REACH/CLP update
DNELs vs OELs: Brief overview

22nd February 2012

Sinead McMickan

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What's new in REACH/CLP?

- **R**egistration update
- **E**valuation/CoRAP
- **A**uthorisation update/Candidate List
- **Ch**emicals: Restrictions & SDSs
- **C**&L Inventory/**C**LH
- **L**&**P** Guidance
- Overview on DNELs/OELs

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What's new with us?

- ***chemicals@hsa.ie***
- 2011 Code of Practice

- Biological Monitoring Guidelines

- Distributor Factsheet

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New Look ECHA!

CLP
Classification, Labelling & Packaging

http://echa.europa.eu/ | CLP legislation, guidance ... | Restrictions under conside... | Homepage - ECHA

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ECHA
EUROPEAN CHEMICALS AGENCY

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About Us | Regulations | Addressing Chemicals of Concern | Information on Chemicals | Chemicals in our Life | Support

ECHA > Homepage

13/02/2012
ECHA launches the Classification and Labelling Inventory of chemicals on the EU market

Over three million submission records covering more than 90,000 chemical substances are now freely accessible from the ECHA website.

- Search the Classification and Labelling Inventory
- About the Inventory
- Video tutorial

Latest News

15/02/2012
The OECD Test Guideline 443 is a new option for investigating reproductive toxicity

The Extended One-Generation Reproductive Toxicity Study (EOGRTS) will, under certain conditions, fulfil the current information requirements for a "two-generation reproductive toxicity study" under REACH. ECHA has already received around 230 testing proposals for the endpoint of reproductive toxicity for phase-in substances registered by the 1 December 2010 deadline.

08/02/2012
The presentations and recording of the Lead Registrant workshop are now available

Material, including presentations and video recordings of the Lead Registrant workshop that took place in Helsinki from 2 to 3 February 2012 are now available.

Press Releases

23/01/2012
Communication on the safe use of chemicals

By the date set in the Classification, Labelling and Packaging (CLP) Regulation, the European Chemicals Agency submitted to the European Commission its study on communication of information on the safe use of chemicals to the general public.

21/12/2011
ECHA recommends thirteen Substances of Very High Concern for authorisation

The European Chemicals Agency has submitted to the European Commission a recommendation that thirteen Substances of Very High Concern should in future not be used without authorisation. These substances are all classified because of their carcinogenic, mutagenic or toxic to reproduction (or a combination thereof) properties. They are used in applications where there is potential for worker exposure.

Search for Chemicals

Name, EC or CAS No

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ACT NOW!
REACH 2013

- Document Library
- REACH IT
- IUCLID 5
- CHESAR
- Identify your obligations
- ECHA-Term

Committee for Socio-Economic Analysis

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Registration update

- ECHA database on registered substances to date:
- contains 4,209 unique substances
- contains information from 25,149 Registration dossiers
- You can search at: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

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Registration update

- Next registration deadline is 31st May 2013 (>100t/yr)
- ECHA has published the list of substances to be registered
- Currently 2300 subs on list
- Useful for checking whether your substance(s) will be registered
- Again, you can check at: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances/identified-substances-for-registration-in-2013

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Evaluation

- 3 processes involved:
- **Compliance check** of dossiers: ECHA quality check of registration dossiers
- **Examination of testing proposals** submitted by registrants: ECHA evaluates proposals to conduct Annex IX and X tests
- **Substance evaluation**: MSCAs evaluate all registration dossiers for a certain substance(s) to evaluate whether their use poses a risk to human health or environment

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Evaluation/CoRAP contd.

- Risk based concern: starting point for subs evaluation (hazard & exposure)
- Substances subject to subs evaluation are listed on Community Rolling Action Plan (CoRAP) covering 3 yr period
- 1st CoRAP expected to be published on ECHAs website end Feb.
- Will list substances to be evaluated in 2012, 2013 & 2014, initial concerns identified & MSCA
- CoRAP updated every year
- Draft version published

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Evaluation/CoRAP

- Publication of CoRAP = start 12 month evaluation period for MSCAs
- Once evaluation completed, MSCA can:
  - draft decision requesting further info from registrant
  - decide sufficient info to conclude there is concern & proceed to risk management (harmonised C&L, Authorisation, Restriction, OEL, etc) or
  - conclude sufficient information to conclude there is no concern
- Further info requested: MSCA evaluates - can decide to proceed to RMM or conclude there is no concern

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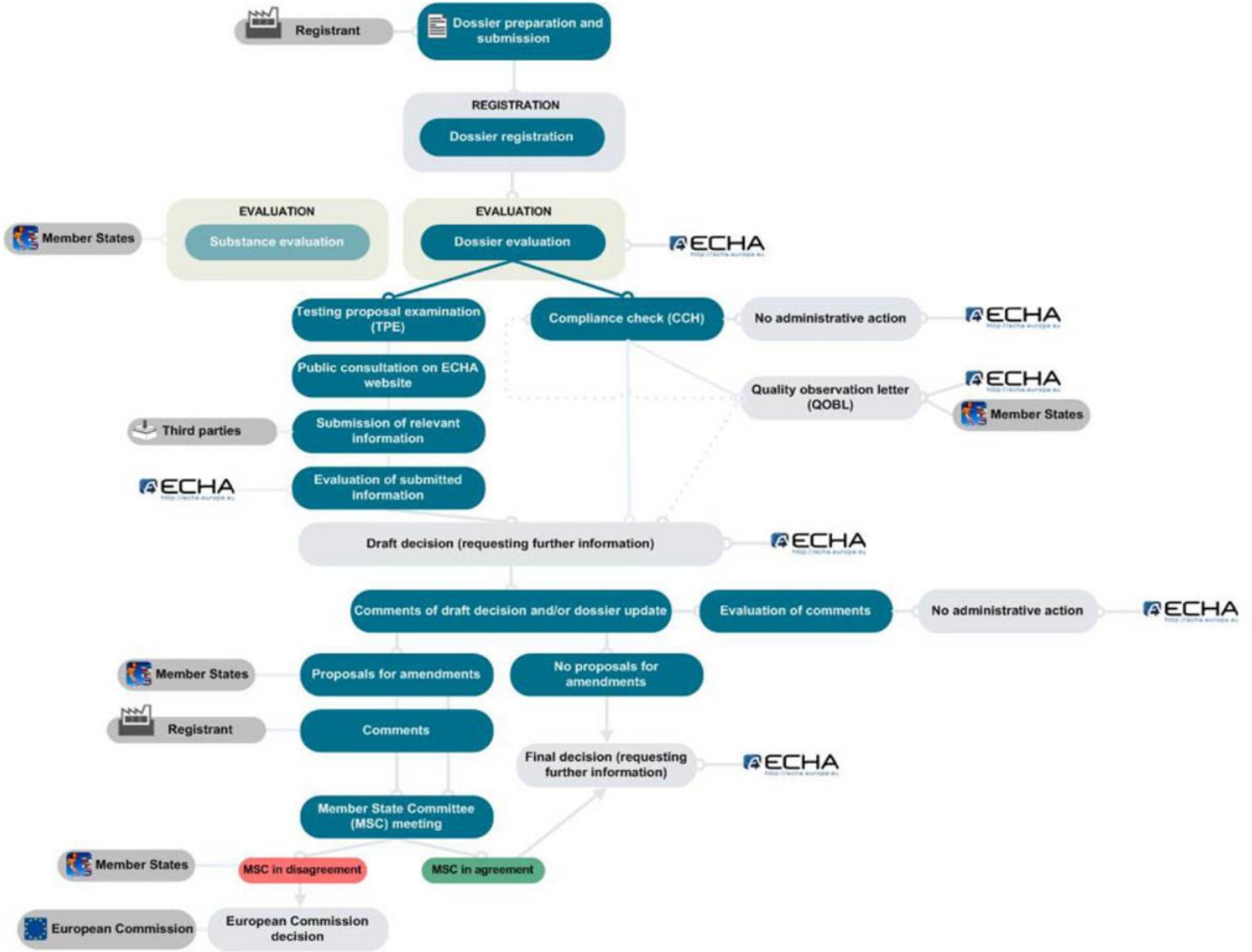
Registrant
Dossier preparation and submission
REGISTRATION
Dossier registration
EVALUATION
Member States
Substance evaluation
EVALUATION
Dossier evaluation
ECHA
Testing proposal examination (TPE)
Compliance check (CCH)
No administrative action
ECHA
Public consultation on ECHA website
Quality observation letter (QOBL)
ECHA
Member States
Third parties
Submission of relevant information
ECHA
Evaluation of submitted information
Draft decision (requesting further information)
ECHA
Comments of draft decision and/or dossier update
Evaluation of comments
No administrative action
ECHA
Member States
Proposals for amendments
No proposals for amendments
Registrant
Comments
Final decision (requesting further information)
ECHA
Member State Committee (MSC) meeting
Member States
MSC in disagreement
MSC in agreement
European Commission
European Commission decision

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Authorisation process

MS/ECHA propose a substance of very high concern (SVHC) – CMR/PBT/ED - for authorisation: submit Annex XV dossier

45 day public consultation – MSC agrees on identification of SVHC

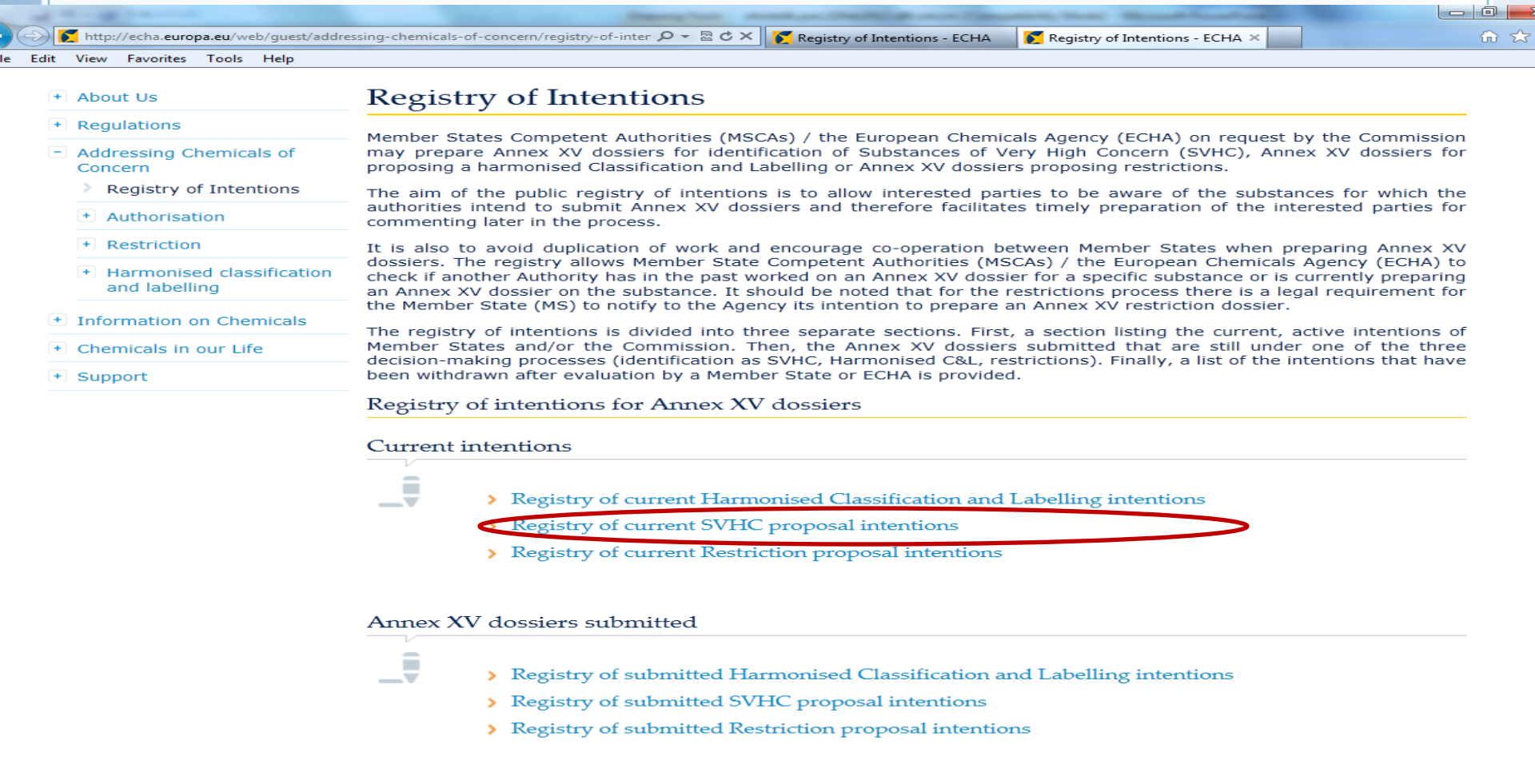
Candidate List

ECHA prioritises SVHCs for Annex XIV – recommendations undergo public consultation – MSC decision-ECHA-Comm

SVHC on Annex XIV – application date & sunset date: no use/placing on market unless authorised

How to keep track.....

- Look up Registry of Intentionson *Addressing chemicals of concern* on ECHA website



RoI SVHCs: Intentions

Viewing ECHA Presenter's D...

http://echa.europa.eu/web/guest/registry-of-current-svhc-intentions

PC-Ware Informat... | HSA - GeoSMART... | PC-Ware Informat... | Registry of cur...

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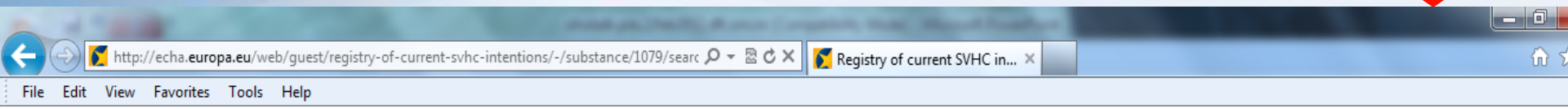
Showing 15 results.

Substance Name	EC Number	CAS Number	Dossier intended by	Notification of intention	Expected date of submission	Scope	
Perfluorooctanic acid (PFOA)	206-397-9	335-67-1	Germany	16/11/2011	28/01/2013	CMR	Details
Distillates (coal tar), heavy oils, pyrene fraction	295-304-5	91995-42-5	ECHA	27/06/2008		PBT	Details
Michler's Ketone (4,4'-bis (dimethylamino)benzophenone)	202-027-5	90-94-8	ECHA	26/01/2012	30/01/2012	CMR	Details
C.I. Basic Blue 26 ([4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl] methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride)	219-943-6	2580-56-5	ECHA	26/01/2012	30/01/2012	CMR	Details
C.I. Solvent Violet 8 (4,4'-bis (dimethylamino)-4''-(methylamino)trityl alcohol)	209-218-2	561-41-1	ECHA	26/01/2012	30/01/2012	CMR	Details
Ammoniumpentadecafluorootanoate (APFO)	223-320-4	3825-26-1	Germany	16/11/2011	28/01/2013	CMR	Details
Further Arsenic compounds	-	-	Norway	30/04/2008		CMR	Details
C.I. Solvent Blue 4 (α,α-bis[4-(dimethylamino)phenyl]-4 (phenylamino) naphthalene-1-methanol)	229-851-8	6786-83-0	ECHA	26/01/2012	30/01/2012	CMR	Details
Distillates (coal tar), heavy oils	292-607-4	90640-86-1	ECHA	27/06/2008		PBT	Details
Di-n-pentyl phthalate	205-017-9	131-18-0	Poland	09/11/2011	28/01/2013	CMR	Details
C.I. Basic Violet 3	208-953-6	548-62-9	ECHA	25/10/2010	30/01/2012	CMR	Details
Residues (coal tar), pitch distn.	295-507-9	92061-94-4	ECHA	27/06/2008		PBT	Details
Distillates (coal tar), pitch, pyrene fraction	295-313-4	91995-52-7	ECHA	27/06/2008		PBT	Details
Michler's Base (N,N,N',N'-tetramethyl-4,4'-methylenedianiline)	202-959-2	101-61-1	ECHA	26/01/2012	30/01/2012	CMR	Details
Diisopentylphthalate	210-088-4	605-50-5	Austria	19/04/2011	30/07/2012	CMR	Details

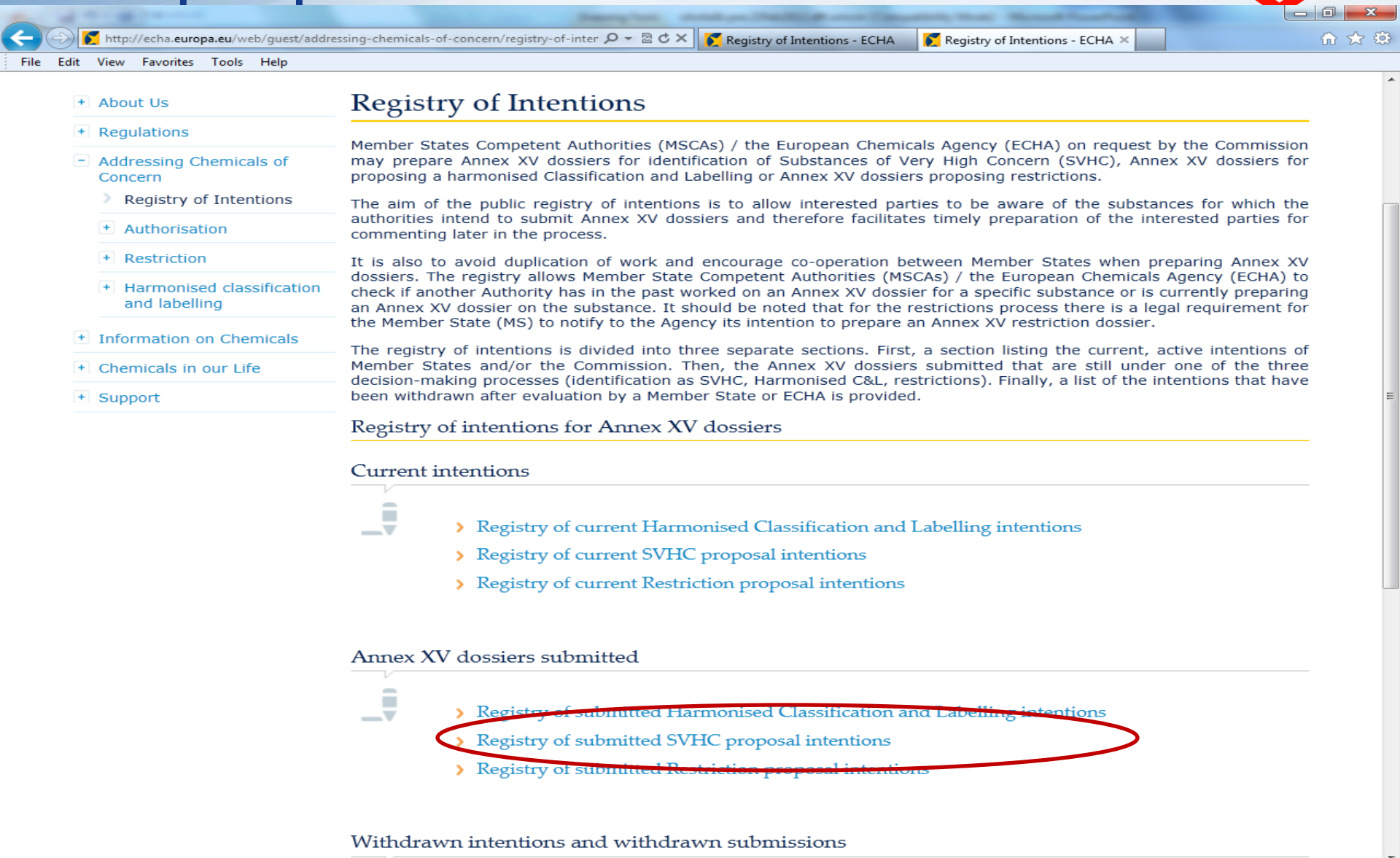
PFOA on "current intentions"



Substance Details

Substance Name	Perfluorooctanic acid (PFOA)
EC Number	206-397-9
CAS Number	335-67-1
CLP Annex VI Index Number	
Other substance information relevant for SVHC	
Dossier intended by	Germany
Notification of intention	16/11/2011
Expected date of submission	28/01/2013
Scope	CMR
Group	Fluorinated substances
Other remarks	The substance will also be identified as PBT

Keep track: submitted proposals..

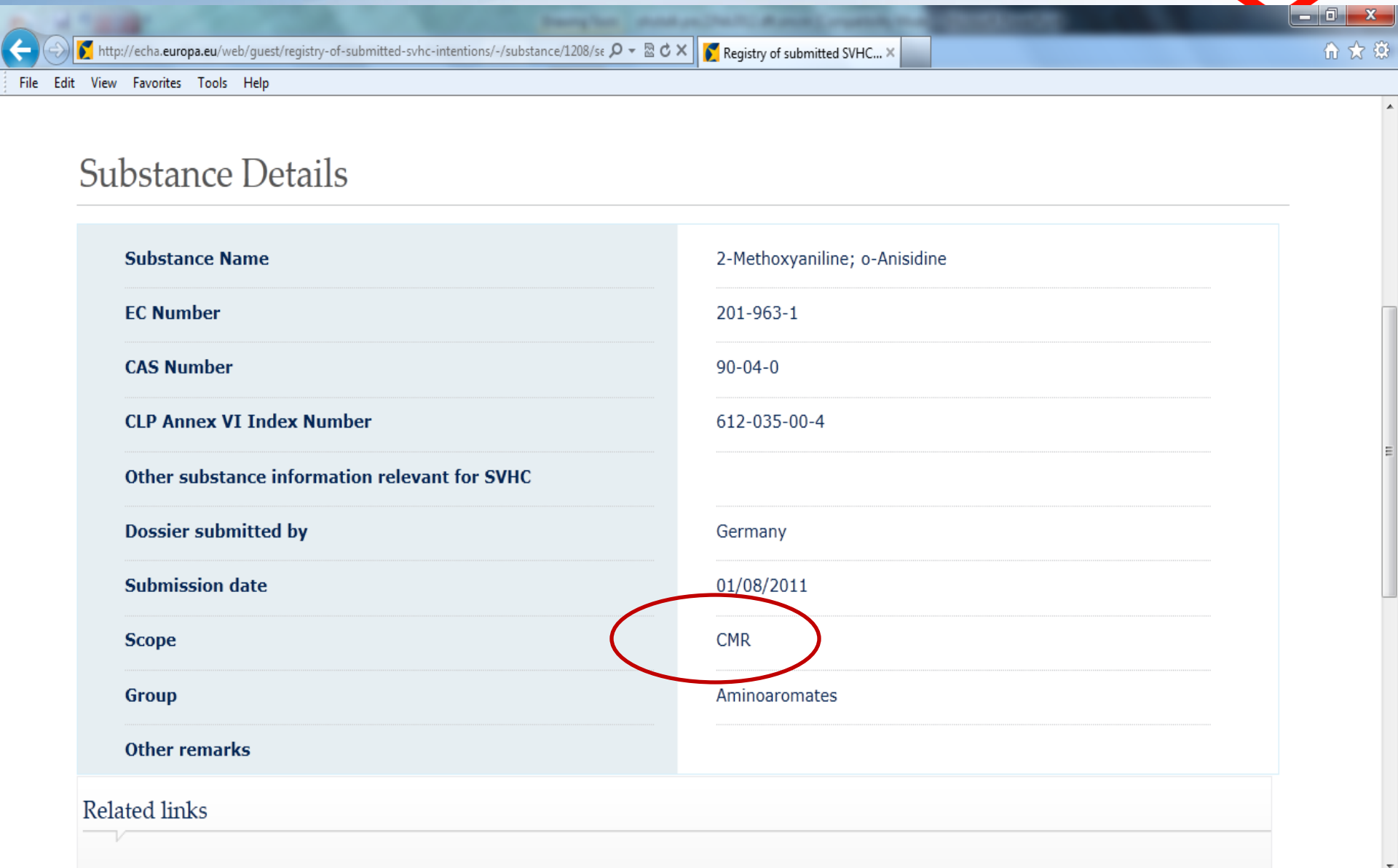


Submitted Intentions

Showing 1 - 20 of 85 results. Items per Page 20 Page 1 of 5 First Previous Next Last

Substance Name	EC Number	CAS Number	Dossier submitted by	Submission date	Scope	
2-Methoxyaniline; o-Anisidine	201-963-1	90-04-0	Germany	01/08/2011	CMR	Details
Calcium arsenate	231-904-5	7778-44-1	Norway	01/08/2011	CMR	Details
1,2-Dichloroethane; ethylene dichloride	203-458-1	107-06-2	Slovakia	01/08/2011	CMR	Details
Bis(2-methoxyethyl) ether	203-924-4	111-96-6	Austria	01/08/2011	CMR	Details
Anthracene oil	292-602-7	90640-80-5	Germany	03/08/2009	PBT	Details
β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl] -1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	423-400-0	59653-74-6	Netherlands	30/01/2012	CMR	Details
Acrylamide	201-173-7	79-06-1	Netherlands	03/08/2009	CMR	Details
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Sweden	27/06/2008	CMR	Details
Cobalt dichloride	231-589-4	7646-79-9	ECHA	21/02/2011	CMR	Details
2-Ethoxyethanol; Ethylene glycol monoethyl ether (EGEE)	203-804-1	110-80-5	Austria	02/08/2010	CMR	Details
Cobalt sulphate	233-334-2	10124-43-3	Netherlands	02/08/2010	CMR	Details

2-methoxyaniline – on C. List



Candidate List

- Currently 73 substances on the Candidate List
- Last updated 19th Dec 2011
- Found at: http://echa.europa.eu/web/guest/candidate-list-table

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Prioritisation for Authorisation

- 13 more substances are on a prioritisation list – proposed for Annex XIV:
- Trichloroethylene
- Chromium (VI) compounds: Chromium trioxide, Acids generated from chromium trioxide & oligomers, Sodium dichromate, Potassium dichromate, Ammonium dichromate, Potassium chromate, Sodium chromate
- Cobalt (II) compounds: Co(II) sulphate, Co dichloride, Co(II) dinitrate, Co (II) carbonate, Co(II) diacetate

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Authorisation

- 8 SVHC added to Annex XIV on 14th Feb
- All carcinogenic and/or toxic for reproduction
  - diisobutyl phthalate (DIBP)
  - diarsenic trioxide
  - diarsenic pentaoxide
  - lead chromate
  - lead sulfochromate yellow (CI Pigment Yellow 34)
  - lead chromate molybdate sulphate red(Pigment Red104)
  - tris (2-chloroethyl) phosphate (TCEP)
  - 2,4-dinitrotoluene (2,4-DNT)
- Currently 14 substances on Annex XIV subject to authorisation for use

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Substance Name	EC Number	CAS Number	Sunset date	application date	Exempted (categories of) uses	
Diarsenic pentaoxide	215-116-9	1303-28-2	21/05/2015	21/11/2013		Details
Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9, 247-148-4	3194-55-6, 25637-99-4, 134237-50-6, 134237-51-7, 134237-52-8	21/08/2015	21/02/2014		Details
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	21/02/2015	21/08/2013	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	Details
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2	21/08/2014	21/02/2013		Details
Diarsenic trioxide	215-481-4	1327-53-3	21/05/2015	21/11/2013		Details
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	21/02/2015	21/08/2013	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	Details
Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	115-96-8	21/08/2015	21/02/2014		Details
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	21/02/2015	21/08/2013		Details
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	21/05/2015	21/11/2013		Details
Lead chromate	231-846-0	7758-97-6	21/05/2015	21/11/2013		Details
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	21/08/2015	21/02/2014		Details
4,4'-Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	21/08/2014	21/02/2013		Details
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	21/05/2015	21/11/2013		Details
Dibutyl phthalate (DBP)	201-557-4	84-74-2	21/02/2015	21/08/2013	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	Details

Authorisation - Help

- Pre-submission information sessions with ECHA available to future applicants for authorisation
- Provides opportunity to clarify regulatory & procedural issues related to application process
- One-to-one sessions would take place no later than 6 months before submission of application
- Webform available to request session (at least 8 months prior to submission)

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Restriction process

MS/ECHA (request Comm) propose to restrict – limit/ban – subs for manufacture/use/place on market: RoI

MS/ECHA prepare dossier (12 months): submit

Public consultation (6 months) after conformity check/Forum/RAC/SEAC comments

Further public consultation (60 days) on SEAC opinion: Final report to Comm

Council/EP agree – restriction agreed and published in OJ amending Annex XVII

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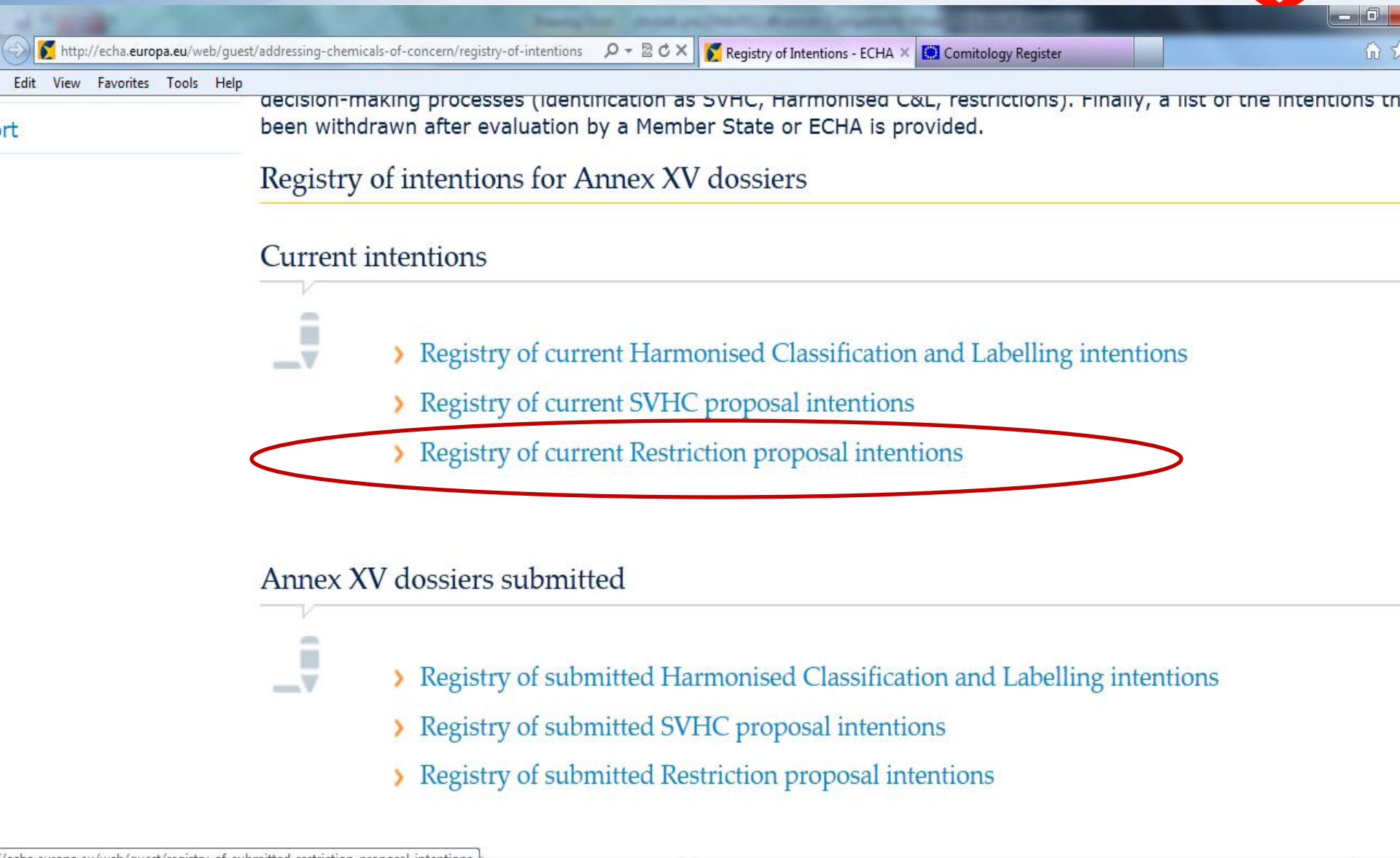
How to keep track....



Current Intentions...

Registry of current Restriction proposal intentions

› Registry of Intentions

Substance Name	EC Number	CAS Number	Notification of intention	Expected date of submission	
1,4-Dichlorobenzene (p-dichlorobenzene)	203-400-5	106-46-7	08/11/2011	19/04/2012	Details
Nonylphenol	246-672-0	25154-52-3	02/09/2011	03/08/2012	Details
Nonylphenol ethoxylates	not specified	not specified	02/09/2011	03/08/2012	Details
4-Nonylphenol, branched	284-325-5	84852-15-3	02/09/2011	03/08/2012	Details

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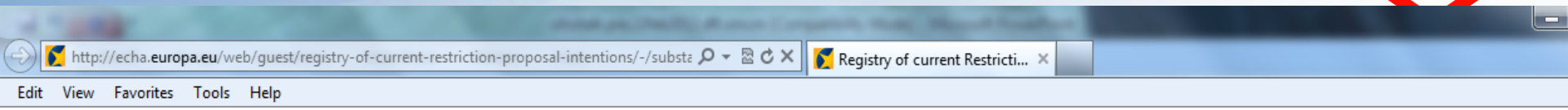
Export in: XML

Export

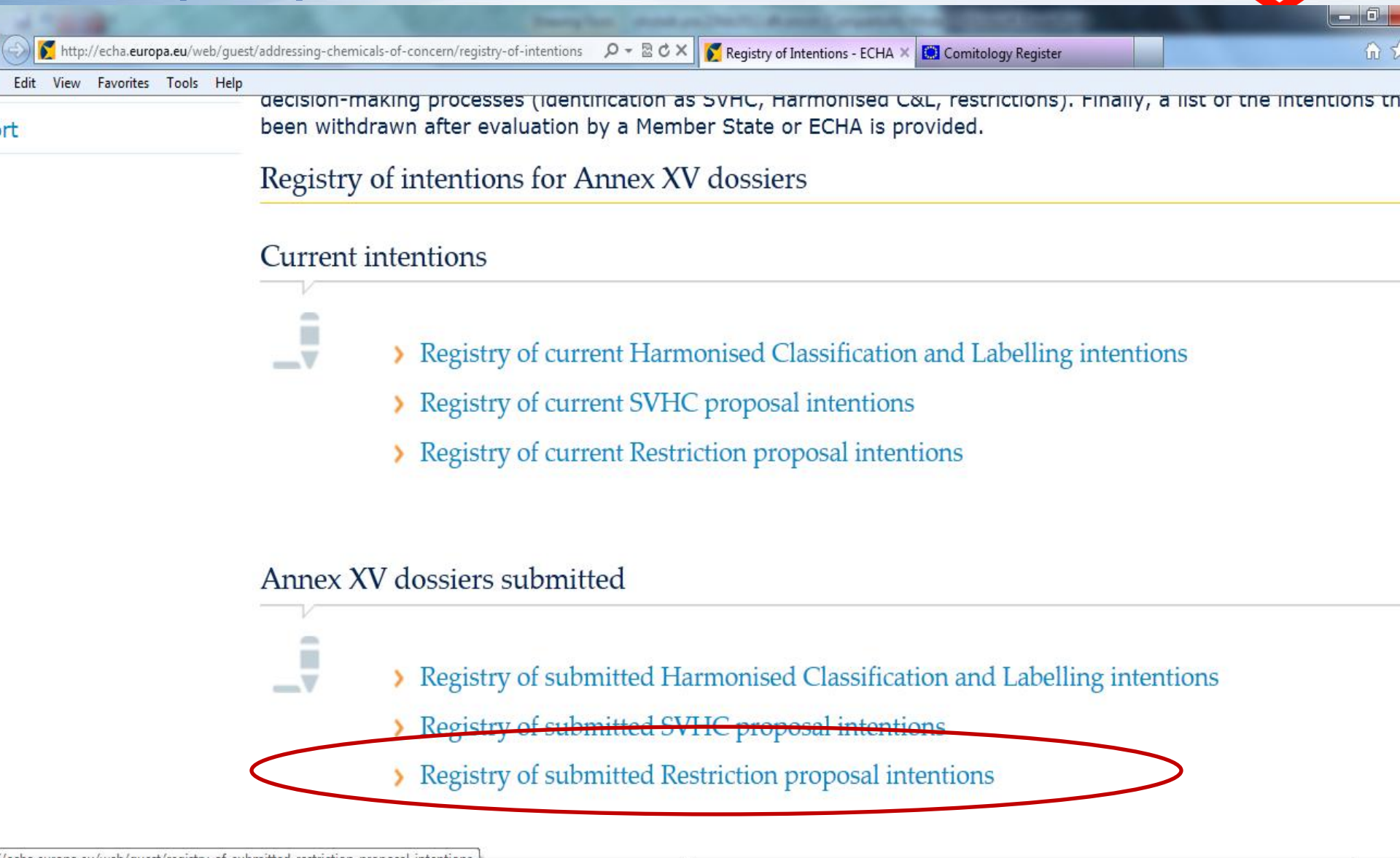
1,4-dichlorobenzene proposal



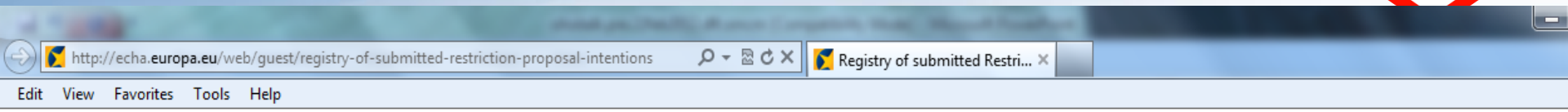
Substance Details

Substance Name	1,4-Dichlorobenzene (p-dichlorobenzene)
EC Number	203-400-5
CAS Number	106-46-7
CLP Annex VI Index Number	602-035-00-2
Dossier intended by	ECHA
Notification of intention	08/11/2011
Expected date of submission	19/04/2012
Group	Aromates, chlorinated/brominated
Other remarks	
Other substance information relevant for restriction	
Reason for restriction	1,4-dichlorobenzene in air fresheners and toilet blocks.

Keep track of submitted proposals....



13 submitted proposals



Substance Name	EC Number	CAS Number	Submission date	
Benzyl butyl phthalate	607-430-00-3	85-68-7	14/04/2011	Details
Mercury in measuring devices	231-106-7	7439-97-6	15/06/2010	Details
Chromium VI in leather articles		18540-29-9	20/01/2012	Details
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	14/04/2011	Details
Phenylmercury neodecanoate	247-783-7	26545-49-3	15/06/2010	Details
Phenylmercuric octanoate	not available	13864-38-5	15/06/2010	Details
Diisobutyl phthalate	201-553-2	84-69-5	14/04/2011	Details
Lead and its compounds in jewellery	231-100-4	7439-92-1	15/04/2010	Details
Phenylmercury propionate	203-094-3	103-27-5	15/06/2010	Details
Dimethylfumarate	210-849-0	624-49-7	15/04/2010	Details
Phenylmercury 2-ethylhexanoate	231-106-7	13302-00-6	15/06/2010	Details
Dibutyl phthalate (DBP)	201-553-2	84-69-5	14/04/2011	Details
Phenylmercury acetate	200-532-5	62-38-4	15/06/2010	Details

Hg in measuring devices

› Registry of Intentions

Substance Details

Substance Name	Mercury in measuring devices
EC Number	231-106-7
CAS Number	7439-97-6
CLP Annex VI Index Number	080-001-00-0
Dossier submitted by	ECHA
Submission date	15/06/2010
Group	Mercury compounds
Other remarks	
Other substance information relevant for restriction	

Related links

› Current intentions

Under consideration...

When a restriction process is undergoing a step that foresees a public consultation open and ongoing (e.g. "Consultation on restriction report" or "Public consultation on SEAC draft opinion") the table is including also the links to the forms for submitting comments to ECHA. Please take note carefully of the deadlines for commenting when reported. Comments received after the deadline cannot be taken into account by the Committees in their opinion making process.

› Restriction

Substance Name	EC Number	CAS Number	Consultation comments	Consultation deadline for comments	Public consultation on SEAC draft opinion	
Mercury	231-106-7	7439-97-6				Details
DMFu	210-849-0	624-49-7				Details
DIBP, DBP, BBP, DEHP	201-553-2 201-557-4 201-622-7 204-211-0	84-69-5 84-74-2 85-68-7 117-81-7	Give Comments	16/03/2012		Details
Phenylmercury compounds	200-532-5 203-094-3 236-326-7 Unavailable 247-783-7	62-38-4 103-27-5 13302-00-6 13864-38-5 26545-49-3				Details
Lead and its compounds	231-100-4	7439-92-1				Details

Showing 5 results.

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Substance Details

Substance Name	Mercury
EC Number	231-106-7
CAS Number	7439-97-6
(Submitted by)	ECHA
Information note on restriction report	
Restriction report	
Consultation comments	
Consultation deadline for comments	
Consultation on restriction report	
Public consultation on SEAC draft opinion	
Opinion of RAC	
Draft opinion of SEAC	
RAC & SEAC Background document	
Compiled RAC and SEAC opinion	
SEAC Minority position	
Final background document	
Commission's proposal	
Adopted restriction	

The information submitted during the consultation procedure is used solely for that purpose. Personal data is never disclosed to the public and will be treated in accordance with Regulation (EC) No 45/2001 of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies. Any party submitting data to ECHA is entitled to access and rectify that data. To exercise these rights you can contact the controller at data-controller-risk-management (at) echa.europa.eu.

Comitology register

http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&g20 — Restrictions under consideratio... — Comitology Register

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Details Back to List

D018566/01 (Draft implementing measure/act) in dossier CMTD(2011)1634 **Enterprise and Industry**

Title: COMMISSION REGULATION (EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards mercury measuring devices

Date: 27 Mar 2012 - 28 Mar 2012

Committee: Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Joint responsibility with DG ENV)

Basic legal act: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Codecision: Yes

Procedure: Regulatory with Scrutiny (art. 5a par. 1-5)

Status: Sent to Committee 21 Dec 2011

Language: BG ES CS DA DE ET EL EN FR IT LV LT HU MT NL PL PT RO SK SL FI SV

COMMISSION REGULATION (EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards mercury measuring devices (74 Kilobytes)

Restrictions: Annex XVII

- Annex XVII updated to take account of:
- CMR substances newly classified under CLP Regulation
  - applies to Entries 28-30 of Annex XVII, which prohibit sale to general public of CMR substances categories 1A & 1B or mixtures containing them in certain conc.
- Boron compounds used as household detergents and cleaners e.g. sodium perborate
  - time-limited derogation applies until 1st June 2013
- Regulation (EU) No. 109/2012: EIF 1st June 2012

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What's new in REACH/CLP?

- **R**egistration update
- **E**valuation/CoRAP
- **A**uthorisation update/Candidate List
- **Ch**emicals: Restrictions & **SDSs**
- **C**&L Inventory/CLH
- **L**&**P** Guidance
- Overview on DNELs/OELs

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Safety Data Sheets

- All SDSs must comply with Regulation (EU) No. 453/2010 from 1st December 2012
- Time now to ensure that updates are being prepared

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What's new in REACH/CLP?

- **R**egistration update
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- **C**&L Inventory/**C**LH
- **L**&**P** Guidance
- Overview on DNELs/OELs

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CLP

CLP
Classification, Labelling & Packaging

- Currently all substances being placed on the market since 1st Dec 2010, must be labelled according to CLP
- SDSs for these substances
- Mixtures still to CPL until 1st June 2015

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C&L Inventory

- Published!
- Database: classification & labelling information on notified & registered substances received from manufacturers & importers through C&L notifications or registration dossiers
- ECHA maintains Inventory, but does not verify the accuracy of the information
- http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

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C&L Inventory

- 1st version of inventory contains:
  - IUPAC* name (& EC name where available)
  - all C&L elements from all notifications
- Following information is not included in Public C&L Inventory:
  - contact details of notifier
  - composition & impurity profile of substances
- Factsheet available

*In certain cases, the IUPAC name may fall under confidentiality claim and therefore is not published.

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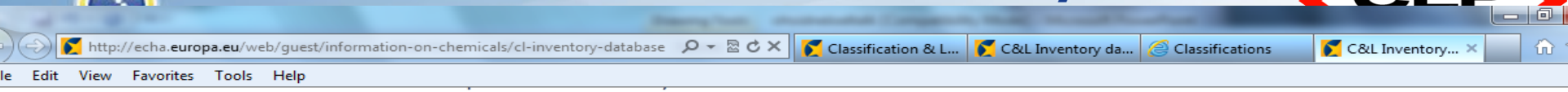
Public C&L inventory



Understanding the CLP Regulation

Search Classification and Labelling Inventory

Search Criteria

Substance Name

Starts with... Contains Matches exactly with...

Other Identifier

Only Harmonised C&L

Classification Details

	Hazard Class and Category Code(s)	Hazard Statement Code(s)
Physical hazards	Diss. Gas Expl. 1.1 Expl. 1.2 Expl. 1.3	H200 H201 H202 H203
Health Hazards	Acute Tox. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4	H300 H301 H302 H303
Environmental Hazards	Aquatic Acute 1 Aquatic Acute 2 Aquatic Acute 3 Aquatic Chronic 1	EUH059 H400 H401 H402

You may select one or more of the above values by using the Control (CTRL) key.

In order to perform a search you need to read through and agree to this legal disclaimer.

Search Clear

Notifications submitted/updated by: 30/11/2011

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Summary Of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

EC Number	CAS Number	Index Number	International Chemical Identification
200-001-8	50-00-0	605-001-00-5	formaldehyde ... %

ATP Inserted / Updated: CLP00

CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code (s)	Hazard Statement Code (s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Acute Tox. 3 *	H301	H301		GHS06 GHS05 GHS08 Dgr	* STOT SE 3; H335: C ≥ 5% Skin Corr. 1B; H314: C ≥ 25% Skin Sens. 1; H317: C ≥ 0,2% Eye Irrit. 2; H319: 5% ≤ C < 25% Skin Irrit. 2; H315: 5% ≤ C < 25%	Note B Note D
Acute Tox. 3 *	H311	H311				
Skin Corr. 1B	H314	H314				
Skin Sens. 1	H317	H317				
Acute Tox. 3 *	H331	H331				
Carc. 2	H351	H351				

Signal Words	Pictograms		
Danger			
	Skull and crossbones	Corrosion	Health hazard

Notified classification and labelling

General Information

EC Number	CAS Number	IUPAC Name
200-001-8	50-00-0	13215_50-00-0

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EC Number	CAS Number	IUPAC Name
200-001-8	50-00-0	13215_50-00-0

Notified classification and labelling according to CLP criteria

Classification		Labelling			Specific Concentration limits, M- Factors	Notes	Number of Notifiers	Joint Entries
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms Signal Word Code (s)				
Acute Tox. 3	H301	H301		GHS06 GHS05 GHS08 Dgr	STOT SE 3: C ≥ 5% Skin Corr. 1B: C ≥ 25% Skin Sens. 1: C ≥ 0,2% Eye Irrit. 2: 5% ≤ C < 25% Skin Irrit. 2: 5% ≤ C < 25%	Note B Note D	985	
Acute Tox. 3	H311	H311						
Skin Corr. 1B	H314	H314						
Skin Sens. 1	H317	H317						
Acute Tox. 3	H331	H331						
Carc. 2	H351	H351						
Acute Tox. 3	H301	H301		GHS06 GHS05 GHS08 Dgr			177	
Acute Tox. 3	H311	H311						
Skin Corr. 1B	H314	H314						
Skin Sens. 1	H317	H317						
Acute Tox. 3	H331	H331						
Carc. 2	H351	H351						
Acute Tox. 3	H301	H301		GHS06 GHS05 GHS08 Dgr	STOT SE 3: C ≥ 5% Skin Corr. 1B: C ≥ 25% Skin Sens. 1: C ≥ 0,2% Eye Irrit. 2: 5% ≤ C < 25% Skin Irrit. 2: 5% ≤ C < 25%	Note B Note D	93	✔
Acute Tox. 3	H311	H311						
Skin Corr. 1B	H314	H314						
Skin Sens. 1	H317	H317						
Eye Dam. 1	H318							
Acute Tox. 3	H331	H331						
Carc. 2	H351	H351						
Acute Tox. 3	H301	H301		GHS06	STOT SE 3: C ≥ 5% Skin Corr. 1B: C ≥ 25%			
Acute Tox. 3	H311	H311						
Skin Corr. 1B	H314	H314						

Harmonised C&L (CLH)

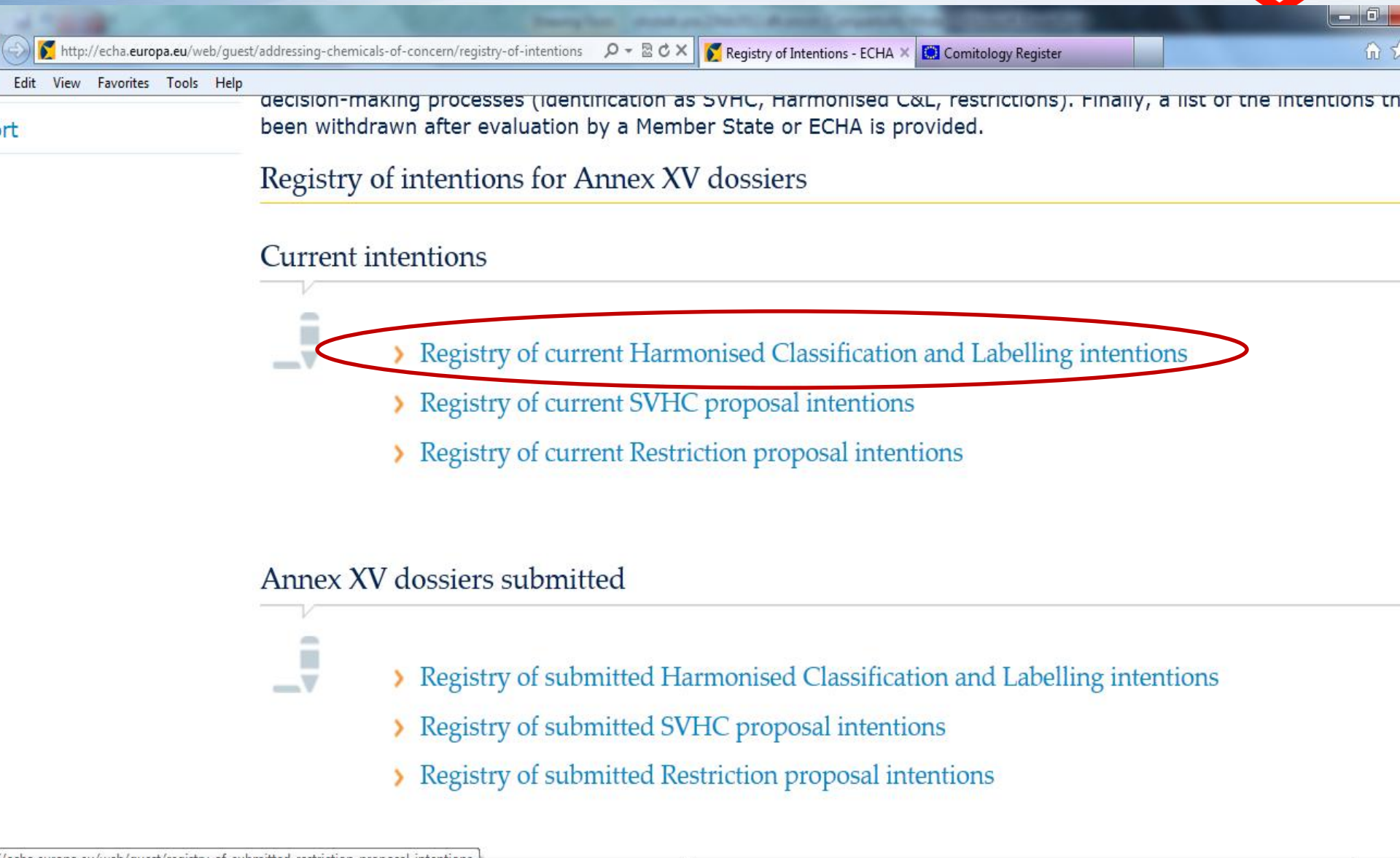
MS/M/I/DU propose harmonised C&L of substance – CMR or resp. sensitiser /active biocidal or PPP/justified: RoI

Public consultation (45 days)

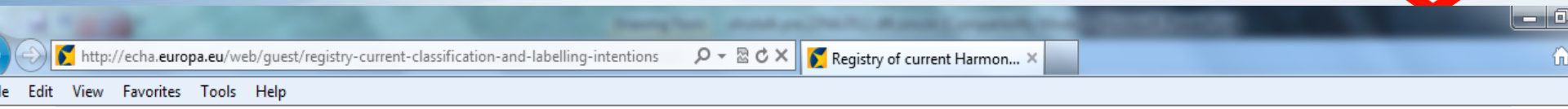
RAC opinion – ECHA- Commission

Agreed by Comm and REACH committee

How to keep track....

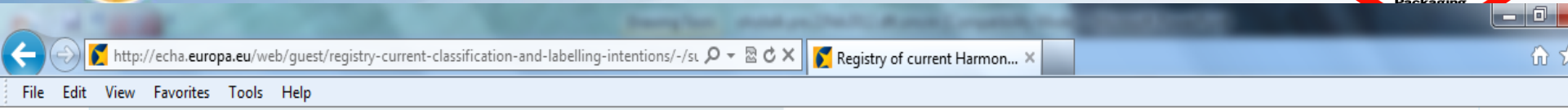


36 proposed intentions..



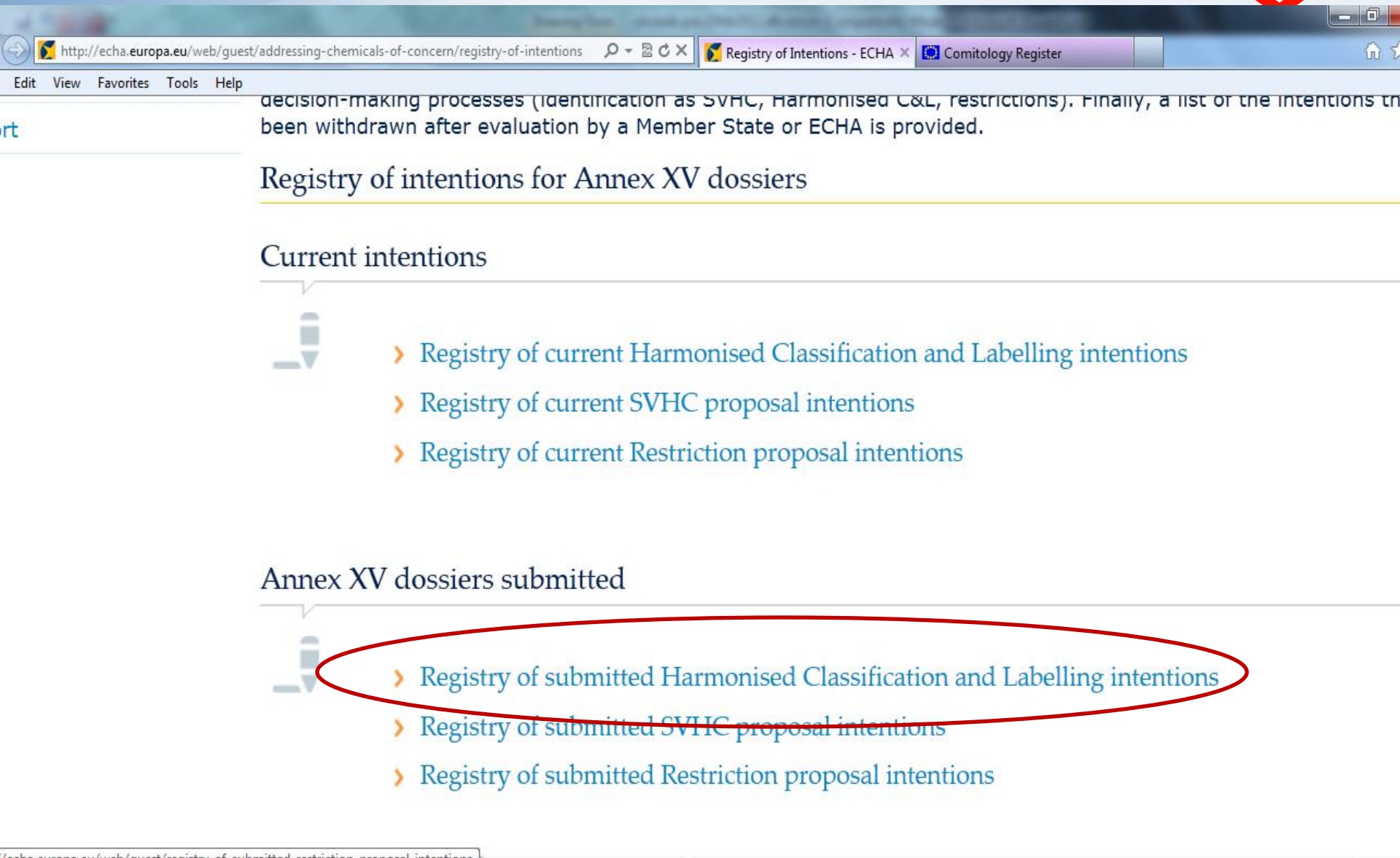
Substance Name	EC Number	CAS Number	Notification_date	Expected date of submission	
1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	271-094-0	68515-51-5	26/09/2011	14/12/2011	Details
disodium tetraborate decahydrate	215-540-4	1303-96-4	09/11/2011	30/12/2015	Details
Tetranatrium 2-(1,2-dicarboxilatoethylimino)succinat	429-200-1	144538-83-0	11/05/2009	01/07/2011	Details
iodomethane	200-819-5	74-88-4	08/06/2011	28/10/2011	Details
1,5-pentanedial (glutaraldehyde)	203-856-5	111-30-8	05/12/2011	30/04/2012	Details
hydroxymethylpentylcyclohexenecarboxaldehyde		31906-04-4	03/01/2012	01/08/2012	Details
TBHP (Hydroperoxide, 1,1-Dimethylethyl)	200-915-7	75-91-2	16/09/2011	15/12/2011	Details
boric acid, crude natural	234-343-4	11113-50-1	09/11/2011	30/12/2012	Details
orthoboric acid	237-560-2	13840-56-7	09/11/2011	30/12/2014	Details
disodium tetraborate	215-540-4	1330-43-4	09/11/2011	30/12/2014	Details
Spiroxamine	na	118134-30-8	14/06/2011	31/12/2011	Details
Metofluthrin		240494-70-6	08/06/2011	19/12/2011	Details

Proposed CLH....



Substance Name	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters
EC Number	271-094-0
CAS Number	68515-51-5
Expected date of submission	14/12/2011
CLP Annex VI Index Number	
Dossier intended by	Sweden
Notification_date	26/09/2011
Other identifier	
Other substance information relevant for CLH	Mixture of three phthalates: CAS nr: 84-75-3, 117-84-0, 84-77-5
Proposed classification according to Directive 67/548/EEC (DSD)	Toxicity to reproduction – fertility, Toxicity to reproduction – development
Proposed classification according to Reg (EC) No 1272/2008 (CLP)	Reproductive toxicity
Regulatory programme	
Other remarks	ReprCat2

Submitted proposals..



170 submitted!

http://echa.europa.eu/web/guest/registry-of-submitted-harmonised-classification-and-labell

Registry of submitted Harm...

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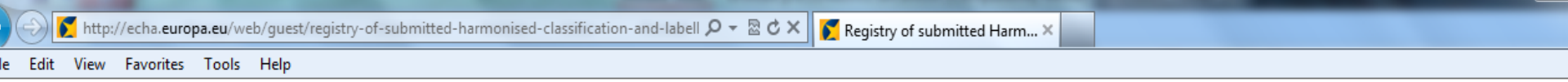
Substance Name	EC Number	CAS Number	Submission date	
Difenacoum	259-978-4	56073-07-5	01/09/2010	Details
Di-n-hexyl phthalate	201-559-5	84-75-3	23/07/2010	Details
Carvone (5-isopropenyl-2-methylcyclohex-2-en-1-one)	202-759-5	99-49-0	30/05/2011	Details
Triadimenol	259-537-6	55219-65-3	21/12/2010	Details
Fyrolflex	425-220-8	5945-33-5	02/02/2011	Details
(Z)-9-tetradecen-1-yl acetate	240-780-1	16725-53-4	14/01/2011	Details
(E)-11-tetradecen-1-yl acetate	251-401-4	33189-72-9	14/01/2011	Details
Cryolite (Trisodium hexafluroaluminate)	239-148-8	15096-52-3	12/03/2009	Details
K-HDO	-	66603-10-9	30/11/2010	Details
Acrolein	203-453-4	107-02-8	18/11/2010	Details
1,1',1''-nitrilotripropan-2-ol (TIPA)	204-528-4	122-20-3	29/10/2010	Details
Warfarin	201-377-6	81-81-2 [racemic mixture]	14/10/2010	Details

Fyrolflex



Substance Details

Substance Name	Fyrolflex
EC Number	425-220-8
CAS Number	5945-33-5
Submission date	02/02/2011
CLP Annex VI Index Number	-
Dossier submitted by	United Kingdom
Other identifier	(1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate
Other remarks	
Other substance information relevant for CLH	
Proposed classification according to Directive 67/548/EEC (DSD)	R53
Proposed classification according to Reg (EC) No 1272/2008 (CLP)	Removal of Aquatic Chronic 4 H413
Regulatory programme	

What's new in REACH/CLP?

- Registration update
- Evaluation/CoRAP
- Authorisation update/Candidate List
- Chemicals: Restrictions & SDSs
- C&L Inventory
- **L&P** Guidance
- Overview on DNELs/OELs

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L&P Guidance

- Look up *Support* tab on ECHA
- http://echa.europa.eu/documents/10162/17217/clp_labelling_en.pdf

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ATP Update

ATP	Regulation	Published	EIF	Topic
2nd ATP	(EC) No 286/2011	30th March 2011	1st Dec 2012	Align to 3rd edition GHS
3rd ATP	(EC) No XXX/2012	XX May 2012	XX June 2013	Update Annex VI (HCL)
4th ATP	(EC) No XXX/2012	XX Nov 2012	XX Q1 2013	Align to 4th edition of GHS
5Th ATP	EC) No XXX/2012	XX May 2013	XX June 2014	Update to Annex VI (HCL)

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What's new in REACH/CLP?

- **R**egistration update
- **E**valuation/CoRAP
- **A**uthorisation update/Candidate List
- **Ch**emicals: Restrictions & SDSs
- **C**&L Inventory
- **L**&**P** Guidance
- Overview on **DNELs/OELs**

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Queries raised

- A brief overview of DNEL and DMEL – how they are derived, some of the terminology
- The differences between DNELs and OEL
- How DNELs are to be interpreted. Will they replace OELs?
- If there are OEL and DNELs on the SDS what is the exposure level OHs will be controlling to & which takes priority for compliance?

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Background/CSR

- For substances imported or manufactured at ≥10 t/yr, registration dossier must contain a Chemical Safety Report (CSR)
- Annex I of REACH sets out how M/I (registrant) should **assess** risks related to substances & how this is documented in the CSR
- Principal element of CSR is description of exposure scenarios (ES) recommended for an identified use
- ESs contain risk management measures (RMM) which M/I recommends to downstream users

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Background/CSA

- CSA is conducted to define conditions of use under which risks can be controlled including operational conditions e.g. temperature & risk management measures e.g. use PPE
- Chemical Safety Assessment (CSA) involves:
  - assessment of human health, physicochem, environmental hazards
  - PBT/vPvB assessment
- If M/I concludes that substance is hazardous, CSA must include:
  - exposure assessment
  - risk characterisation

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Q1

- A brief overview of DNEL and DMEL – how they are derived, some of the terminology

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Where does DNEL fit in?

- Human health hazard assessment requires registrant to identify **Derived No-Effect Level (DNEL)**
- REACH Annex I (1.0.1) defines DNEL as *"...level of exposure to a substance above which humans should not be exposed"*

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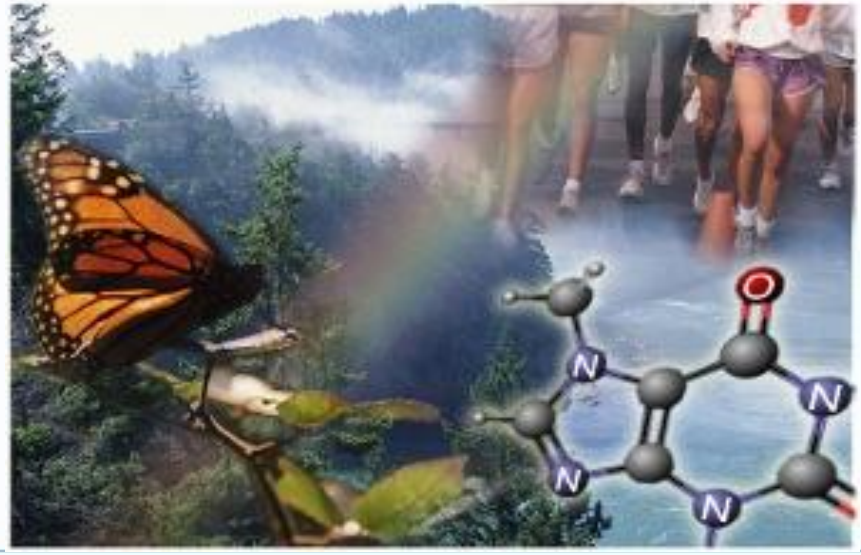
How to derive a DNEL

ECHA

Guidance on
information requirements and
chemical safety assessment

Chapter R.8: Characterisation of dose [concentration]-response for human health



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Deriving a DNEL

- A number of DNELs can be derived for a single substance, taking account of:
  - likely routes of exposure
    - Oral
    - Dermal
    - Inhalation
  - duration & frequency of exposure (long-term, short-term)
  - populations to be exposed (worker, consumer, man exposed via environment incl. certain sub-populations such as children or pregnant women)
- Consider uses of subs & potential exposures

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Deriving DNEL

- Starting point: identification of dose descriptor (NO(A)EL/LOAEL)
- Modify, when necessary, the relevant dose descriptor(s) per endpoint to correct starting point
- Then apply assessment factors to take into account uncertainties & variability between test data & actual human exposure situation
- Use it for Risk Characterisation....

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Risk characterisation

- In REACH risk characterisation is performed by deriving a Risk Characterisation Ratio (RCR)
  - RCR = Exposure/DNEL
  - RCR> 1: risk is not controlled
  - RCR<1: risk is controlled
- In practice, DNELs can only be derived for endpoints where a threshold can be established & so a quantitative risk characterisation can be performed i.e. comparison of DNEL with exposure estimate ...so....

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DMEL

- ....where DNELs cannot be derived for non-threshold effects like mutagenicity & carcinogenicity (or for endpoints where data does not allow identification of DNEL e.g. Irritation, sensitisation), 2 approaches possible:
  - Qualitative e.g. strict RMM/OCs so exposure is minimised (similar to ALARA (as low as reasonably achievable) principle)
  - Semi-qualitative: derivation of **DMEL (derived minimal effect level)** concept

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DMEL

- DMEL: reference risk level which is considered to be of very low concern i.e. tolerable level of effects & not a level where no potential effects are seen
- DMELs are not equivalent to DNELs since DMEL represents an **acceptable level of risk** whereas DNEL is an exposure level where **no effects expected**
- DMEL not strictly required under REACH but guidance strongly recommends the approach for non-threshold effects where data allows it

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Note:

- REACH Guidance points out that REACH does not overrule the Carcinogens and Mutagens Directive (2004/37/EC), which requires that workplace exposures are avoided/minimised as far as technically feasible
- Therefore, the approach under REACH should comply with this minimisation requirement

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Q2 & 3

- The differences between DNELs and OEL?
- How DNELs are to be interpreted. Will they replace OELs?

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Occupational Exposure Limits (OELs)

- An OEL represents an **airborne concentration** at which it is **unlikely** that significant adverse health effects occur in the overwhelming majority of an exposed workforce
  - OELs: estbd. by regulatory authorities using scientific input
  - MSs set national OELs
  - Where national OELs are binding, they have to be complied with even if the DNEL for the same substance is higher

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OELs contd.

- Indicative Occupational Exposure Limit Values (IOELVs) are non-binding, health-based limits below which adverse health effects should not occur (approx 90)
  - Established under CAD
  - MSs required to set national exposure limits that take account of IOELVs (can set national limits at different levels where approp.)
- Binding Occupational Exposure Limit Values (BOELVs)Annex I of CAD
  - MSs required to set national OEL at value not exceeding BOELV
  - BOELV in Annex III of Carcinogen & Mutagens Directive

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Differences between OELs & DNELs

- OELs are explicitly developed for occupational S&H purposes
- OELs are an instrument for authorities: distinct regulatory function in individual MSs combined with option to improve compliance by workplace measurements
- IOELVs & BOELVs as established by DG Employment
- SCOEL-Committee have a similar function assisting MSs in establishment of national OELs & supporting harmonisation
- DNELs primarily not intended to play role within OS&H regs
- DNELs represent a tool for CSA of chemicals >10t/yr
- DNELs serve industry to implement RMM if assumed exposure exceeds DNEL

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Differences/similarities

- There are different actors in establishment of these reference values: national/international scientific committees and regulatory agencies for OELs on one side & industry experts for DNELs on the other
- Basically DNELs and OELs could be regarded as having same objective: a concentration which in general would not result in health impairments of workers after occupational exposure

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Interface

REACH	CAD	Interface
DNEL	OELs	
•Requires registrant to develop health-based Derived No-Effect Levels (DNELs) used to RMM that must be communicated to employers •DNELs apply to all routes of exposure (inhalation, dermal, oral) and for workers and consumers	•Commission proposes healthbased indicative occupational exposure limit values (IOELVs) which MSs must take into account when setting national OELs •OELs apply to worker exposure by inhalation, with a notation to indicate the potential for uptake via the skin •Also small number of binding limit values (BOELVs) based on assessments of risk to health and socioeconomic factors required to control exposure	•Although **both DNELs and IOELVs are health-based**, they are not necessarily set in the same way •The primary duty is to comply with risk management measures and good control practice. This should also mean compliance with relevant exposure reference levels.

Use of OELs as DNELs?

- Possible to derive a DNEL from existing OEL although number of provisos:
  - Where there is an Indicative Occupational Exposure Limit (IOEL), registrant **can** use IOEL instead of DNEL for same exposure route & duration (unless registrant has info to indicate that IOEL is not appropriate e.g more recent scientific data available than that used to derive the IOEL)
  - Where there is a Binding Occupational Exposure Limit (BOEL), registrant **cannot** use it in place of a DNEL without evaluating the basis behind value (because these values take into account socio-economic and technical feasibility factors in addition to toxicological data)

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Q4

- If there are OEL and DNELs on the SDS what is the exposure level OHs will be controlling to & which takes priority for compliance?

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What to do....

- An extended SDS may carry new info chemical: may need to reassess your risk assessment
- Must be able to demonstrate that your assessment is adequate - that you have identified and applied all appropriate measures to adequately control risks, based on info provided by your supplier
- If you can demonstrate that existing control measures in your RA are sufficient to achieve the DNEL, do not need to apply RMM recommended
- Importantly, if you do not accept that some, or all, of RMM recommended under REACH are appropriate, you must provide feedback to your suppliers to pass this back up the supply chain – CSA adjusted or you are advised RMM stands
- Where new information from REACH requires it, you should change existing control measures, making sure that resulting control measures fulfil the criteria of CAD

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Summary: what is a DNEL?

- Derived No-Effect Level: REACH Tool for human Risk Assessment: Exposure level, above which humans should not be exposed
- DNEL used for: Risk characterisation
- DNEL: is there a risk? The risk to humans can be considered to be adequately controlled if exposure levels do not exceed the appropriate DNEL
- Employers' obligations are not duplicated
- Where already meeting CAD requirements, review RMM in light of new info received & implement changes where necessary

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Guidance & Help

- HSA: **LoCall: 1890 289389**
  - **Email**: chemicals@hsa.ie
- ECHA:
  - http://echa.europa.eu/home_en.asp
- Commission:
  - doc on Guidance for employers on Controlling Risks from Chemicals

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