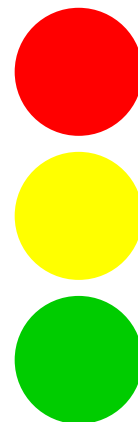


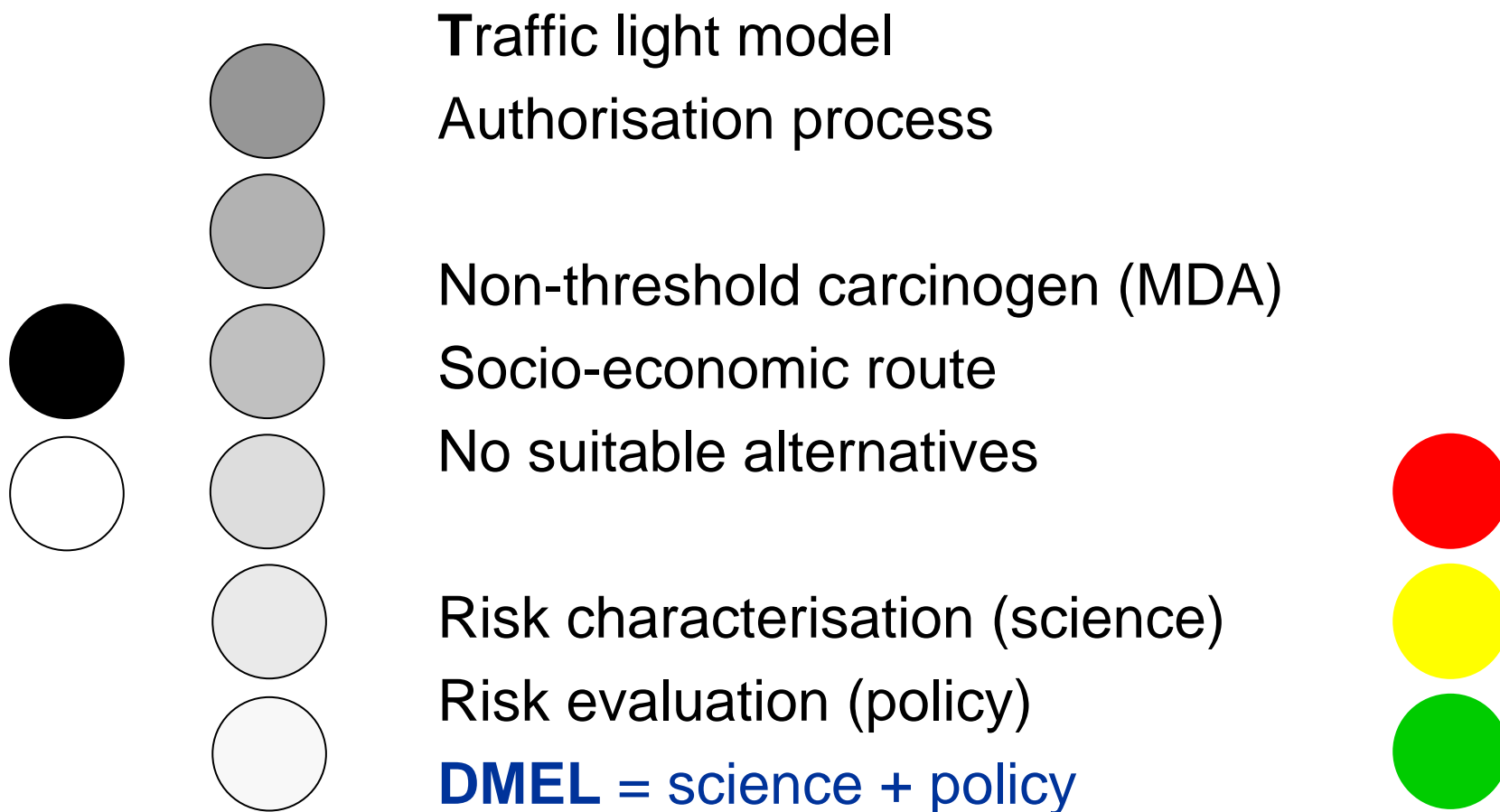


Bundesanstalt für Arbeitsschutz und Arbeitsmedizin



To grant
or
not to grant
.....

The basic topics

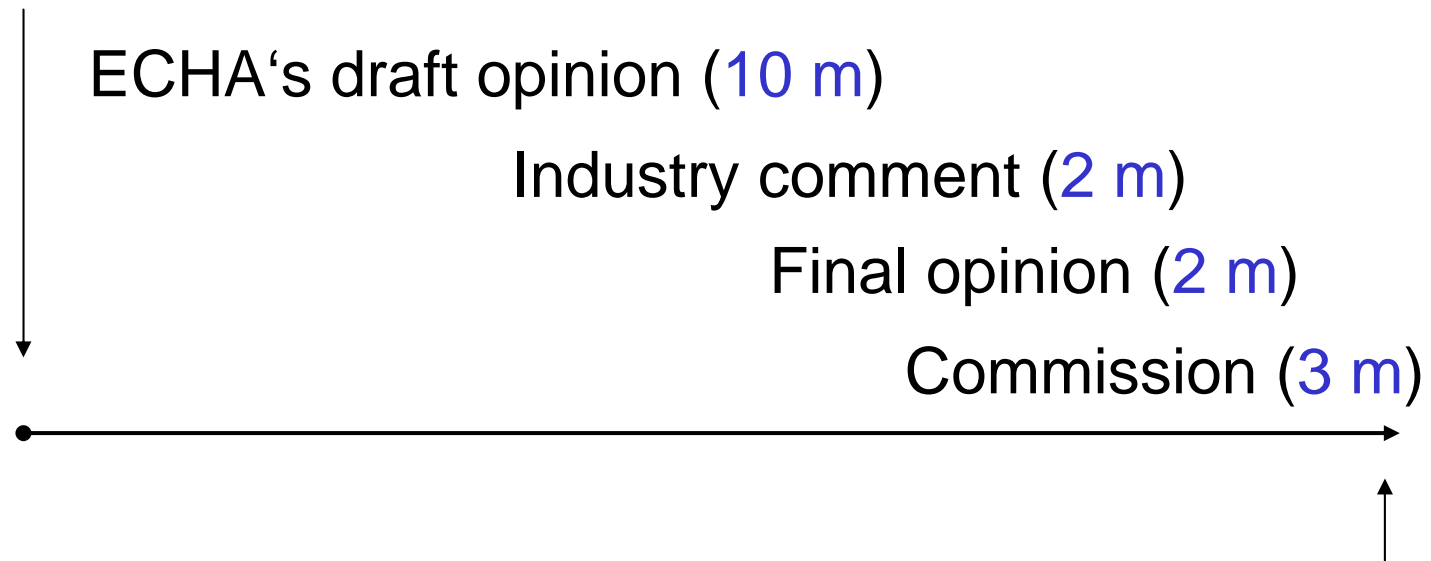


No time to waste ...

17 m

Application of
authorisation

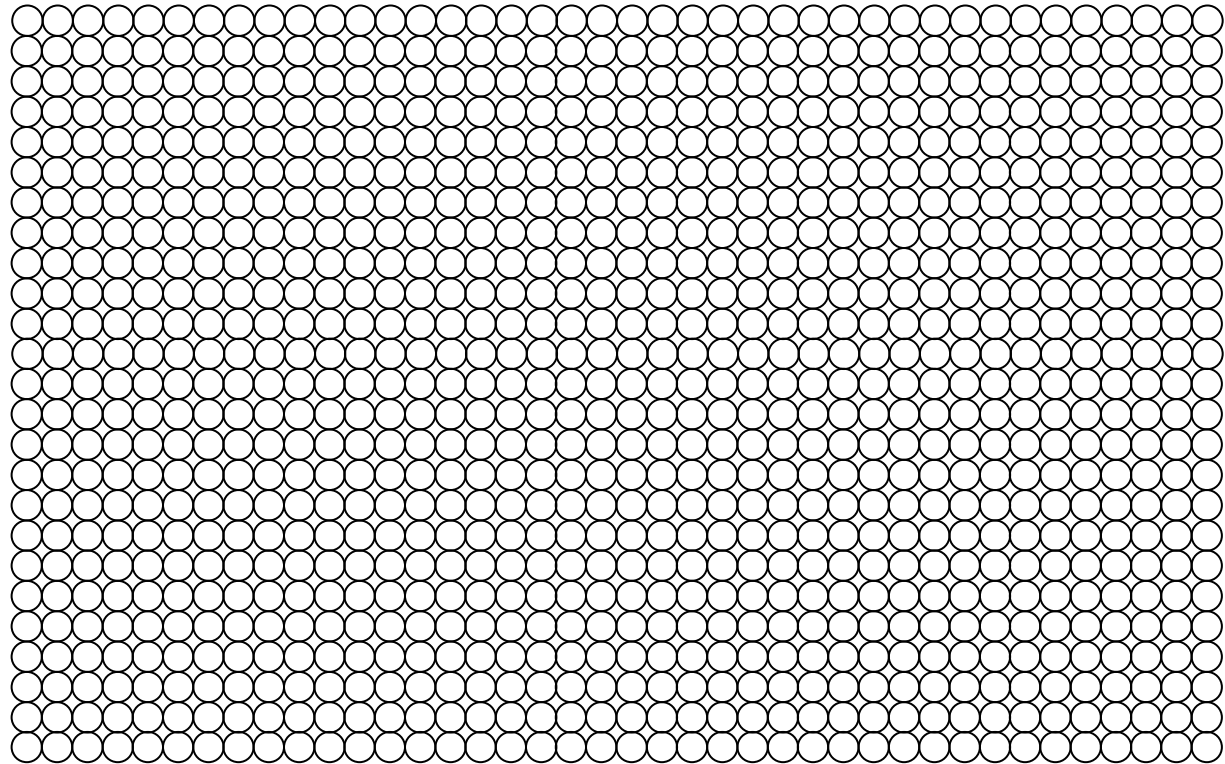
to think about
risk evaluation and DMELs



Draft decision by
the Commission

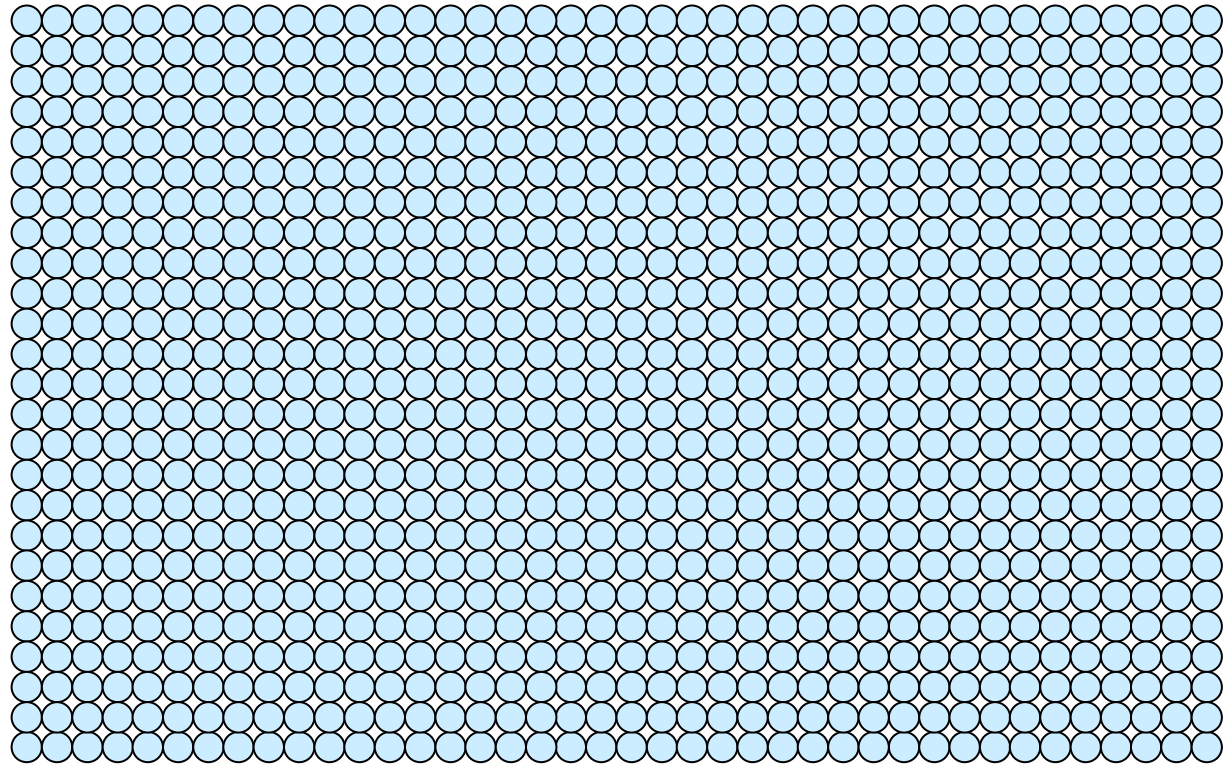
Working lifetime risk (I)

1.000 workers



Working lifetime risk (II)

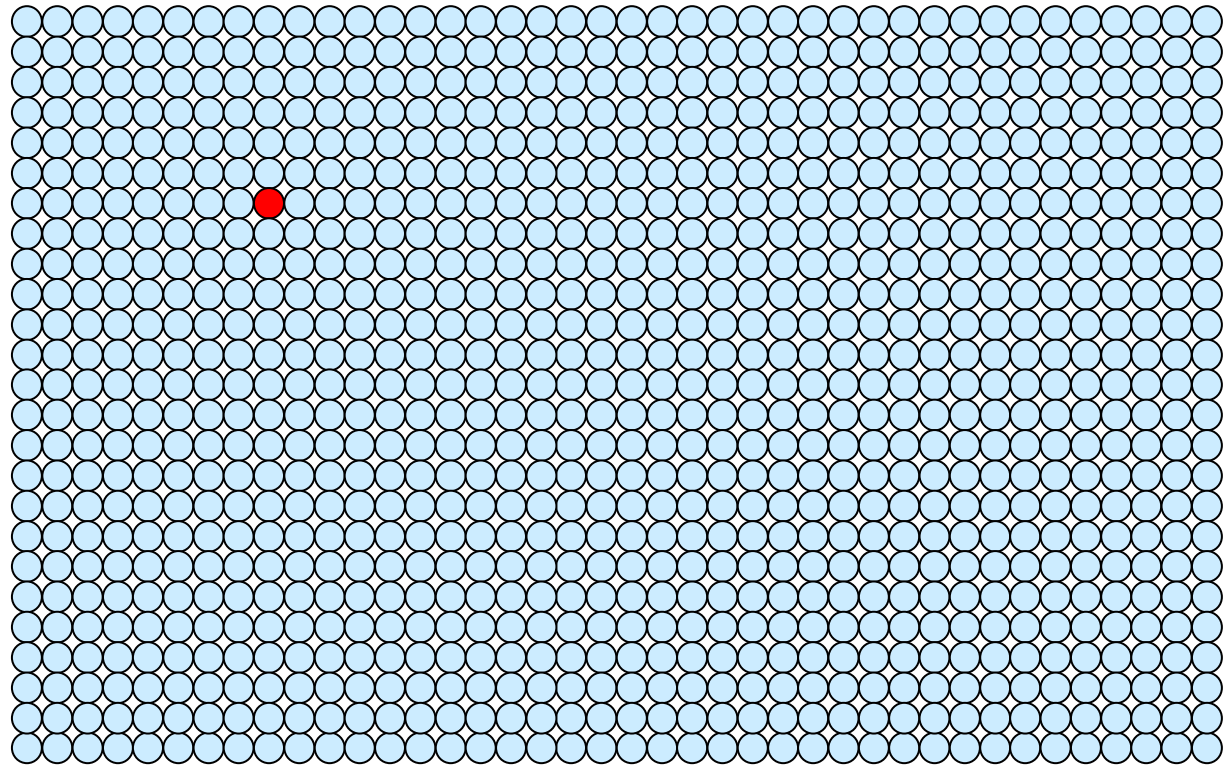
1.000 workers
identically exposed to a carcinogen
for their working lifetime of 40 years



Working lifetime risk

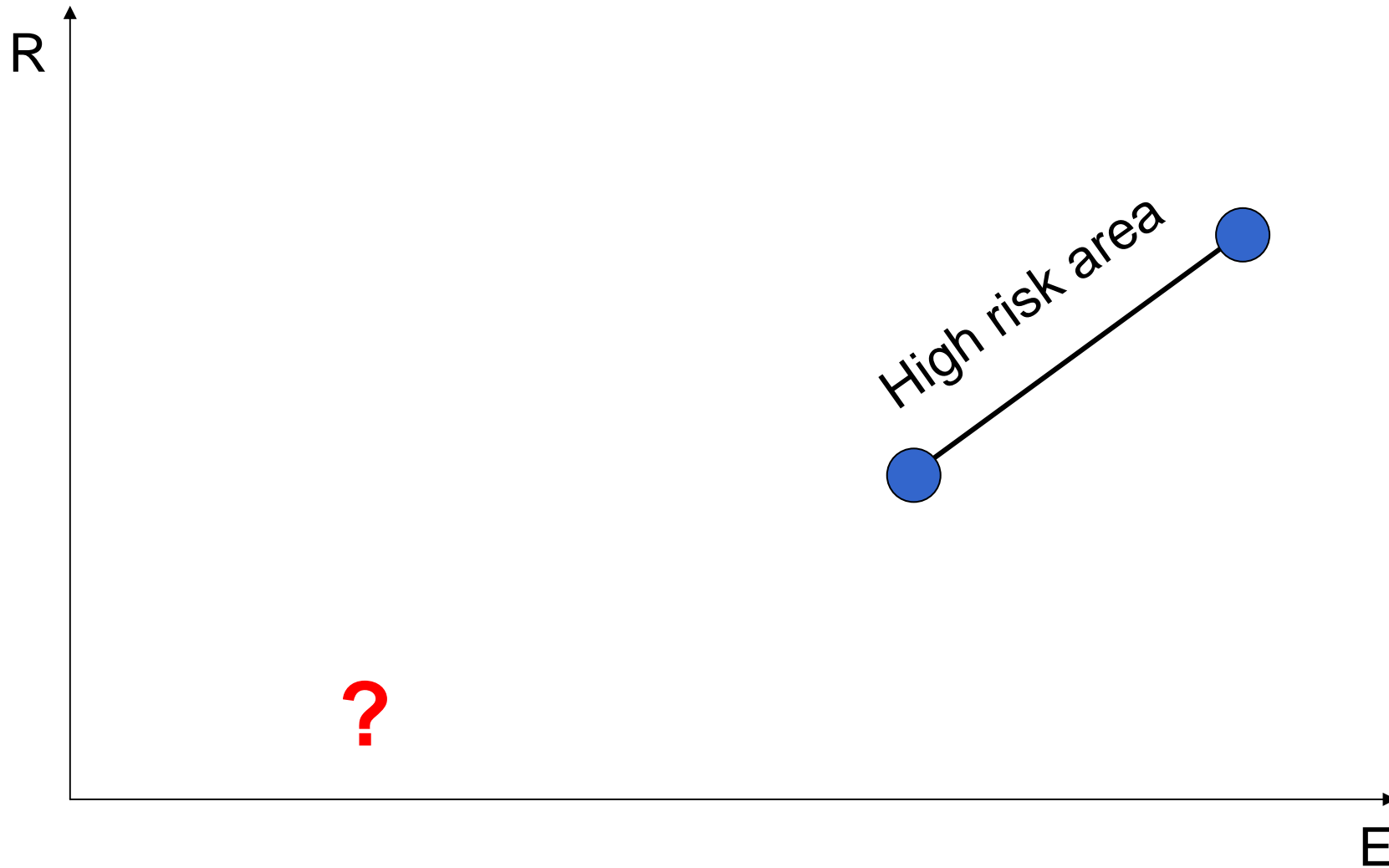
● One of these 1.000 workers gets cancer because of a specified 40-year exposure to the carcinogen:

Working
lifetime risk
of 1 : 1.000

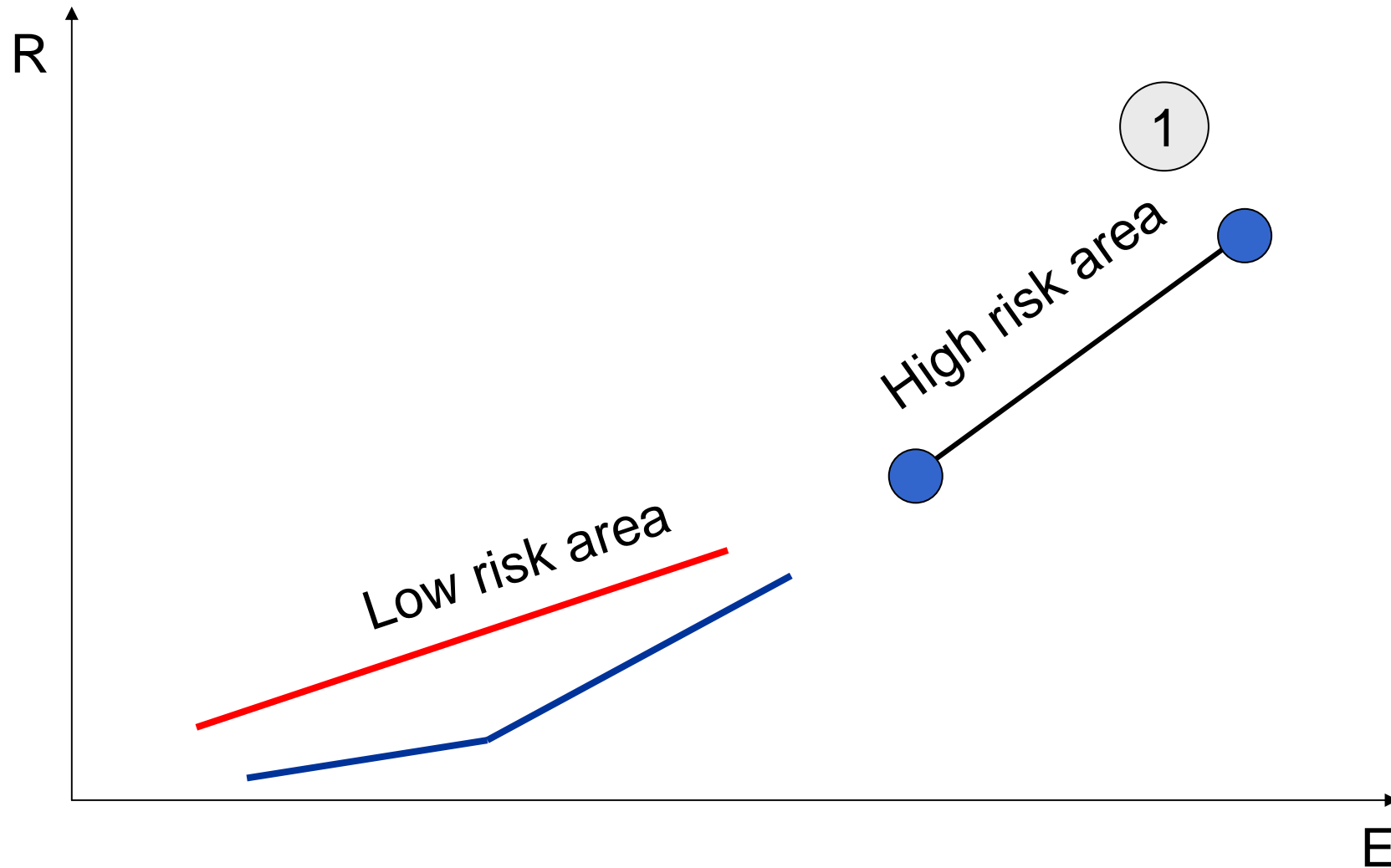


It is an
excess risk

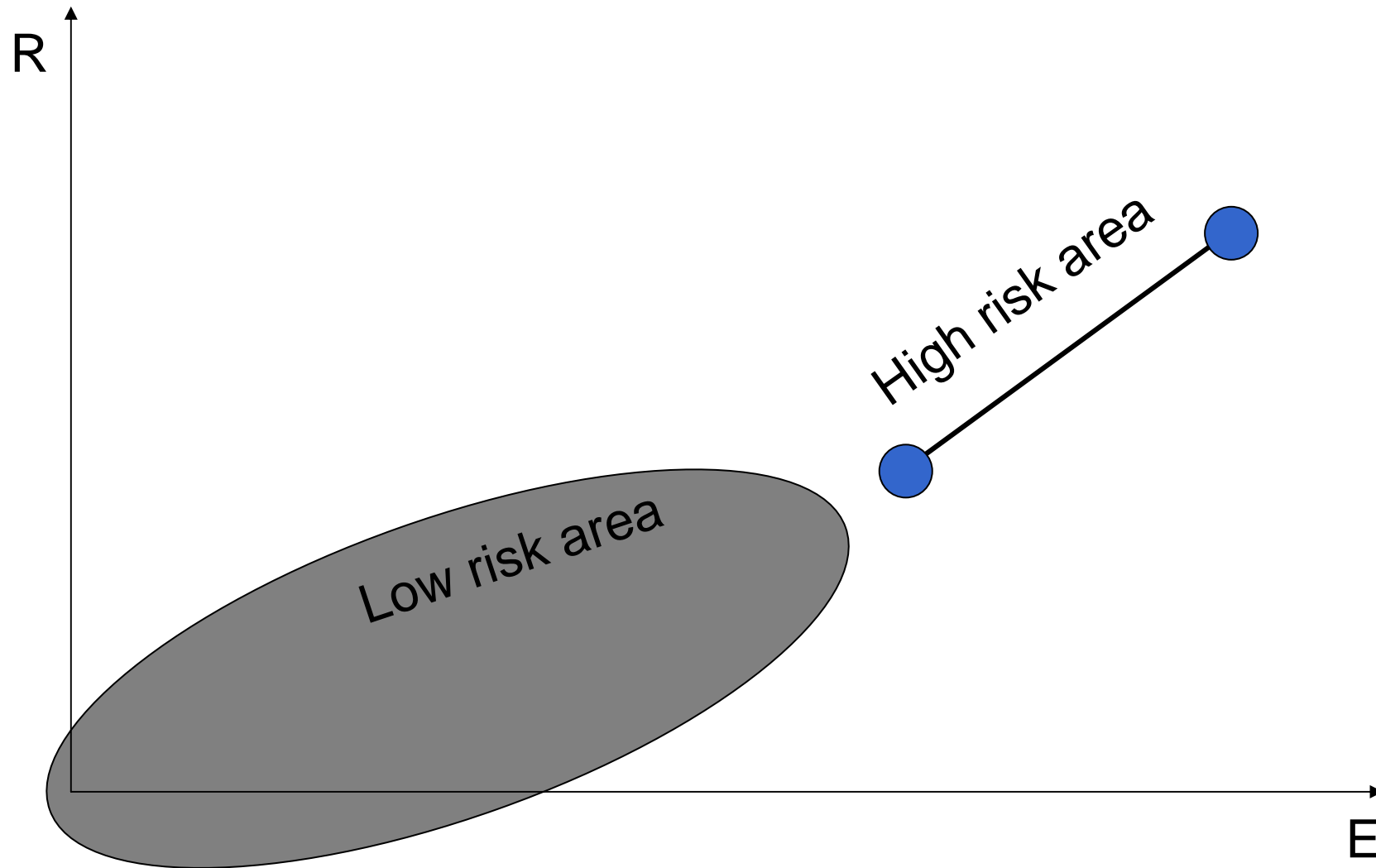
High and low risk areas



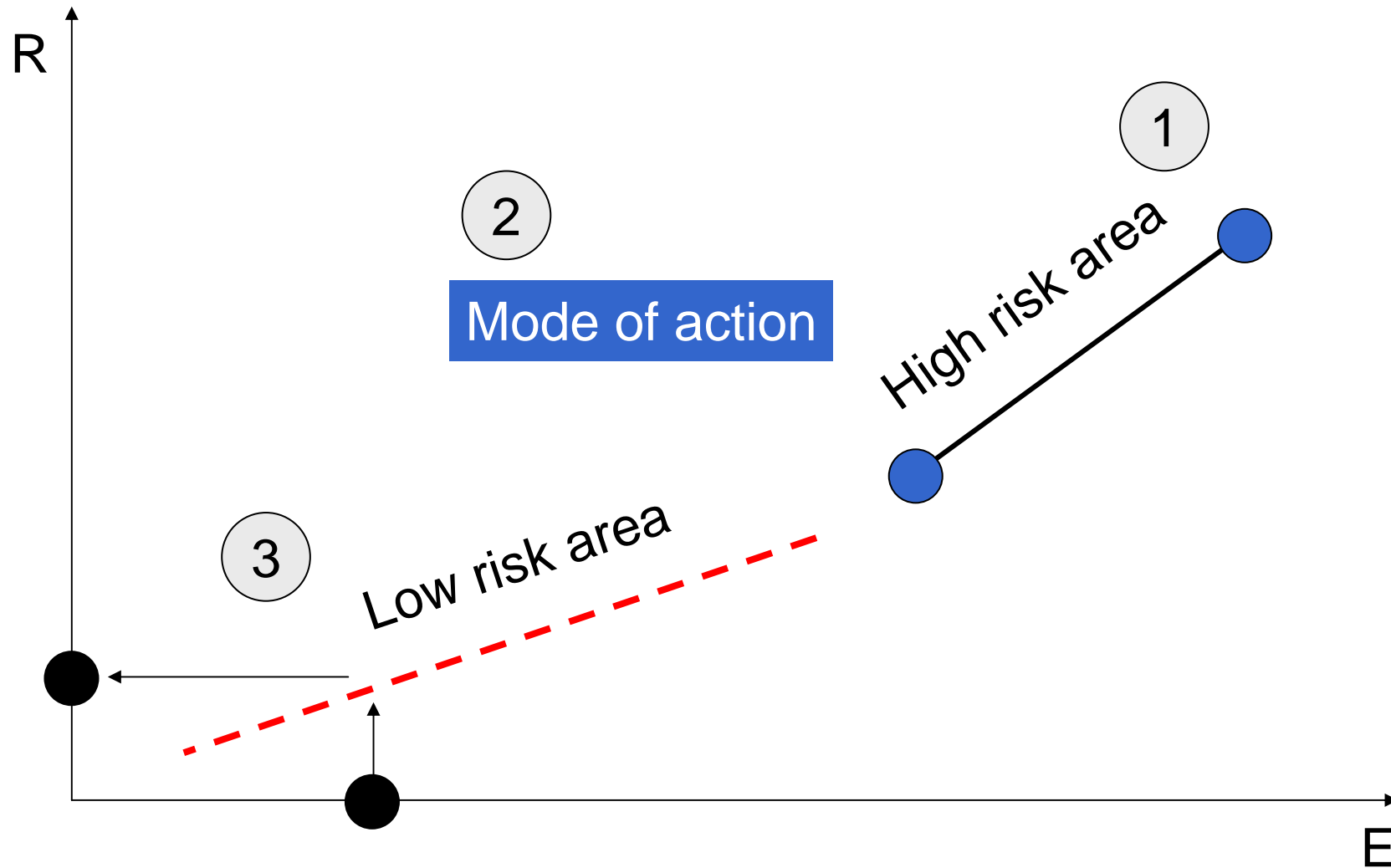
A true dose response in the low risk area



A black cloud covering the low risk area



Probability of probability of getting cancer



Reach guidance

Reach regulation

A qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario should be carried out ...

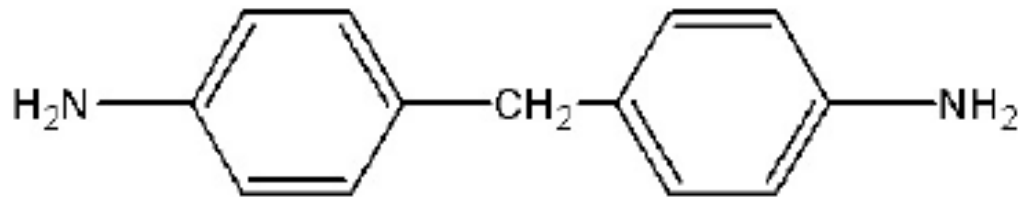
[Guidance document](#)

Two methodologies to characterise and evaluate risks:

Linear approach

Large assessment factor approach

MDA in the **high** risk area



Genotoxic
Liver tumours in rats
Control: 1/50
9 mg/kg/d: 13/50
16 mg/kg/d: 26/50

→
With
R to R
extrapolation

Point
of departure
for
both approaches:

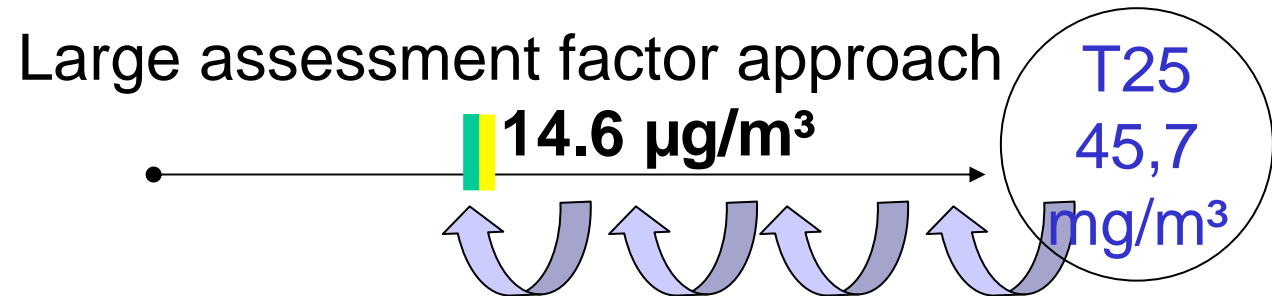
T25
45.7 mg/m³

An extra cancer risk for workers of **25:100** at 45.7 mg/m³

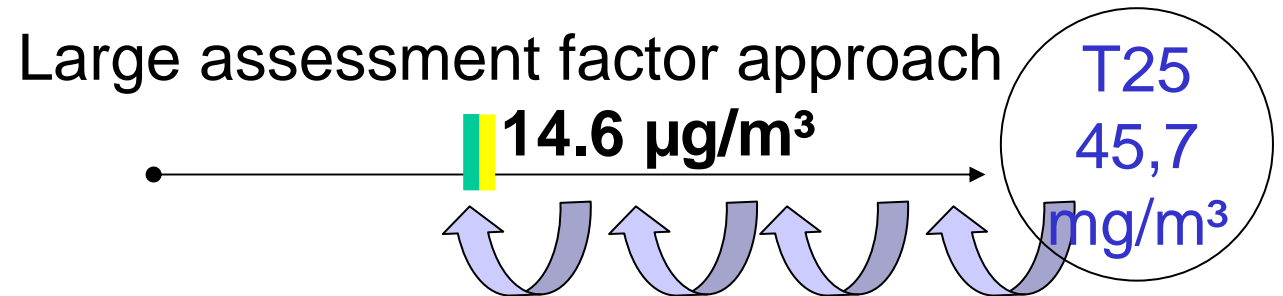
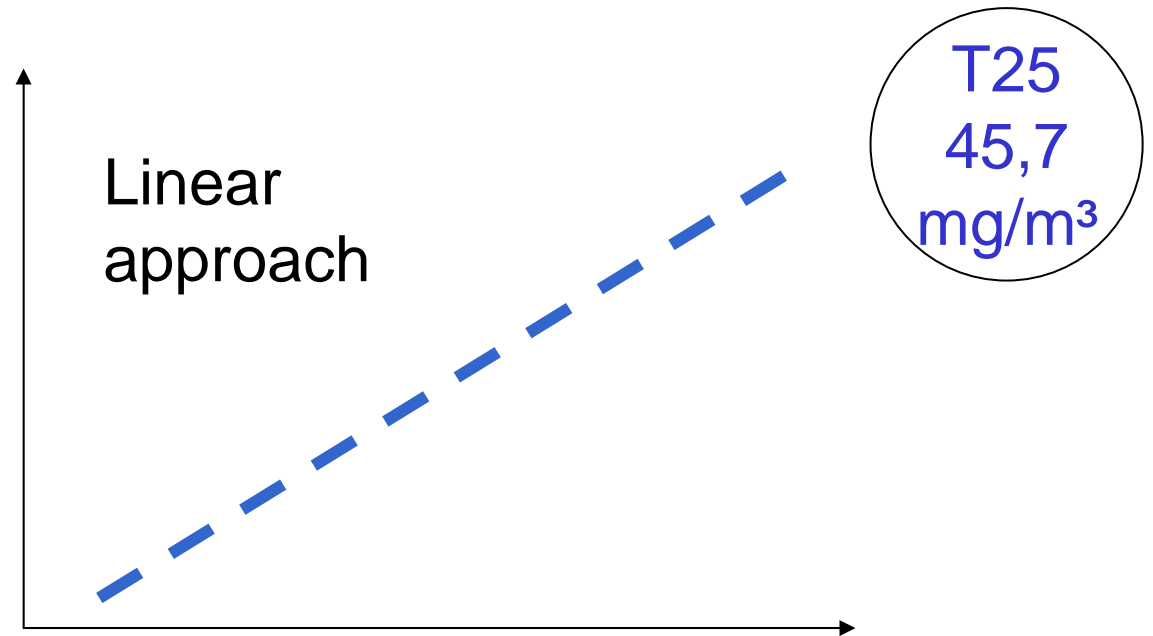
MDA in the **low** risk area

Linear approach T25 of 45,7 mg/m ³		Large assessment factor approach T25 of 45,7 mg/m ³	
		2.5	Interspecies
		5	Intraspecies
		10	Nature of carc. process
		10	Point of comparison
		2.5	2.5 in case of starting with T25
		45.700 / 3.125	
Reference value linear approach	?	14.6 µg/m³	Reference value for LAFA

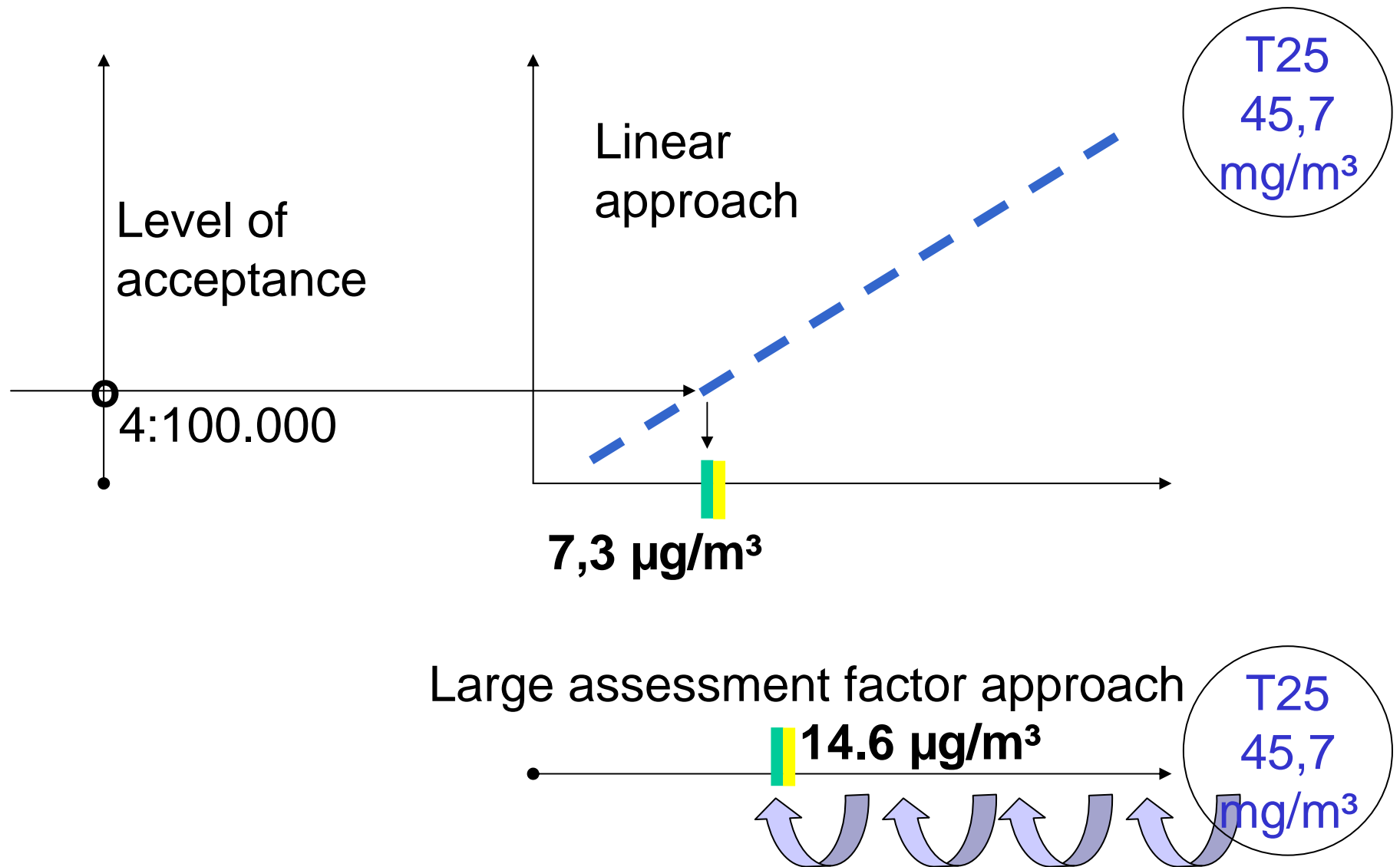
MDA (comparing both approaches)



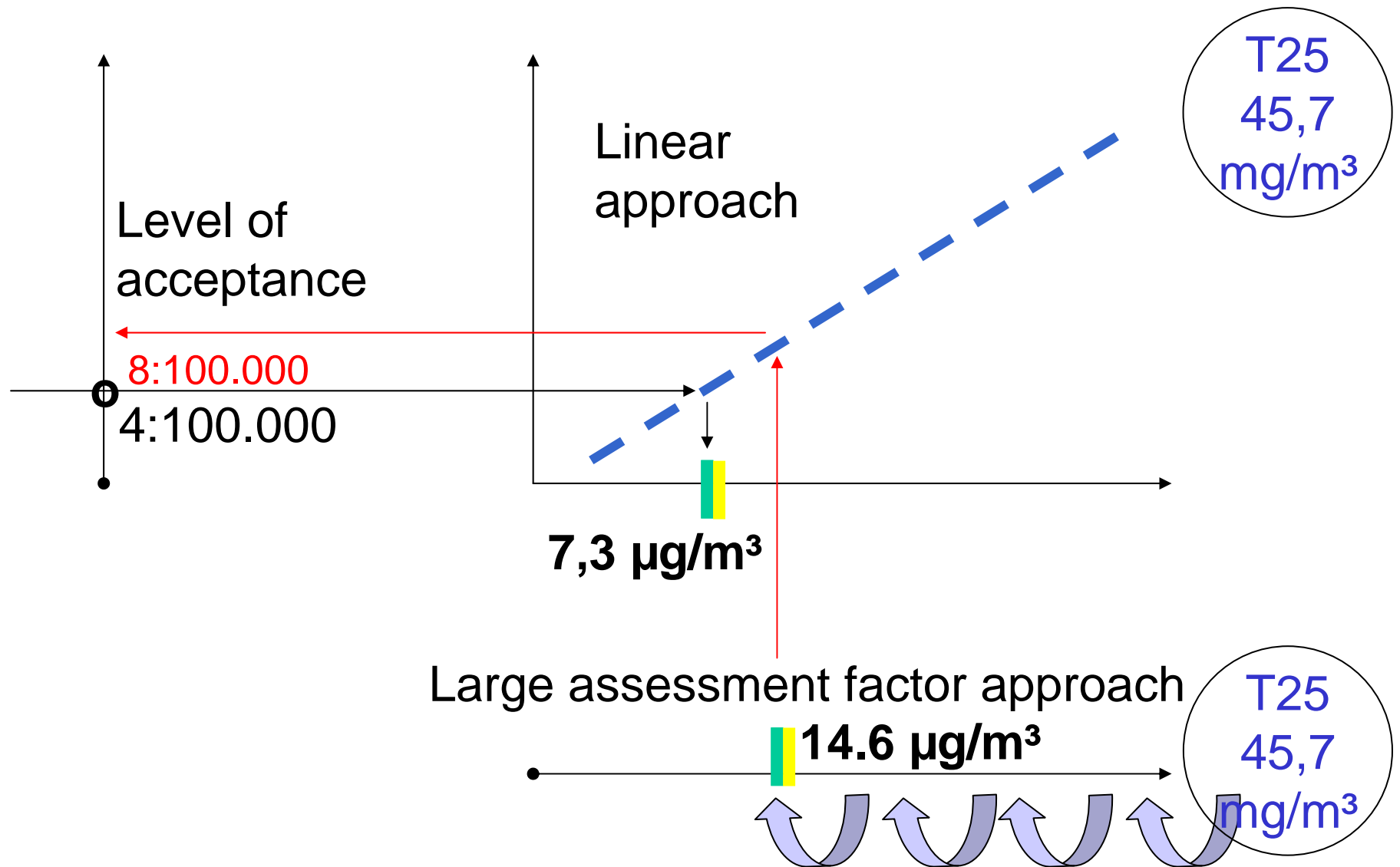
MDA (comparing both approaches)



MDA (comparing both approaches)



MDA (comparing both approaches)



Reach elements of decision finding

To describe the risks posed by the uses

To consider the appropriateness and effectiveness of RMM

To consider socio-economic aspects

To conclude whether socio-economic benefits outweigh the risk

To grant or not to grant the authorisation



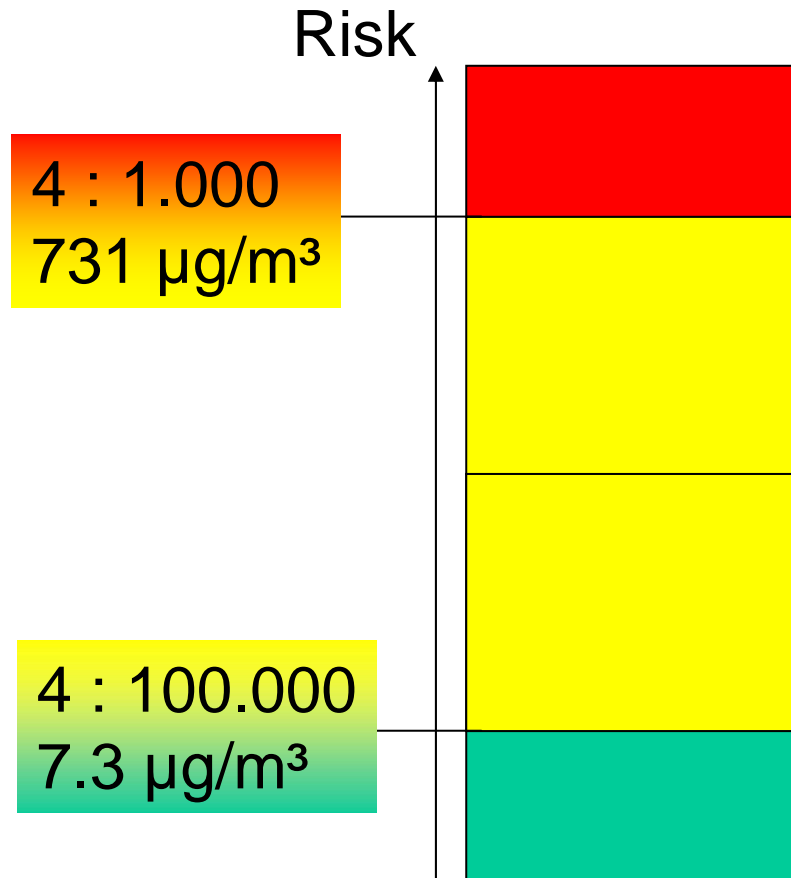
Risk
evaluation !?

Responsibilities

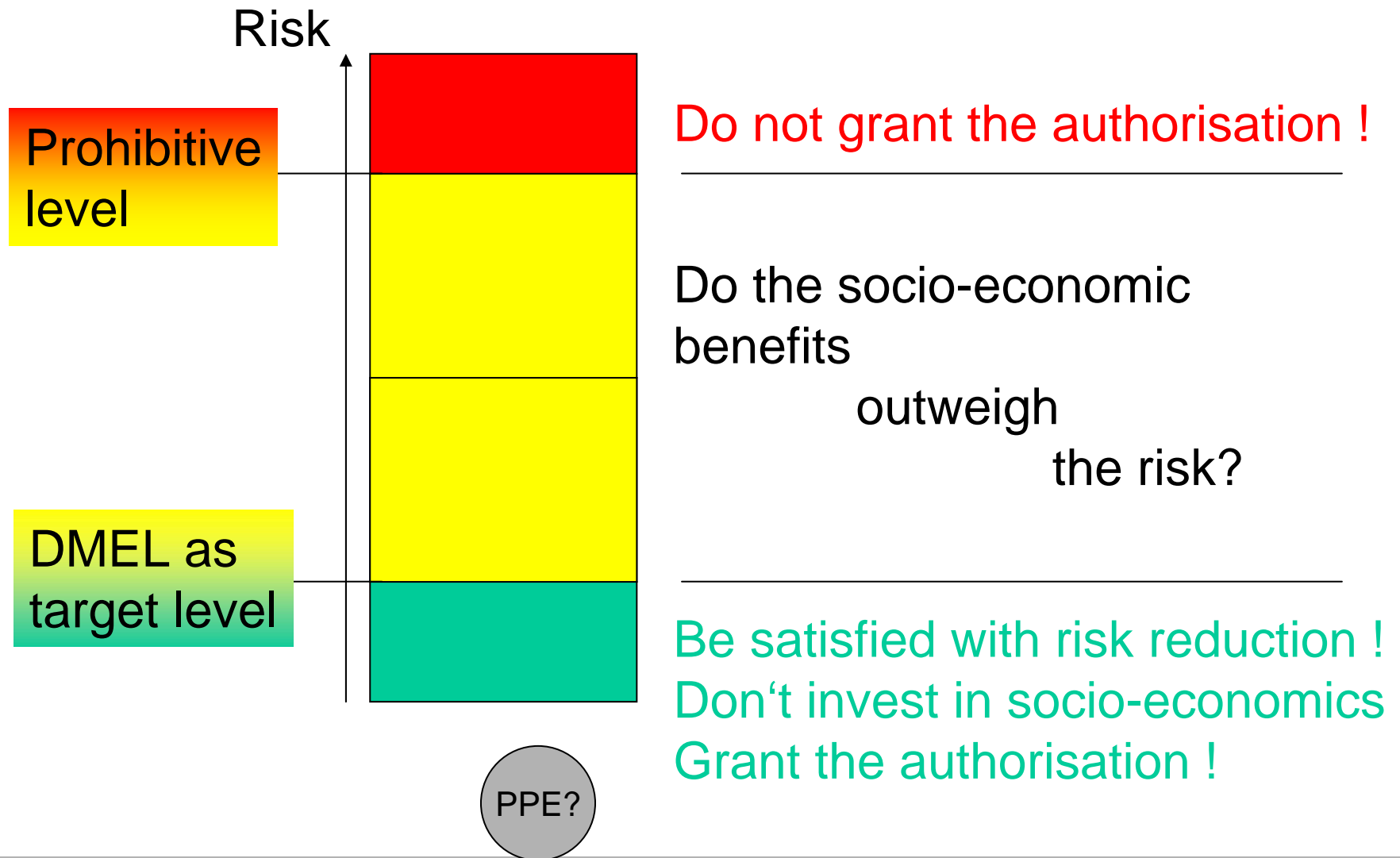
	RAC	SEAC	ECHA	COM
Exposure	○			
Dose response	○	X		
Risk characterisation	○			
Risk evaluation (RE)	○ ←			○ ?
Socio-economics (SE)		○		
SE versus RE			○	
Opinion			○ ?	
Decision				○

X = large assessment factor approach

Traffic light model for MDA (linear approach)

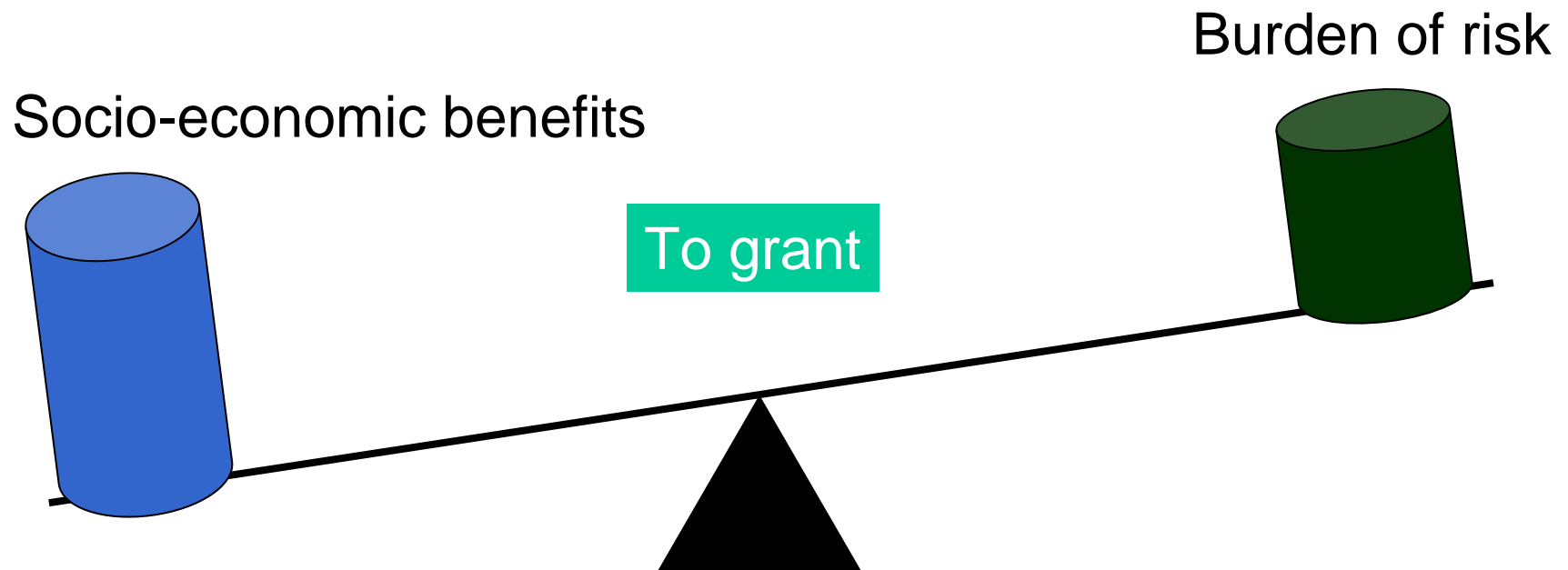


Traffic light model and authorisation process



How to compare ?

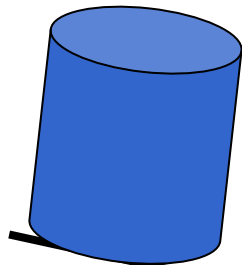
... ideally you need to have the same weight unit on both sides of the balance ...



How to compare ?

... ideally you need to have the same weight unit on both sides of the balance ...

Socio-economic benefits



or not to grant ...

Burden of risk

