



Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

***DMEL and risks in occupational exposure  
to carcinogenic compounds: The way forward***

***A closer look to DMELs and the  
German „traffic light model“***

***Dortmund, May 17th 2011***

# Program

Time	Person (organisation/country)	Title
<b>10:00 – 10:15</b>	<b>Registration, coffee</b>	
10:15 – 10:20	Moderator	Preview
10:20 – 10:40	Mr. Michael Koll (BMAS/ DE)	Opening
10:40 – 11:10	Mr. Herbert Bender (AGS/DE)	History of German Traffic light model
11:10 – 11:40	Mr. Henning Wriedt (AGS/DE)	Minimizing exposure to carcinogens: Risk limits and their interplay with risk reduction measures
11:40 – 12:10	Mr. Norbert Rupprich (BAuA /DE)	Carcinogenic risk assessment and evaluation in the upcoming Reach authorisation process
<b>12:10 – 13:00</b>	<b>Lunch break</b>	
13:00 – 13:30	Mr. Joe Püringer (AUVA / AT)	Risk considerations from Austria
13:30 – 14:00	Mr. Nathan Kuper (Min. Soc. Aff. & Employment / NL)	Risk values in the Netherlands
14:00 – 14:30	Mr. Aart Rouw (BAuA/DE)	“Real DMELs” – What do they look like?
<b>14:30 – 14:45</b>	<b>Coffee Break</b>	
14:45 – 15:45	All	Recommendations/ Conclusions of the workshop
<b>15:45 -16:00</b>	<b>Moderator</b>	<b>Closing remarks</b>

# Why this workshop ? (1)

- 2007 : Implementation of REACH
- 2008 : Publication of German BekGS 910  
(describing the „Ampel Modell” = Traffic light model)
- 2008 : Publication of ECHA  
„Guidance Document R8\*”  
(includes DMEL concept – not part of REACH text !)
- 2010 : Debates on usefulness of DMEL concept\*\*

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\* „Guidance on information requirements and chemical safety assessment  
Chapter R.8: Characterisation of dose [concentration]-response for human health“

\*\* J. Püringer : Gefahrstoffe - Reinhaltung der Luft; 70(5), 175, 2010

## Why this workshop ?(2)

- 2010 : German considerations on possibility to merge risk based “traffic light thinking” and DMEL
- 2010 : German CA sends paper to CARACAL
- 2011 : Presentation in CARACAL on DMEL/Traffic Light → Follow-up discussion offered

***2011/12/13 : The first  
authorisations  
are coming !***

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## The objectives for today

- Present “Traffic light” model as a tool to manage risks
- Experiences & feelings about risk based management tools in other MS
- Evaluate DMELs derived in registration dossiers.
- Collect/discuss proposals on how to proceed :  
*Feedback to CARACAL /  
+ Other stakeholders*  
*(DG Employment/ DGE Environment/DG Enterprises)*

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## And now.....?

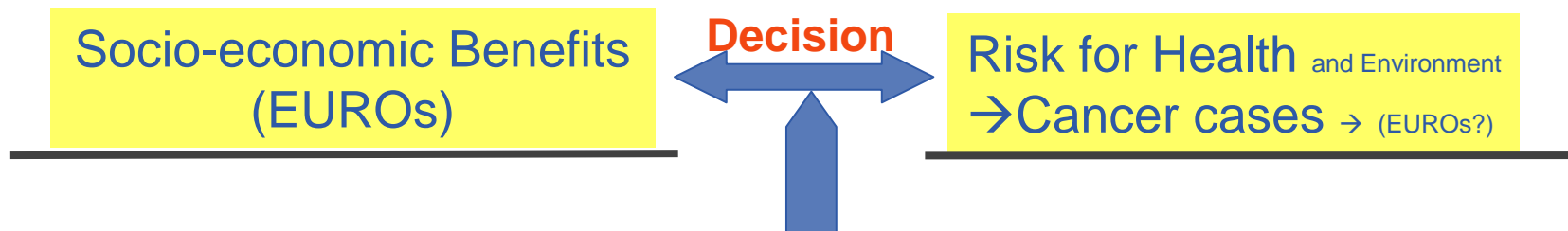
Summarizing what we discussed today :

- *Where we agree and see need for clarification/ action*
- *Where we differ in opinion and see need for further discussion.*

*Dortmund, May 17th 2011*

## Starting Point: *(here we should agree...)*

- REACH wants to protect human health....
- REACH art. 55 defines a risk based approach for authorisation of SVHCs ( & also wants substitution where possible)
- Art. 60 : Authorisations for non- threshold carcinogens can *only* be granted if Socio-economic benefits outweigh risks.



- DMELs are meant to help comparing cancer risks and thereby help to take rational decisions

## Statements where debate may start....

- At least some carcinogens will be granted an authorisation and be around for the foreseeable future - and be of concern. *(no alternative, too important....)*
- We need a strategy to separate big problems from small ones. Essential elements:
  - *common language to talk about “risks” (otherwise difficult to compare)*
  - *agreement on what defines small/big problems.*
- We need to concentrate efforts where it matters.
  - *define & implement Risk Management Measures for those cases that have a high residual risk. (& save lives !)*

**Note : Registration dossiers have been submitted,  
and we need to accept & use them as such !**

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# Role of DMEL and „traffic light“

## ➤ DMEL :

- Separates two risk & measures regions ( ≠ “Safe”/“Not safe!”)
- Necessary : Transparent indication of risk levels

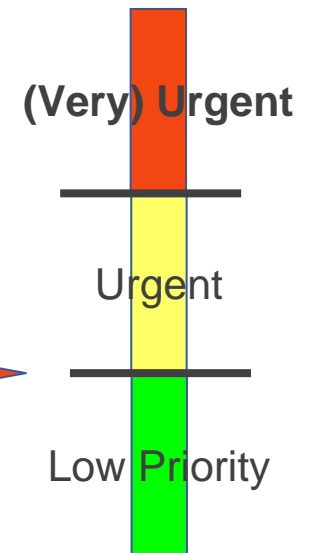
*Many DMELs from dossiers need critical review before use !*

- Important : Where to place the limit(s) of risk?

## ➤ Traffic light model:

- Two limits (challenging but achievable)
- Define risk & measures regions

➤ ***We propose at least one risk limit value (DMEL)***  
***This will allow prioritisation***



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## Questions/ Statements to agree on

- What do we (the „experts“) advise society („politicians“) to use as limits of risk to separate the small risks from the bigger risks
  - We propose DMEL = Green/Yellow borderline (4:100.000)
- What quality of data do we need ?
  - We recommend a critical review of DMELs in dossiers to set common standards. (Dossier + Substance evaluation, RAC disc.)
- How to satisfy “minimisation” requirement in different risk regions ?
  - We advise a staged approach (less demanding in green area)

## *Issues to be discussed :*

## Problems that will follow *need to be solved by others* *(RAC, SEAC, EU commission.....etc)*

- Consequences of different risk regions for the authorisation process?
  - *Substitution plan & sunset-date will differ*
  - *Different depth of analysis (SEA) to compare risk /benefits quick & plausible in green → in-depth in yellow*
- How can REACH regulations create a pressure for substitution in different risk regions ?
  - *Set different timeframes for review of authorisations - Art. 60(8)*
  - *Pressure for substitution plans*

## Who may be may be the next steps?

➤ Who ?

➤ What ?

➤ Where ?

➤ When ?