

**Information requirements on chemicals in
articles in the new
EU Chemicals regulation - REACH.**

Informal Workshop on Stakeholders' Information Needs on
Chemicals in Articles/Products
9-12 February 2009
Geneva, Switzerland

Eva Sandberg
International relations
European Chemicals Agency
Helsinki, Finland

REACH

- The new European Chemicals regulation on **Registration, Evaluation and Authorisation of Chemicals, REACH**, entered into force 1 June 2007
- It became operational on 1 June 2008. From this date on the process for requiring authorisation for the use of substances of very high concern (SVHC) could start

Information obligations in REACH



- On substances and preparations
 - SDS
 - other cases linked to i.e. authorisations and restrictions

- **On substances in articles**
 - **linked to the identification process of substances that may need to be authorised**

<http://echa.europa.eu>

3

Article according to REACH



“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 Regulation article 3.3 Definitions)

<http://echa.europa.eu>

4

REACH – Authorisation



- Scope: substances of very high concern (SVHC)
- Placing on the market (including import) **for specific uses** and if
 - risks are adequately controlled
 - and/or socio-economic benefits outweigh risk
- Ultimate objective: substitute SVHC by less hazardous substances or technologies

<http://echa.europa.eu>

5

Substances of Very High Concern (SVHC)



- **Carcinogenic, Mutagenic or toxic to Reproduction (CMR)** category 1 or 2, according to the criteria of Directive 67/548/EEC
- **Persistent, Bioaccumulative and Toxic (PBT)** according to the criteria in Annex XIII of the REACH Regulation or
- **very Persistent and very Bioaccumulative (vPvB)** according to the criteria in Annex XIII of the REACH Regulation and/or
- Identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to humans or the environment of an equivalent level of concern as those above e.g. endocrine disrupters.

<http://echa.europa.eu>

6

Authorisation process - steps



- 1: Identification of Substances of very high concern
- 2: Inclusion in Candidate list**
- 3: Draft Recommendation on Priority substances for authorisation
- 4: Commenting period (1st recommendation until 14 April)
- 5: ECHA Recommendation to Commission
- 6: Commission decision = inclusion in Annex XIV
 - application date
 - sunset date

<http://echa.europa.eu>

7

Authorisation - Annex XIV



- Sets application date = last date for application of authorisation for the use of a substance in the Annex
- Sets sunset dates = the date after which the use of such a substance can not continue unless it is authorised (at least 18 months after application date)
- Sets review times, if appropriate (review periods will be set in each authorisation decision)

<http://echa.europa.eu>

8

Information obligations



From the **date of inclusion** on the Candidate list of Substances identified as being of Very High Concern (SVHC), **Information Obligations** regarding the use of these substances in articles **come into force**

<http://echa.europa.eu>

9

Information obligations



Any supplier of an article which contain substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information, available to them,

- to the recipients (professional and industrial users, distributors) and
- on request, to a consumer - free of charge - within 45 days of the receipt of the request

This information must ensure safe use of the article including as minimum the name of the substance.

<http://echa.europa.eu>

10

Candidate list

- The first candidate list containing 15 different substances was adopted on 28 October 2008 and thus the information obligations for these substances are already in force
- No format or detailed requirements for how this information should be supplied are identified in the legislation

First Candidate list

* Included in draft recommendation for authorisation

<u>Substance</u>	<u>Basis for SVHC</u>
➤ Anthracene	➤ PBT
➤ 4,4'-Diaminodiphenylmethane*	➤ C cat 2
➤ DBP*	➤ R cat 2
➤ Cobalt dichloride	➤ C cat 2
➤ Diarsenic pentaoxide	➤ C cat 1
➤ Diarsenic trioxide	➤ C cat 1
➤ Sodium dichromate	➤ CMR cat 2
➤ Musk xylene*	➤ vPvB
➤ DEHP*	➤ R cat 2
➤ HBCDD, α -HBCDD, β -HBCDD, γ -HBCDD*	➤ PBT
➤ SCCP*	➤ PBT, vPvB
➤ Bis(tributyltin)oxide	➤ PBT
➤ Lead hydrogen arsenate	➤ CR cat 1
➤ BBP*	➤ R cat 2
➤ Triethyl arsenate	➤ C cat 1

* Included in 1st draft recommendation for authorisation, commenting period until 14 April

Other obligations for substances in articles linked to the Candidate list



As from 2011 *Notification of substances in articles*

- Art. 7(2) – **notification** of SVHC substance in an article is required if both two following conditions are met:
 - The substance is present in those articles in quantities totalling over one tonne per producer or importer per year
 - The substance is present in those articles above a concentration of 0.1% (w/w)
 - For substances included in the candidate list before 1 December 2010 the notifications have to be submitted not later than 1 June 2011
 - For substances included on the candidate list on or after 1 December 2010 the notifications have to be submitted no later than 6 months after the inclusion.

<http://echa.europa.eu>

13

Obligations linked to the candidate list



- A notification is **not required** when
 - The producer or importer of an article can exclude exposure of humans and the environment during the use and disposal of the article. In such cases, the producer or importer shall, however, **supply appropriate instructions to the recipient of the article**
 - The substance has already been registered for that use up the same supply chain or any other supply chain.

<http://echa.europa.eu>

14

Other obligations for substances in articles

Registration of substances in articles

- Art. 7(1) – registration of substance in article – both two following conditions have to be met:
 - The substance is present in those articles in quantities totalling over one tonne per producer or importer per year
 - The substance is intended to be released under normal or reasonably foreseeable conditions of use

- These paragraphs shall not apply to substances that have already been registered for that use.

Notification → Registration

The Agency can require registration if

- The substance is present in those articles (from one supplier or importer) over one tonne per producer or importer
- The Agency has grounds for suspecting that
 - The substance is released from the articles
 - The release of the substance from the articles presents a risk to human health and the environment.

To sum up



- Obligations for supplying
 - the (professional) recipient of an article
 - a consumer, on request free of charge, within 45 days of the receipt of the request

with **information** on certain hazardous substances **in articles** have been in force since 28 October 2008 in the EU

- The obligation applies to imported articles as well as those manufactured within the EU

<http://echa.europa.eu>

17



<http://echa.europa.eu>



Thank you for your attention!

- BG** Европейска агенция по химикалите
- CS** Evropská agentura pro chemické látky
- DA** Det Europæiske Kemikalieagentur
- DE** Europäische Chemikalienagentur
- EL** Ευρωπαϊκός Οργανισμός Χημικών Προϊόντων
- EN** European Chemicals Agency
- ES** Agencia Europea de Sustancias y Preparados Químicos
- ET** Euroopa Kemikaaliamet
- FI** Euroopan kemikaalivirasto
- FR** Agence européenne des produits chimiques
- HU** Európai Vegylenyug-ügymökség
- IT** Agenzia europea per le sostanze chimiche
- LT** Europos cheminių medžiagų agentūra
- LV** Eiropas ķīmikāliju aģentūra
- MT** L-Agenzja Ewropea għas-Sustanzi Kimici
- NL** Europees Agentschap voor chemische stoffen
- PL** Europejska Agencja Chemikaliów
- PT** Agência Europeia dos Produtos Químicos
- RO** Agenția Europeană pentru Produse Chimice
- SK** Európska chemická agentúra
- SL** Evropska agencija za kemikalije
- SV** Europeiska kemikaliemyndigheten

European Chemicals Agency Helsinki, Finland