

Bisphenol A

No. 2019/04, The Hague, March 26, 2019

Executive summary

Health Council of the Netherlands



At the request of the Ministry of Social Affairs and Employment, the Health Council of the Netherlands has derived a health-based advisory value for bisphenol A. This advisory report has been composed by the Dutch Expert Committee on Occupational Safety (DECOS). More information on the tasks of this permanent committee of the Health Council of the Netherlands can be found at www.gezondheidsraad.nl. The members of the Committee are listed on the last page of this report.

Bisphenol A: Hazardous to eyes, skin, airways and reproduction

Bisphenol A (BPA) is a plasticizer. It is used in a wide range of consumer products such as plastic bottles. Bisphenol A is classified as reproduction toxicant (Category 1B; for fertility). Exposure to bisphenol A can also lead to damage to the eyes, allergic skin reactions and irritations of the airways. Bisphenol A has been restricted in several products in the EU. For instance, bisphenol A is restricted in thermal

paper since 2016 and banned from infant feeding bottles since 2011. Also, bisphenol A can be used in materials that are in contact with food, but there is a maximum amount that is allowed to leach out of the material.

Health-based advisory value

For hazardous substances to which people can be occupationally exposed, the Committee determines whether a concentration can be derived at which no adverse health effects are expected. These health-based advisory values are the basis at which the State Secretary can set an occupational exposure limit.

In 1996, the Health Council has derived an advisory value for occupational exposure of 10 milligram (mg) inhalable bisphenol A per cubic metre (m³), and an advisory value of 5 mg/m³ for respirable bisphenol A. Currently, an occupational exposure limit of 2 mg inhalable bisphenol A per m³ air is applied. This occupational exposure limit is based on a recommendation of the *European Scientific*

Committee on Occupational Exposure Limits (SCOEL) from 2013.

Since 2013, many studies have been published on the toxicity of bisphenol A. For the evaluation of studies until 2015, the Committee has adopted the conclusions of the 2015 opinion of the *European Food Safety Authority (EFSA)*. Publications from 2015 and onwards were evaluated by the Committee itself.

Monotonic or non-monotonic dose-response relationship?

When deriving health-based advisory values, the principle is applied that an effect increases with an increasing dose (a monotonic dose-response relationship). Some investigators assume that for bisphenol A, effects can develop according to a non-monotonic exposure-response relationship. The Committee is of the opinion that there is insufficient evidence of such a relationship and therefore applies its usual approach.



Preference for inhalation studies

For derivation of health-based advisory values in air, the Committee preferentially uses studies with exposures by inhalation. In recent years, only few inhalation studies with bisphenol A were published and in none of them, clear adverse effects have been observed. The Committee therefore uses the rat inhalation study by Nitschke et al. (1988), in which animals developed inflammation in the epithelium of the anterior portion of the nasal cavity. This study was used by the Committee for its previous report and it also forms the basis of the SCOEL recommendation from 2013. From the Nitschke et al. (1988) study the Committee has derived a health-based advisory value of 3.3 mg/m³. This value is lower than the Committee's previous value, and differs from the recommendation of the SCOEL. These differences can be explained by differences in methodology. Namely, for its previous advisory value the Committee did not

apply an uncertainty factor for extrapolation from animals to humans and the SCOEL applied the so-called preferred value approach.

For effects on reproduction oral studies taken into account

In the study by Nitschke et al. (1988), possible effects of bisphenol A on reproduction were not addressed. Many animal studies are available (mostly with rats and mice) investigating possible effects on reproduction after oral exposure to bisphenol A. Many of these studies are of insufficient quality and do not meet international testing guidelines. The Committee has translated the results of the most relevant oral study with bisphenol A, in which no specific effects on reproduction were observed, to derive a value in air. This value is comparable with the advisory value that is based on the inhalation study by Nitschke et al. (1988).

Skin exposure

The Committee concludes that the data available do not indicate that a skin notation for bisphenol A is warranted. Dermal absorption does not substantially contribute to the internal exposure to bisphenol A, at the level of the advisory value.

Advice to the State Secretary

For occupational exposure to bisphenol A, the Committee derives a health-based advisory value of 3.3 mg bisphenol A per m³ air. The value relates to the inhalable fraction (the fraction of the substance in air that can be inhaled through mouth and/or nose) and represents a mean concentration during an 8-h working day.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

This publication can be downloaded from www.healthcouncil.nl.

Preferred citation:

Health Council of the Netherlands. Bisphenol A. Health-based recommendation on occupational exposure limits. The Hague: Health Council of the Netherlands, 2019; publication no. 2019/04.

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