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# Risk Considerations from Austria

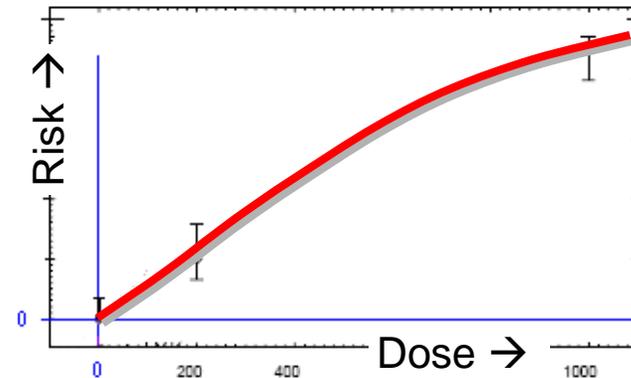
- A. Losert (Environment Agency Austria)
- J. Püringer (Workers Compensation Board)
- C. Streissler (Chamber of Labour)

# Background

The attempt to establish **risk based** exposure limits for genotoxic substances is appreciated

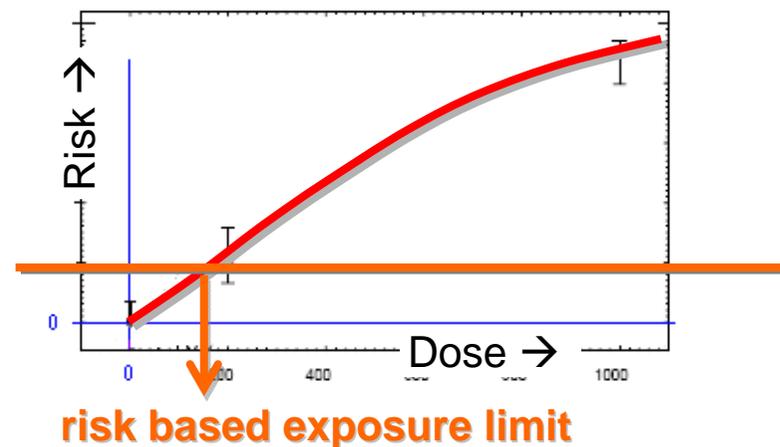
Two elements are needed:

1. **Exposure–risk–relationship**  
(non-linear, linear)



2. Consensus on  
**acceptable risk level**

to be decided on  
a political level  
**MISSING until now**



# No DMEL without acceptable cancer risk

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There is a need for political decision  
(e.g. for substance evaluation, ...)

## Possible steps forward:

*In longer perspective:*

- Invite the Council and the Parliament to initiate a process with the aim to **lay down a general EU wide acceptable risk level** for additional cancer cases due to anthropogenic causes.

*As a transitional measure:*

- For the period until a harmonised acceptable risk level will be determined it is proposed to follow a conservative approach by **using the ratio of 4:100.000** as a benchmark for lifetime risk.

# Accompanying Steps

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## **As accompanying measures:**

- Invite ECHA and MS CAs to assess whether the first set of registrations shows a consistent picture of the application of the DMEL concept by registrants.  
Should this not be the case, invite CARACAL to revise Guidance R.8 appropriately.
- ECHA should request that registrants have to communicate (in addition to the DMEL value) the risk level on which the DMEL is based.

# Inappropriate Methodology

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An **explicitly specified acceptable risk level** is needed for a transparent DMEL derivation.

- **No specified acceptable risk level** in the “**Large Assessment Factor**” approach (Chapter R.8.5.2.2)
- It was developed by EFSA SC in a totally different context
  - It was designed for giving guidance on risk management measures if carcinogens are unintendedly present in food,
  - as a tool for priority setting for action.
  - It uses a fixed set of “assessment factors”, not being compatible with a general and explicit risk level.
  - EFSA SC points out that the assessment factors have to be societally consented prior to using them (*Not adopted by the guidance!*)
  - EFSA SC emphasises minimisation as the major task (*Not adopted by the guidance!*)

## “Large Assessment Factor” approach

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**An approach which does not explicitly take into account an acceptable risk level should not be used for the derivation of risk based limit values.**

### **The step to be taken:**

- The “Large Assessment Factor” approach is inappropriate in the context of DMEL derivation.  
**It should be removed from the guidance.**

# Severe Ethical Fault

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- The guidance seems to support the objective that a 10-fold higher risk level is imposed on workers compared to the population at large.
- We assume that this is not the authors' intention, but an error caused by confusing risk level with susceptibility level or risk levels associated with exposures in reality.
- Different acceptable risk levels would contradict the unconditional values of Equity and respect for Human Dignity.

## The step to be taken:

- **Make clear that a different acceptable risk level for workers and for the population at large is not acceptable on ethical grounds.** Any reference or suggestion on a divided acceptable cancer risk for different groups of humans should be deleted from the guidance.

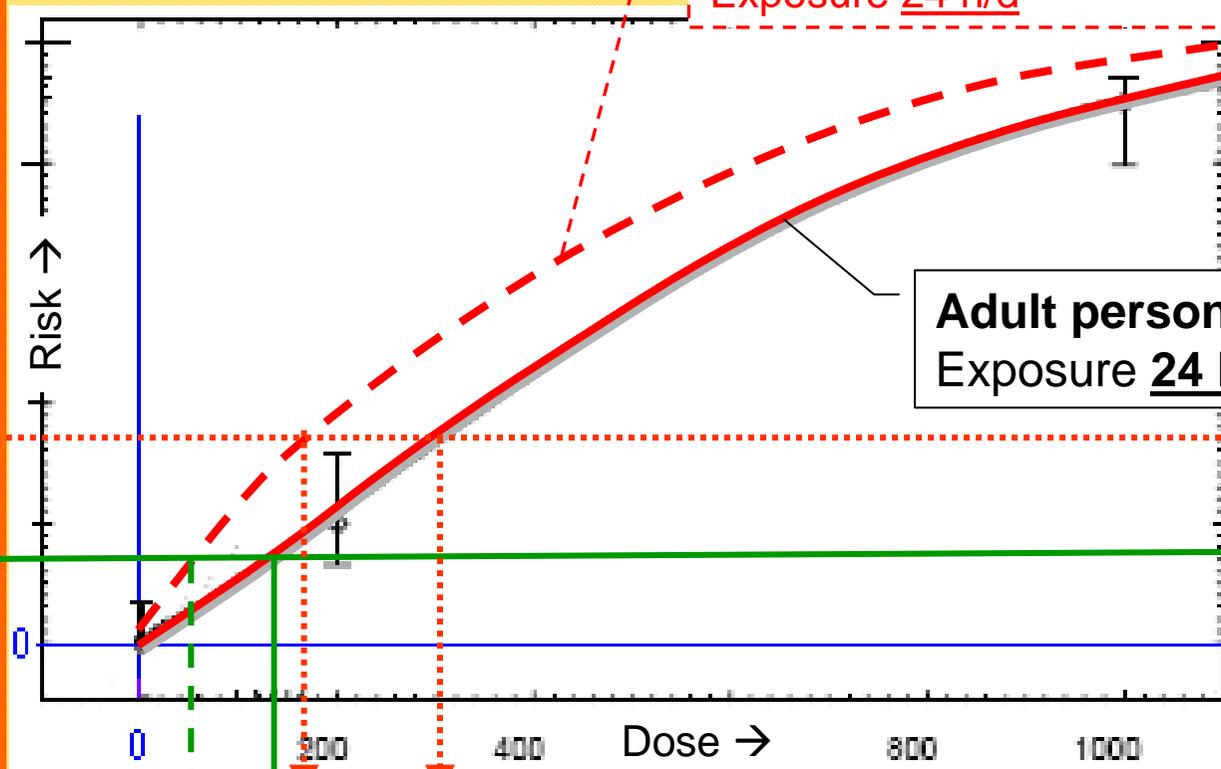
# Same Risk Level, but different **Exposure Limits** for different Groups

**Political  
Debate &  
Decision**

acceptable  
risk level 2

acceptable  
risk level 1

**Scientific Research**



**Babies, specifically sick...**  
Exposure 24 h/d

**Adult persons**  
Exposure 24 h/d

risk based limit value for exposure 24 h/d

→ **3-fold value for exposure 8 h/d** (for Workers?)

→ **Adaption for high respiratory volume** → lower value

→ possibly other modifications

# Minimisation Principle

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- The Minimisation Principle should be emphasised in the guidance documents.
- *Consumer sector:* possible 0.1 % carcinogen content in everyday products contributes to the general cancer burden
- *Occupational sector:* The minimisation principle imposed by CAD and CMD should be strengthened by emphasising it in the guidance, in particular to raise the awareness of persons responsible for preparing ES and SDS.

## For more Details see ...

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- Room document: DMEL – Problems and Steps to be taken
- Recommendation of the Austrian Workers Compensation Board not to derive DMEL values until an acceptable cancer risk is societally concluded:  
[http://www.auva.at/mediaDB/703789\\_DMEL-Position\\_EN.pdf](http://www.auva.at/mediaDB/703789_DMEL-Position_EN.pdf)
- J. Püringer, DMEL values as a limit values for carcinogens – a problematic approach in the wake of REACH, Gefahrstoffe – RdL 2010, 175 (English summary):  
[http://www.auva.at/mediaDB/703790\\_DMELs\\_Problematisches\\_Konzept.pdf](http://www.auva.at/mediaDB/703790_DMELs_Problematisches_Konzept.pdf)