concawe

Beyond Reach to rEACH: What Happens After Registration?

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9th CONCAWE Symposium

14-15th March 2011

Background

Registration marks the end of one phase of REACH and the start of several others ...

- *Dissemination*
- *Evaluation*
- *Restriction*
- *Authorisation*
- *Public C&L inventory*
- *'Post Registration' obligations .. new data; dossier updates; REACH Guidance updates; etc.*

❖ ***What is CONCAWE doing in order that our responses remain timely and relevant?***

Outline

- Dissemination
- C&L inventory
- Evaluation
- Restriction
- Authorisation
- CONCAWE organisation

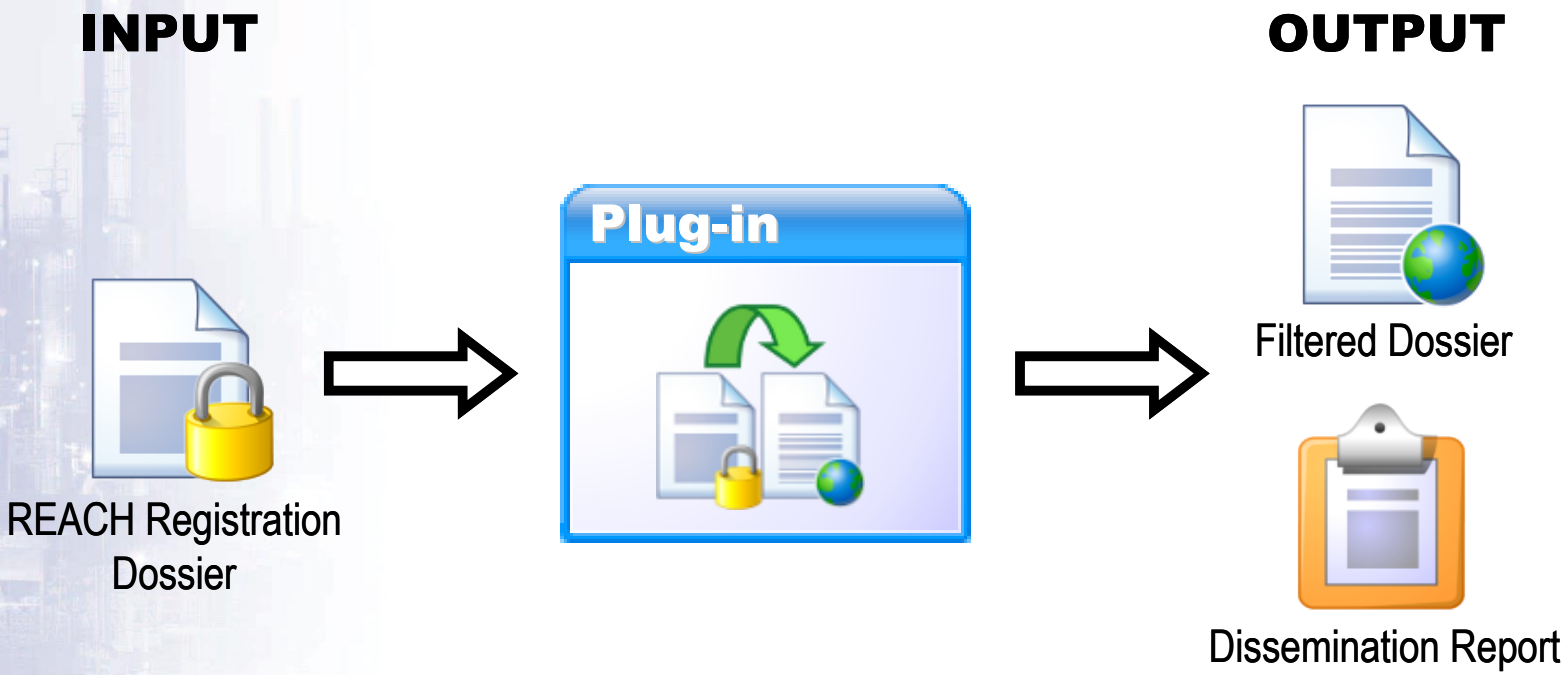
Dissemination

- Dissemination = publication of information from the registration dossiers on the ECHA website
  - Content covered under Arts 119(1) and (2)

- Dossiers submitted or updated from 1.12.2010:
  - published without further communication with the registrant
  - registrants to submit dossiers fit-for-dissemination
- Dossiers submitted before 1.12.2010:
  - published after 1.3.2011 or 2 months after receipt of the registration letter (whichever is latest)
  - registrants can update their dossier until this date
  - then published without further communication with the registrant

- The ECHA Dissemination Portal is also participating to the OECD eChemPortal

IUCLID dissemination plug-in

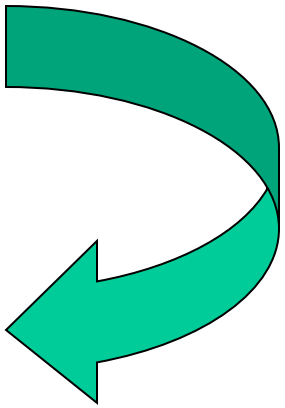


Dissemination : Summary

- Goes public in March 2011
- Process is automated
- Quality of outputs is a function of the quality of the inputs
  - CONCAWE's CSRs/IUCLIDs ensure that the basis for the dissemination reports is complete, comprehensive and relevant
- But missing from the dissemination reports are
  - The endpoints summaries;
  - The basis for DNELs/PNECs, or
  - The CSA/ES information.
- In the absence of any planned inclusion of this information in the dissemination portal, the revision of the CONCAWE product dossiers provides one opportunity to communicate this information

Public C&L Inventory

- C&L inventory
  - C&L from registration dossiers
  - C&L from notifications
  - harmonised C&L
  - Company name(s)



information which corresponds to the information referred to in Article 119(1) shall be publicly available

- public C&L inventory
  - substance name
    - IUPAC name can be claimed confidential → alternative name
    - EINECS name always published
  - harmonised Classification and labelling
  - classification and labelling according to CLP criteria from notifications and registration dossiers
- planned publication mid-2011
- Inventory remains to be tested regarding how it will work for UVCB substances derived from categories

Dossier Evaluation : Aims

One of ECHA's major tasks during 2011 ...

Evaluation type	ECHA questions	ECHA examination conclusions	Numbers and timelines
Testing Proposal Examination (TPE)	Is the proposed test adequate and justified? Unnecessary animal testing avoided?	Article 40(3) draft decision: ▸ Accept testing ▸ Reject testing ▸ Change test conditions ▸ Request additional testing	All testing proposals ▸ non phase-in: draft decision in 6 months ▸ phase-in submitted by 1 Dec 2010: draft decision by 1 Dec 2012
Compliance Check (CCH)	Information requirements adequately fulfilled? Adaptations adequately justified?	Article 41(3) draft decision: ▸ Request further information Other outcomes: ▸ Quality Observation Letter – indicates elements to be improved ▸ No further action	Select 5% of total received for each tonnage band ▸ Randomised and 'concern driven' selection criteria ▸ draft decision within 12 months of start CCH

ECHA Communications on Evaluation

- The proposed ECHA process for how dialogue with the LR will be pursued has now been described (Practical Guide #12)

1. Message (draft decision) sent to LR via REACH-IT mailbox
2. LR has 30 days to respond to ECHA in case of queries
3. Process for comments relating to testing proposals involves 45 day window via public web portal prior to ECHA making draft decision
4. Quality observation letters (QObL) also sent where shortcomings in dossier identified which are not necessarily related to data deficits

- The ECHA process does not explicitly consider issues associated with the need to inform/consult (mega)SIEFs; complexity/nature of the request; or (administrative etc) costs
- It is hoped that ECHA's processes will be empathetic to these challenges
  - Including, for example, extended time periods for more complex messages and direct communication with 3rd parties nominated by the LR e.g. CONCAWE and other consortia, together with direct email to alert registrant outside of REACH-IT inbox

Evaluation Outcomes

- Many of the CONCAWE substances have been the focus of regulatory interest over many years
- This is reflected in the comprehensive 'pre-REACH' framework of regulation that exists for petroleum products e.g. DSD nota, IPPC, AQFD, OELs, etc.
- It is clearly desirable for any 'post-REACH' interventions
  - To be cognisant of these precedents
  - To strive maintain a 'coherency' of regulation
  - To account for the dynamics of the relevant manufacturing and supply chains
- The ECHA Risk Assessment (RAC) and Member State (MSC) committees will oversee evaluation
  - Their processes will need to allow opportunity for full and proper discussion among all stakeholders on substances having a potentially profound bearing on society

Restriction

- Regulate the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to health or the environment
- Proposals for restrictions can be prepared by Member States or by ECHA on request of the Commission (Annex XV dossier)
- The drivers for how this process will develop still remain somewhat unclear
- Discussions on some restrictions proposals have commenced but these began prior to 2010 Registrations
  - Restriction of mercury in measuring devices; phenyl mercury; lead and its compounds in jewellery; dimethyl fumarate in articles

Authorisation

- The Authorisation process has now started
- New substances/SVHCs continue to be proposed by ECHA and the MSs for inclusion onto the Candidate List
  - Mostly those that are CMRs
- The first list of 6 Annex XIV substances has now been published
  - Together with a corresponding consultation on 'sun setting' dates
- None of the current proposed inclusions directly affect CONCAWE
  - Although the proposals relating to anthracene could impact some industrial products
- Not yet anticipated that Authorisation will affect CONCAWE (as M/Is) in a major way
  - Fuels and Intermediates uses are exempt from Authorisation
  - But DU implications have still to be clarified e.g. cobalt catalysts

Dossier Maintenance & Update

- REACH places an obligation (Art 22) on the registrant to update the Registration *without undue delay* to account for new information :
  - Tonnages; uses; hazards and risks; classification & labelling; etc.
  - Expected to use IUCLID 5.3 from April 2011
- New and revised REACH Guidance continues to be developed which also needs to be accounted for
- New information will also be forthcoming about petroleum products
  - Significant testing proposals for 5 categories
  - 2 generation reprotoxicity studies (~ €5m, ~13K animals)
- CONCAWE has initiated processes and activities to monitor and respond to these developments
  - REACH Dossier Coordination Group (RDCG)

Summary

- CONCAWE's REACH activities successfully completed their first major milestone with the Dec 2010 Registrations
- The next step in the process is expected to be ECHA's Evaluation of the test proposals associated with 5 Categories
  - Straight-run gas oils; Vacuum Gas Oils/Hydrocracked Gas Oils/Distillate Fuels; Residual Aromatic Extracts; Bitumen; Oxidized Bitumen
- The process of Registration has served to confirm the overall integrity of the industry's understanding of H&E risks
  - But also highlighted some areas where our knowledge needs to be improved to further underpin the basis of risk management strategies
- CONCAWE's health and environmental groups are now
  - Finalising the publication of information that serves to further increase the transparency and integrity of CSRs
  - Identifying where targeted research is advisable to reduce uncertainties in the chemical safety assessment of petroleum products

Back-Ups

Article 119

Article 119(1)

(a) the name in the **IUPAC Nomenclature**, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g);

(b) if applicable, the **name of the substance** as given in EINECS;

(c) the **classification and labelling** of the substance;

(d) **physicochemical data** concerning the substance and on pathways and environmental fate;

(e) the result of each **toxicological and ecotoxicological study**;

(f) any **derived no-effect level** (DNEL) or **predicted no-effect concentration** (PNEC) established in accordance with Annex I;

(g) the **guidance on safe use** provided in accordance with sections 4 and 5 of Annex VI;

(h) **analytical methods** if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

Article 119(2)

(a) if essential to classification and labelling, the **degree of purity** of the substance and the **identity of impurities and/or additives** which are known to be dangerous;

(b) the **total tonnage band** (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;

(c) the **study summaries** or **robust study summaries** of the information referred to in paragraph 1(d) and (e);

(d) **information**, other than that listed in paragraph 1, contained in the **safety data sheet**;

(e) the **trade name(s)** of the substance;

(f) the **name in the IUPAC Nomenclature** for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;

(g) the **name in the IUPAC Nomenclature** for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:

(i) as an intermediate;

(ii) in scientific research and development;

(iii) in product and process orientated research and development.

The Dissemination Process

registration is complete

registration dossier is scheduled for dissemination

registration dossier is filtered
= only information listed in article 119 is left in the dossier

for joint submissions: filtered dossiers are aggregated
= the information on the substance from all dossiers in the joint submission are merged into one dossier

dossier is disseminated on ECHA website