Session 1

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(1) How should one interpret the term “significant” in relation to a threshold dose for a carcinogen?

Two interpretations are possible. One is concerned with a value judgment in which “significance” is similar to “importance”. The other is concerned with the statistical meaning of the term: i. e. that the probability of making an error should be as low as possible. In this connection a false positive error is less crucial than a false negative error. The latter type cannot be controlled by the usual statistical methods.

(2) Does a threshold dose exist?

It follows from biochemical considerations that there must be a finite amount which will be dealt with by the metabolic activity of the organism and which will therefore be inactivated before it can reach the target organ. At present there are no unequivocal experimental findings which can answer this question. For human carcinogenesis much more use should be made of epidemiological information either already in existence or to be collected through prospective studies.

(3) Should one define a carcinogen or alternatively the process of carcinogenesis?

The question of definition should not be discussed at length at this meeting since many other attempts have been made with questionable success in this field. Perhaps the existence of the term “carcinogen” was regrettable as it may defy definition eventually. It may perhaps be more profitable to consider the criteria for the establishment of carcinogenicity in animals and man. There are many reasons for this e. g. lack of knowledge of the precise mechanisms, the multifactorial nature of the process of carcinogenesis, the difficulty in defining cancer pathologically.

(4) What results are required from a bioassay to allow its evaluation?

Five points were suggested:

Statistical significance of the results.

Demonstration of a dose-response relationship.

Demonstration of tumor without complicating pathology.

Continuation of carcinogenic event after withdrawal of stimulus.

Features of malignancy.

In discussion not all points were agreed upon as being necessary and an evaluation may have to be done individually on each compound.

(5) What possibilities exist for reducing the hazard to man from environmental carcinogens?

Exposure to man-made carcinogens could be reduced or eliminated and similar action could be taken for naturally occurring carcinogens like aflatoxin and bracken fern. Measures to counteract carcinogens might be developed where residues have to be tolerated.