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# Risk Assessment of Furan Exposure in the Norwegian Population

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#### Authors' contributions

This work was carried out in collaboration among all authors. The opinion has been assessed and approved by the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of VKM. All authors read and approved the final manuscript.

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**Grey Literature** 

### **ABSTRACT**

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has on request of The Norwegian Food Safety Authority performed a risk assessment of furan intake in the Norwegian population based on the most recent national food consumption surveys.

National occurrence data of furan concentrations in food were preferentially used in the risk assessment. When national data were lacking, VKM has used occurrence data of furan from other countries. The assessment has been performed by the VKM Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics and the VKM Panel on Contaminants.

Furan is a volatile and lipophilic compound formed in a variety of heat-treated commercial foods and contributes to the sensory properties of the product. The substance has been found in a number of foods such as coffee, canned and jarred foods including baby food containing meat and various vegetables. High concentrations of furan have been found in coffee and the presence of furan in jarred baby food and infant formulae has received much attention since such products may be the sole diet for many infants. The occurrence of furan in a variety of foods suggests that there are multiple routes of furan formation rather than a single mechanism.

The Norwegian Food Safety Authority has in 2008 and 2009 collected data on furan concentrations in different food products sold on the Norwegian market (Norwegian Food Safety Authority, 2008). In 2011, the Norwegian Food Safety Authority also decided to analyse commercial porridges for infants and children sold on the Norwegian market, to see if furan could be detected in such products.

The calculated furan exposures from food and beverages are based on data from the nationally representative food consumption surveys; Spedkost, Småbarnskost, Ungkost and Norkost. The consumption for each relevant food or food category in the dietary surveys were multiplied with the corresponding mean furan concentrations and totalled for each individual.

The liver is the main target organ for furan toxicity both in mice and rats, but the rat is the most sensitive species. A dose-dependent increase in hepatocellular adenomas and carcinomas was observed in mice and rats, and an increase in the incidence of cholangiocarcinomas was observed in rat liver. Cholangiocarcinomas in male and female rats were the most sensitive toxicological end point observed in rodents. On the basis of the available data, VKM considers that rat cholangiocarcinomas may be relevant for assessing human risk from furan.

Available in vivo data with furan indicate that a reactive metabolite, most likely cis-2-butene1,4-dial (BDA), is formed and that this metabolite can react with DNA and induce mutations. To VKM's knowledge, no in vivo studies on genotoxicity of BDA have been performed, but BDA was found to be genotoxic in several in vitro tests. VKM therefore considers that a genotoxic mechanism in furan-induced carcinogenesis cannot be excluded and the substance was assessed as a genotoxic carcinogen.

VKM used the Margin of Exposure (MOE) approach in this risk assessment. The suitability of different studies on cholangiocarcinomas for dose-response modelling was considered. The 9-month interim evaluation of a 2-year study from NTP (1993) was chosen because it demonstrates a dose-response relationship. From this study, a point of departure of 0.02 mg/kg bw/day was chosen, based on a benchmark dose lower bound (BMDL10) of 0.14 mg furan/kg bw/day and a correction factor of 7 for shorter than full life-time (2 years) study duration.

For 6-, 12- and 24-month-old children, the main source of furan exposure is jarred baby food. For 4-, 9- and 13-year-old children, the major food source to the furan exposure is breakfast cereals. In adults, the major contribution to the furan exposure is coffee. The highest furan exposure was calculated for 12-month-old infants and ranged from 0.62-1.51  $\mu$ g/kg bw/day. In adults the furan exposure ranged from 0.27-0.82  $\mu$ g/kg bw/day.

For mean exposure among infants, children and adolescents, the MOE-values ranged from 29 in 12-month-infants to 2000 in the 13-year-old adolescents. Among high consumers in these groups, the MOE-values ranged from 13 to 400. In adults, the corresponding MOE-values ranged from 59 to 74 for mean furan exposure and from 24 to 26 for high exposure.

It should be noted that this risk assessment of furan contains notable uncertainties and limitations. The use of the 9-month interim study in rats including a correction factor of 7 to derive a point of departure, instead of a full life-time study (2-year) study, likely overestimates the hazard of furan. A possible over-diagnosis of the cholangiocarcinomas, due to the similarities in histopathology between cholangiofibrosis and cholangiocarcinomas in rats, may overestimate the hazard. There are also limitations in assessing food consumption and furan content in foods, leading to uncertainties in estimation of furan exposure.

VKM considers that the current exposure to furan in all age groups, particularly among infants and children, is of health concern.

Keywords: Furan; risk assessment; intake; BMD calculations; cancer; genotoxicity.

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#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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