Interface between REACH and CAD:
Comparison of central building blocks of risk assessment under both pieces of legislation
(DNELs and OELs, RMMs and control measures)

6th Seminar on
Workers’ Protection & Chemicals
ETUI-REHS, Brussels, 28 – 29 January 2011

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Overview

Employers’ situation under CAD plus REACH:
More information, additional obligations

Risk assessment

Limit values

Protection and prevention measures

Substitution

Discussion at EU level

Questions for discussion
Employers’ situation under CAD plus REACH

Additional information provided

- Additional information in eSDS / exposure scenario(s)
  - identified uses
  - risk management measures (RMMs)
    (for identified uses)
  - DNEL (or DMEL)
Employers’ situation under CAD plus REACH

Additional obligations

REACH obligations for downstream users (= employers)
- check identified use
- implement RMMs (art. 37 (5) / art. 39 (2))
- achieve DNEL
- observe authorisation obligations

without prejudice of remaining CAD obligations for employers (= downstream users)
- perform risk assessment (art. 4 (1), (2)) art. 5, art. 6
- implement control measures in prescribed order: S T O P (art. 5 & 6)
- achieve OEL (art. 6 (5))

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Employers’ situation under 
CAD plus REACH

Legal obligations under two pieces of legislation vs. real-life situation

Legal obligations which have to be applied in parallel:
- REACH (Regulation (EC) 1907/2006)
- Workers’ health legislation –
  CAD (Chemical Agents Directive – Dir. 98/24/EC)
  CMD (Carcinogens and Mutagens Directive – Dir. 2004/37/EC)

application of the directives is complicated by national differences arising from national transposition of minimum requirements

Real life: DU (downstream user) / employer –
- one and the same person who has to act consistently and coherently
At least two approaches to remedy any potential conflict between the two pieces of legislation have been derived so far:

- **Guidance for employers on controlling risks from chemicals – interface between CAD and REACH at the workplace** (endorsed by the Advisory Committee on Safety and Health at work, ACSH: [http://ec.europa.eu/social/BlobServlet?docId=6126&langId=en](http://ec.europa.eu/social/BlobServlet?docId=6126&langId=en))

Introduction: obligations under two separate pieces of legislation

Structure of presentation

In this presentation, certain elements from the two approaches will be addressed:

- starting point
- risk assessment – the interface between REACH and CAD
- focus on two building blocks of risk assessment process:
  - limit values
  - protection and prevention measures

Reminder
Focus exclusively on interface between REACH and OSH – explicitly not on
- REACH / environmental legislation or
- REACH / consumer protection legislation
Risk assessment

Types of risk assessment

REACH

Chemical safety assessment (CSA – annex I, REACH):
- assessment of identified use, i.e. for certain generic operational conditions: generic risk assessment

CAD

Assessment of risk (art. 4 (1) CAD):
- assessment of real-life workplace situation, i.e. including both other chemicals and other than chemical hazards: specific risk assessment
Risk assessment

Obligations – the legal texts (1)

<table>
<thead>
<tr>
<th><strong>REACH</strong> (Art. 37 (5))</th>
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<tbody>
<tr>
<td><strong>Any downstream user shall</strong> identify, <strong>apply</strong> and where suitable, recommend, <strong>appropriate measures to adequately control risks</strong> identified in any of the following</td>
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<tr>
<td>(a) the safety data sheet(s) supplied to him;</td>
</tr>
<tr>
<td>(b) his own chemical safety assessment;</td>
</tr>
<tr>
<td>(c) any information on risk management measures supplied to him in accordance with Article 32.</td>
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</table>
Risk assessment

Obligations – the legal texts (2)

**CAD (Art. 4 (1))**

In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall first determine whether any hazardous chemical agents are present in the workplace. If so, he shall then assess any risk to the safety and health of workers arising from the presence of those chemical agents, taking into consideration the following:

- their hazardous properties,
- information on safety and health that shall be provided by the supplier, ...
- the level, type and duration of exposure,
- the circumstances of work involving such agents, including their amount,
- ...
- the effects of preventive measures taken or to be taken,
- ...

...
Risk assessment

Resulting questions:

- **Does the employer** (under CAD) **still have to perform his own risk assessment, or can he rely on the results of the CSA, communicated in an exposure scenario (ES)?**

- **If the latter, under which preconditions?**

  (Cf. questions 2.4 and 4.1 in “Announcement 409”)

Answers – given in German guidance:

- **Yes**, he still has to perform his own risk assessment.

- **Under certain preconditions** (as described elsewhere), the ES may be directly used for **certain parts of the risk assessment**.
Limit values

**Similarities** and differences between DNELs and OELs

- health-based

- prescribed methodology for derivation
  - DNELs: REACH guidance
  - IOELVs: SCOEL methodology
  - AGWs (German OELs): TRGS 901

- method structurally similar, yet certain technical differences
  - prescribed assessment factors vs. role of expert judgement

- **caveat** (re. national OELs)
  - national OELs derived under various approaches, e.g. in some MS consideration of socio-economic aspects
Limit values

Similarities and **differences** between DNELs and OELs

- **sponsors** structurally different
  - DNELs: company (manufacturer / SIEF)
  - IOELVs: state-like body (EU Commission)

- **deriving bodies** ("contractors") structurally different
  - DNELs: in-house expertise / commercial contractor
  - IOELVs: SCOEL (international body of experts; formalized, recorded meetings, i.e. process open to external scrutiny)

...
Limit values

Similarities and **differences** between DNELs and OELs

- **(in-)transparency on reasoning behind resulting values**
  - DNELs: no publicly available documentation – results not accessible to public scientific criticism
  - IOELVs: scientific documentation publicly available – results easily accessible to scientific criticism

**scientific documentation: cornerstone of quality control**

Resulting **question:**
- Can the employer rely on DNELs and IOELVs in the same way?

**Answer** – to be discussed **afterwards**
Limit values

Additional aspect: other types of limit values not to be discussed at this seminar – separate event needed

- limit values with socio-economic component
  - REACH: not foreseen
  - CAD / CMD: binding OELs (BOELs)
  - some MS: certain national OELs

- risk-based limit values for non-threshold effects (primarily for carcinogens)
  - REACH: DMELs (not part of the legal text, solely recommendation in guidance; useless without communication of underlying risk level)
  - CMD: not foreseen – minimization of exposure obligatory
  - some MS: new approaches based on consensus on risk levels
Limit values

Application

DNELs
indirectly applied –
by prescribed risk management measures (RMMs)
which additionally have to rely on
- exposure estimates and
- assumptions on efficacy of RMMs

IOELVs
directly applied –
as benchmark for assessing
- the efficacy of implemented control measures
- when (if) true exposure has been determined

caveat: basic weakness –
direct application reliant on exposure determination
Protection and prevention measures

Differences between REACH and CAD

- **hierarchy of control**
  - REACH: not addressed in the legal text, only (rather hidden) in guidance document
  - CAD: requested in art. 6 (2) – the STOP principle

- **role of PPE as a permanent protection measure**
  - REACH: not addressed in the legal text
  - CAD: measure of last resort in the order of priority
  - transposition of CAD in Germany:
    - permanent use of burdensome RPE not permitted; OEL has to be achieved outside RPE

-...

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ETUI-REHS Seminar
Brussels, Jan. 2011
Protection and prevention measures

Differences between REACH and CAD

**Resulting question:**
- If the RMMs communicated in the eSDS contradict the STOP principle,
  or if RPE is prescribed to achieve the DNEL,
  do those situations constitute cases as referred to in Art. 34 b) of REACH,
  i.e. do they “call into question the appropriateness of the RMMs identified in an SDS”?
(Cf. question 14.1 in ECHA’s FAQs on REACH)

**Answer** – to be given by ECHA?
Protection and prevention measures

Differences between control measures

scenario “established use of substance” – the most likely situation imagine:

- **REACH:** RMMs with regard to OSH communicated in the eSDS **differ from established control measures** at DU level (derived as part of risk assessment under CAD)

- **CAD:** established OSH control measures **achieve DNEL** communicated under REACH

Resulting **question**: ...
Protection and prevention measures

Differences between control measures

Resulting question:
- Is employer / DU in conformity with both pieces of legislation if he has maintained the established control measures for OSH (and if he has used his documentation of risk assessment as DU CSR)? (Cf. questions 4.2 and 4.3 in “Announcement 409”)

Answer – given in German guidance on OSH legislation:
- Yes.
  Should, according to REACH, the DU be obliged to prepare a DU CSR, his documentation of risk assessment would suffice for the OSH part of the CSR.

... and the opinion of ECHA?
Protection and prevention measures

Real-life workplace situation

scenario “exposure to several substances plus additional hazards” – standard situation at real workplaces is simultaneous
  - use of several substances or mixtures
  - occurrence of additional, process-generated substances
  - occurrence of other than chemical hazards

Resulting question:
  - How likely is it that outcome of generic risk assessment (i.e. CSA under REACH) will suffice for such real-life situations?

Answer – to be discussed afterwards
Substitution

Authorized use of a SVHC vs. substitution

**obligations under REACH**
- a DU may use a substance ... provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use (Art. 56(2))
- DU using a substance in accordance with Art. 56(2) shall notify the Agency (Art. 66(1))

**obligations under CMD**
- the employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, ... (Art. 4(1))

...
Substitution

Authorized use of a SVHC vs. substitution

Resulting question:
- Does the existence of an authorisation under REACH render the substitution obligation under the CMD superfluous? (Cf. question 6.1 in "Announcement 409")

Answer – given in German guidance:
- No, the authorisation of a use under REACH does not exempt the employer from conducting a substitution check. The findings of an authorisation procedure based on a socio-economic analysis may, however, provide valuable information for the information check.
Discussion at EU level

International Workshop:
How to Use REACH Information for Health and Safety at Work
- organized by German Ministry of Labour and Social Affairs,
  Berlin, 6 Dec. 2010 – contributions available at:

ECHA workshop:
- to be organized by ECHA / DG ENTR / DG ENV / DG EMPL
- scheduled for end of 2011
Questions for discussion (1)

Risk assessment
- Does the employer (under CAD) still have to perform his own risk assessment, or can he rely on the results of the CSA, communicated in an exposure scenario (ES)?
- If the latter, under which preconditions?

Limit values
- Can the employer rely on DNELS and on IOELVs in the same way?
Protection and prevention measures

- If the RMMs communicated in the eSDS contradict the STOP principle, or if RPE is prescribed to achieve the DNEL, do those situations constitute cases as referred to in Art. 34 b) of REACH, i.e. do they “call into question the appropriateness of the RMMs identified in an SDS”?

- Is employer / DU in conformity with both pieces of legislation if he has maintained the established control measures for OSH by which he achieves the DNEL (and if he has used his documentation of risk assessment as DU CSR)?

- How likely is it that the outcome of generic risk assessment (i.e. CSA under REACH) will suffice for real-life situations?
Questions for discussion (3)

**Substitution**

- Does the existence of an authorisation under REACH render the substitution obligation under the CMD superfluous?