to Notify

Notification not required if:

- Exposure to humans and environment can be excluded during normal conditions of use, including disposal
 - Must be able to demonstrate that SVHC does not come into contact with man/environment
- Substance already registered for that use (ie process by which is included in article)
 - Any registration, same/other supply chain
 - Same substance and use covered in dossier



Who & When to Notify

- Producers or Importers of Articles
- Notification to be made at latest 6 months after substance on CL; starting 1st June 2011
- Substances on list before 1st Dec 2010, deadline is 1st June 2011
- Substances on list on/after 1st Dec 2010, notification must be submitted no later than 6 months after inclusion

What to Notify

- General Information
 - 1.1 Identification
 - 1.2 Composition
 - 1.3 Identifiers
- Classification and Labelling
- Manufacture, use and exposure
 - 3.2 Estimated quantities
 - 3.3 Sites
 - 3.4 Form in the supply chain
 - 3.5 Identified uses

How to Notify

The Candidate List

Download Substance Dataset
from CL



Import substance dataset &
Create Notification Dossier
Export Dossier



Submit Dossier to ECHA



3. Duty to communicate Information on SVHCs in Articles

- Article 33(1); supplier of article (containing SVHC at >0.1% w/w) to give recipient sufficient information to allow safe use of article
- Recipient: industrial or professional user, including distributor, excluding consumer
- If no particular information relevant, then substance name to be provided as minimum
- 33(2); info to be provided to consumer upon request, within 45 days



How to Communicate Info on SVHCs

- REACH does not specify format
- Must be readily available to recipient
- Possible formats:
 - Modification of existing documents
 - Information on labels
 - Links to website with up-to-date info
 - Standard formats developed by industry associations

SVHCs and the Candidate List

Substances of Very High Concern

- Identified in accordance with criteria in article 57 of REACH
 - CMRs
 - PBTs or vPvBs
 - Substances of equivalent concern
- Proposed by ECHA/Member States
- Agreed by ECHA's Member State Committee
- Included on Candidate List



SVHCs and the Candidate List

- SVHCs are listed on the Candidate List
- Currently 46 substances on list
- Added to ~ twice yearly by ECHA
- Maintained by ECHA on their website
- http://www.echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp
- Registry of intentions on ECHA website – substances that may be identified as SVHCs
- http://www.echa.europa.eu/chem_data/reg_intentions_en.asp



Candidate List SVHCs and Annex XIV

- Candidate List substances can be included onto Annex XIV and as such subject to Authorisation
- Pre-approval for use
- Currently 6 substances included on Annex XIV

Substances Subject to Authorisation

- 5-tert-butyl-2,4,6-trinitro-m-xylene (**Musk xylene**) vPvB
- 4,4'-Diaminodiphenylmethane (**MDA**)
Carcinogenic(category 1B)
- Hexabromocyclododecane (**HBCDD**) PBT
- Bis(2-ethylhexyl) phthalate(**DEHP**) Toxic for reproduction(category 1B)
- Benzyl butyl phthalate(**BBP**)Toxic for reproduction (category 1B)
- Dibutyl phthalate(**DBP**) Toxic for reproduction (category 1B)

Authorisation

- Pre-approval system for the use of Annex XIV substances
- Beyond a certain date (The Sunset Date) these substances cannot be used unless and Authorisation has been applied for and granted for that use

Authorisation

- First Annex XIV published;
http://www.echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp
- Applications and sunset dates given
- Expected to be updated yearly
- Applications can be submitted (see ECHA website)

SVHCs and Public Consultation

- Two Consultation periods for interested parties;
 1. When substance is being identified as an SVHC (30 days)
 2. When SVHC is being prioritised for inclusion on Annex XIV (3 months)

Details on the ECHA website

Safety Data Sheets & CLP



Safety Data Sheets

- Supplier of substances or mixtures classified as hazardous must provide SDS in accordance with Article 31 of REACH
- New Reg. (EC) No. 453/2010 amends Annex II of REACH & adapts it:
 - to the criteria for classification as given in CLP Regulation
 - to take account of SDS rules as set out in GHS

CLP Update

- CLP entered into force Jan 2009
- All substances required to be classified and labelled under CLP from 1st Dec 2010 & mixtures from 1st June 2015
- All substances on their own or in a mixture M/I and placed on the EU market to be notified to the C&L Inventory within one month of placing on market
- 3.1M Notifications >89,000 from Ireland

SDS and CLP Transition

- C&L elements in section 2 of SDS must be consistent with the label
- Transitional arrangements for CLP apply to SDS
- Existing (CPL) and new (CLP) classifications must appear in parallel from 1st Dec 2010 to 1st June 2015



SDS & CLP Transition

2. Hazard Identification

2.1 Classification of the substance

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP)
Flam. Liq. 2, H225
Acute Tox. 3 H301

2.1.2 Classification according to Directive 67/548 EEC
F; R11
T; R23/24/25

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Hazard Pictograms



Signal word: *Danger*

Hazard Statements:
H225 *Highly Flammable*
H301 *Toxic if swallowed*

Precautionary Statements:
P210 : *Keep away from heat/sparks/open flames/hot surfaces. -No smoking*
P301 + P310 **IF SWALLOWED: Immediately call a POISON CENTRE or Doctor/Physician**

From 1st Dec 2010
to 1st Jun 2015

CLP & DSD

CLP Only

Role of the HSA and ECHA in relation to REACH & CLP



REACH



Role of the Health & Safety Authority

- Competent Authority for REACH and CLP in Ireland
- Represents Ireland on ECHA committees and expert groups
- Operates a dedicated helpdesk for REACH and CLP
- Enforcement role under the Chemicals Act

Role of ECHA

- Established under REACH
- Ensures consistent implementation at EU level
- Manages and coordinates all REACH and CLP related tasks incl;
 - Dossier submission and dissemination of info
 - Manages REACH IT and operates a dedicated Helpdesk
 - Provides guidance and support to Industry and MS
 - Publishes the Candidate list
 - Makes recommendations to COM re inclusion of SVHCs onto CL



Guidance & Support

- Guidance on Substances in Articles (updated)
- Guidance on Preparation of Application for Authorisation
- Applications for Authorisation on web-form
- Web-pages on SIA and SVHCs

www.echa.eu

Guidance & Support

- Data Submission Manual Part 20
- Guidance on SDS (due 2011)
- ECHA Webinar 19th May live web-streaming available on ECHA website
- ECHA Chem for information on substances
- Helpdesk reach-clp@hsa.ie
- Website www.hsa.ie