



Arbeidsinspectie
Ministerie van Sociale Zaken en
Werkgelegenheid

Risk considerations in the Netherlands

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Health Council of The Netherlands (Gezondheidsraad)

On request by the Minister of Social Affairs and Employment the Health Council evaluates and assesses the carcinogenic substances and substances toxic for reproduction

The Health Council produces health-based limits

The Social and Economic Council of the Netherlands (SER)

As an advisory and consultative body of employers representatives, union representatives and independent experts, the Social and Economic Council of the Netherlands (SER) aims to help create social consensus on national and international socio-economic issues.

Advices the Minister of Social Affairs and Employment



On the basis of current scientific insights there is a group of substances for which no safe limit can be set.

To exclude all risk these substances should be banned.

Work in the Netherlands on carcinogenic limits has been done in respect to occupational exposure limits

The Health Council is devising a system for calculating DMELs

As long as the substances can not be missed, meaning that society request the application of such substances (e.g. cytostatics), the chances for exposure and resulting risk of cancer can not be excluded.

An added risk of 10^{-4} per substance is prohibited.

An added risk of 10^{-6} should be obtained.

A feasibility study is required to show whether 10^{-6} is possible

When 10^{-6} is not achieved, the study should be repeated every 4 years

The Health Council assesses the mechanism on which the carcinogenicity is or might be based.

On the basis of this information it can be decided whether a safe (health-based) limit can be derived.

If this is not possible, the risk of the substance is mapped by calculating so-called reference values (risk numbers).

These risk numbers are used as a starting point for setting a public occupational exposure limit.

In the Netherlands classification takes place in order to make a list of carcinogenic substances.

The Health Council used until 2010 criteria derived from the directives 93/21/EEC and 67/548/EEC (Dangerous Goods Directive).

The Dutch system has been comparable to the system used by the European Union.

The benefit of standard phrases is the direct link to the carcinogenic properties of the substance.

Due to scientific developments, the system is being reviewed

The difference in the working mechanism is reflected in the method of risk estimation

The risk estimation for (stochastic) genotoxic substances is being carried out by linear extrapolation.

This results in a reference value (risk number). This is a level of exposure (concentration in air) that is consistent with a predetermined added chance of mortality due to cancer.

The reference value implies that exposure, no matter how low, always holds risk and that there is no safe limit below which no incidence of mortality due to cancer will occur.



At this moment a new system is being devised

A new system is needed because of new scientific insights

Questions regarding mortality play a role

The starting points will remain the same:

The use of risk evaluation and risk numbers



Remaining questions:

What do DMELs account for?

What is the experience in other countries

What do DMELs look like?

And a remark: dossier requirements are limited...



System under review:

Categorie	Oordeel van de commissie (GRGHS)	Vergelijkbaar met EU-categorie	
		EU-richtlijn 67/548/EEC	EU-richtlijn 1272/2008
1A	<i>De stof is kankerverwekkend voor de mens.</i> <ul style="list-style-type: none">• De stof heeft een stochastisch genotoxisch werkingsmechanisme, of• De stof heeft een niet-stochastisch genotoxisch werkingsmechanisme, of• De stof heeft een niet-genotoxisch werkingsmechanisme, of• De genotoxiciteit is onvoldoende onderzocht. Het is niet bekend wat het werkingsmechanisme is.	1	1A
1B	<i>De stof moet beschouwd worden als kankerverwekkend voor de mens.</i> <ul style="list-style-type: none">• De stof heeft een stochastisch genotoxisch werkingsmechanisme, of• De stof heeft een niet-stochastisch genotoxisch werkingsmechanisme, of• De stof heeft een niet-genotoxisch werkingsmechanisme, of• De genotoxiciteit is onvoldoende onderzocht. Het is niet bekend wat het werkingsmechanisme is.	2	1B
2	<i>De stof wordt ervan verdacht kankerverwekkend te zijn voor de mens.</i>	3	2
3	<i>De gegevens zijn niet voldoende om de kankerverwekkende eigenschappen te evalueren.</i>	n.v.t.	n.v.t.
4	<i>Het is niet waarschijnlijk dat de stof kankerverwekkend is voor de mens.</i>	n.v.t.	n.v.t.