4. Summary of Data Reported and Evaluation

4.1 Exposure data

Tea is an aqueous infusion prepared from the dried leaves of *Camellia sinensis*, which has been consumed since ancient times in Asia and since the late seventeenth century in most other parts of the world. Tea is the most widely consumed beverage in the world. About 80% of world production of tea is in Asian countries. Depending on manufacturing techniques, teas can be divided into two main types: black tea, which has undergone an enzymic oxidation called 'fermentation' during processing, and green tea, which has not. Black tea represents about 80% of world production.

Annual tea consumption varies from country to country, ranging from a high level of about 3 kg *per caput* to negligible values in many countries. World consumption is approximately 0.5 kg *per caput*. Green tea is the primary form consumed in China, Japan and some Middle Eastern countries. Instant tea and decaffeinated tea consumption is small, but the latter is becoming more significant in the USA.

Over 400 volatile compounds comprising many structural categories have been identified in black teas and over 200 in green teas; these contribute to the flavour and aroma of the beverage. In addition to the expected components of leaf matter (e.g., flavonols, flavanols and phenolic acids), other nonvolatile components are present; bisflavanols, theaflavins and thearubigins are found in black tea. Average caffeine levels in both black and green teas are 3-4% on a dry weight basis, resulting

in about 30-50 mg caffeine per cup. Some black and green teas have traditionally been flavoured with natural agents such as oil of bergamot and jasmine flowers.

4.2 Experimental carcinogenicity data

Tea was tested for carcinogenicity in one study in rats by repeated subcutaneous injection of a total aqueous extract of tea leaves. A nonsignificant increase in the incidence of local tumours was observed.

In a number of studies, various known carcinogens were administered by different routes either simultaneously or sequentially with tea or its constituents by various routes. In one study in mice, skin application of black tea infusion containing 1% tannin after a single application of benzo[*a*]pyrene did not affect the incidence of skin tumours.

Administration of polyphenolic extracts of green tea in combination with known carcinogens resulted in decreased incidences of skin tumours in mice treated with benzo[*a*]pyrene diol epoxide, 3-methylcholanthrene or 7,12-dimethylbenz[*a*]anthracene and of duodenal tumours in mice treated with *N*-ethyl-*N'*-nitro-*N*-nitrosoguanidine, within a limited period of observation.

4.3 Human carcinogenicity data

Correlation studies on cancer risk associated with tea consumption have provided inconsistent reports of increased risks for cancers of the breast, intestine, larynx, lung and colon. Ecological studies of villages in the Caspian littoral have shown a broad correspondence between the occurrence of oesophageal cancer and tea consumption. An additional report found a relationship with the temperature at which the tea was drunk. A geographical study showed that in areas of Japan with high reported consumption of tea-gruel there were higher mortality rates from oesophageal cancer.

(a) Bladder and urinary tract cancer

In two cohort studies in which bladder cancer risk was examined, no association was reported.

The overall evidence from 12 case-control studies indicates no consistent association between measures of tea consumption and risk for bladder cancer. Although the data are limited, a similar pattern of trend was apparent for transitional-cell cancers of the renal pelvis and ureter.

One cohort study found a positive dose-response relationship for cancer of the kidney, but there was inadequate adjustment for confounding. Case-control studies on adenocarcinoma of the kidney are scarce and do not provide evidence of an association with tea drinking.

(*b*) *Pancreatic cancer*

The effect of tea consumption was examined in four cohort studies: three reported no association, and one documented a small protective effect.

Six case-control studies were designed to evaluate the relationship between tea consumption and pancreatic cancer: one showed a positive association.

(*c*) *Breast cancer*

None of five studies in which results on tea consumption were presented showed an association with breast cancer.

(*d*) *Ovarian cancer*

In two case-control studies, there was no association between tea consumption and ovarian cancer.

(*e*) *Cancer of the large bowel*

One cohort study found a strong positive dose-response relationship for cancer of the rectum, but another indicated no relationship with rectal cancer and a nonsignificant 'protective' effect for colon cancer.

The association between tea consumption and cancer of the colon and rectum was investigated in four case-control studies. Two showed no association. One study found a decreased risk for cancer of the rectum but not for cancer of the colon among drinkers of black tea relative to nondrinkers; another found an increased risk in the high consumption group. Taken together, these studies do not suggest the existence of an association.

(*f*) *Gastric cancer*

One cohort study found an increased risk for gastric cancer, which remained after inadequate adjustment for social class.

The role of tea drinking as a risk factor for cancer of the stomach was considered in five case-control studies. Four of these found no association. A negative association was observed in one study, but no dose-response relationship was seen.

(*g*) *Cancer of the oesophagus*

Five case-control studies were carried out, in Iran, the USSR, Brazil and Singapore, to investigate the effect of tea drinking on the frequency of cancer of the oesophagus. One study in Brazil did not show an association between tea drinking

and oesophageal cancer, but the subjects were not asked about the temperature at which they drank tea. The other four studies, three of which were conducted in the Caspian area, stressed the role of the temperature of tea. All four studies showed that ingestion of very hot tea was associated with a two- to three-fold increase in the risk for oesophageal cancer. Only one of these studies investigated the effect of frequency of tea ingestion irrespective of temperature; no association was found. Taken together, these studies suggest that the temperature may be more important than the composition of the beverage, but the results are not conclusive.

One case-control study on oral cancer and one on cancer of the extrahepatic bile ducts reported no clear association with tea drinking.

(*h*) *Nasopharyngeal cancer*

Three case-control studies showed no evidence of an association between tea drinking and nasopharyngeal cancer.

(*i*) *Cancers at other sites*

One cohort study found no association with liver cancer. Another showed a significant positive dose-response relationship for lung cancer after adjusting for age and smoking; these findings could, however, be attributed to residual confounding by smoking.

One case-control study showed no association between tea drinking and cancer of the vulva. Another indicated a possible effect of maternal tea drinking during pregnancy on the frequency of Wilms' tumour in the offspring.

4.4 Other relevant data

The few informative studies concerning the effect of tea consumption during pregnancy on the frequency of adverse reproductive effects did not show an association.

In a number of studies, no association was seen between consumption of tea and the frequency of coronary heart disease.

Black tea, green tea and several unspecified teas were mutagenic to bacteria. Teas were found to reduce the activity of known mutagens both *in vivo* and *in vitro*.

4.5 Evaluation[1]

There is *inadequate evidence* for the carcinogenicity in humans of tea drinking.

There is *inadequate evidence* for the carcinogenicity in experimental animals of tea.

Overall evaluation

Tea is *not classifiable as to its carcinogenicity to humans (Group 3).*