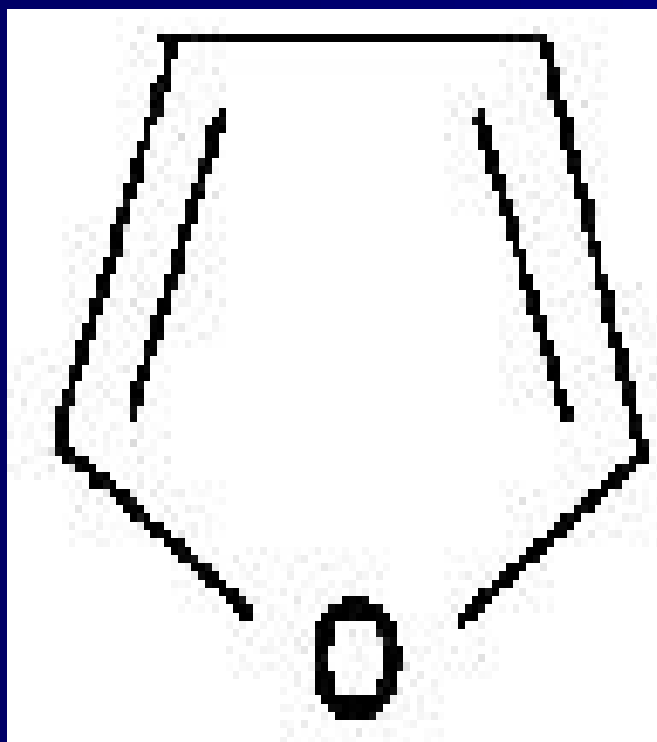


# Background on Furan in Foods

Nega Beru, Ph.D.  
Director, Division of Plant Product Safety  
Office of Plant and Dairy Foods  
Center for Food and Applied Nutrition  
Food and Drug Administration



# What is furan?



- ✍ Synonyms: furfuran, oxole, tetrole, divinylene oxide, oxacyclopentadiene
- ✍ Formula:  $C_4H_4O$
- ✍ MW: 68.07
- ✍ MP:  $-85.6^{\circ}C$
- ✍ BP:  $31^{\circ}C$

# What is furan and how is it formed in foods?

- ✍ Colorless liquid used in some segments of the chemical manufacturing industry, e.g., as a solvent for resins, formation of lacquers
- ✍ Furan was the subject of a 2-year bioassay by the NTP (1993)
- ✍ Listed in the DHHS report on carcinogens because it has been found to cause cancer in rodents
- ✍ Formed in food during traditional heat processing techniques such as cooking and canning
- ✍ Mechanisms of formation are beginning to be elucidated



# Discovery of furan in foods

- ✍ Not new – furan reported in a variety of foods since the 1960s although very little quantitative data
- ✍ FDA has developed a quantitative method to measure low levels in food and has found that furan forms in a wide variety of foods including baby foods
- ✍ In addition to FDA, Health Canada, NFPA-industry are investigating furan levels in foods



# What foods are being tested?

- ✍ Foods that appeared to have high levels during an initial screen using a semi-quantitative method
- ✍ Foods that could potentially result in high exposures
- ✍ Two or three manufacturers for each food (two lots per food)



# What foods are being tested?

- ✍ Baby foods such as apple juice, apple sauce, sweet potatoes, carrots, and green beans
- ✍ Infant formulas (liquid and powder)
- ✍ Adult foods such as baked beans, soups, chilis, spaghetti sauce, tuna, coffee, chicken broth



# Public Announcement of the Data

✍ May 7, 2004

- Results obtained through April 28, 2004, the method, and a set of questions and answers posted on FDA's web site
- FDA issued a Call for Data through a notice in the Federal Register
- FDA issued a notice of this meeting of the Food Advisory Committee



# Message Points Accompanying Release of Data

- ✍ Finding furan in foods a concern because, based on studies in rodents, furan is a potential carcinogen in humans
- ✍ Did not suddenly appear in food; has been reported in food before; what is new is its discovery in a variety of foods including baby foods
- ✍ Not an immediate public health concern based on preliminary data, and therefore consumers should not change eating habits





# Message Points, Cont'd

- ✍ FDA will conduct an expanded survey of different foods and foods as eaten to determine exposure and risk to consumers
- ✍ FDA will look at what additional studies are needed to determine furan's potential risk to human health as well as studies on mechanism of formation and reduction methods



# Message Points, Cont'd

✍ FDA will seek input from its Food Advisory Committee, at a meeting scheduled for June 7-8, 2004, on what data are needed to fully assess the risk posed by furan to consumers.

✍ FDA will evaluate the available data and develop an action plan that could include an expanded survey, mechanisms of formation/reduction, toxicity studies to address mechanism and dose response



# Data Needs: Occurrence and Exposure

- ✍ Particular foods in which furan occurs
- ✍ Levels of furan in these foods
- ✍ Formation and occurrence in home-prepared foods
- ✍ Environmental sources of exposure to furan for the typical consumer



# Data Needs: Mechanisms of Formation

- ✍ Possible mechanisms of furan formation
- ✍ Variables that enhance or mitigate furan formation
- ✍ The stability or dissipation of furan in foods
- ✍ The effect of post-production practices on furan levels in foods



# Data Needs: Toxicology of Furan

- ✍ Mechanism(s) of furan toxicity, mutagenicity, and carcinogenesis
- ✍ The reproductive and developmental toxicology of furan
- ✍ The metabolism of furan *in vivo* including characterization of reactive furan metabolites



# Data Needs: Toxicology of Furan

- ✍ The diversity of furan pharmacokinetics in humans or the alteration of furan metabolism as a result of dietary, medical, or environmental interactions
- ✍ Data on whether sub-cytotoxic furan doses produce any adverse effects, such as a change in enzyme activities or ATP levels



# Data Needs: Toxicology of Furan

- ✍ The effects of furan doses lower than those used in the NTP study
  - To establish a dose-response curve for various toxicological endpoints
  - To determine whether furan toxicity, including carcinogenesis, is a threshold dependent event
  - To determine whether carcinogenic activity is secondary to hepatotoxic effects



# Data Needs: Toxicology of Furan

- ✍ The mutagenicity of furan in the TA100 strain in the Ames test
- ✍ The behavior of furan in other *in vivo* assays for mutagenicity or toxicity





# Charge to the Committee

- ✍ The Food Advisory Committee and Contaminants and Natural Toxicants Subcommittee are being asked to provide input on data that would be helpful for further evaluation of potential risks posed by the presence of furan in food.



# Question to the Committee

- ✍ Taking into consideration the data needs already identified in the Federal Register notice requesting data on furan, and the presentations at this meeting, are there any additional data that are needed to fully assess the risk of furan in food?

