

Minute statement Point 15. (Contaminants) - Request for urgent opinion on the JECFA report on aflatoxins prepared at its 49th meeting, Rome 1997.

The SCF was asked at short notice to give its advice concerning the JECFA report on aflatoxins adopted at its 49th meeting in Rome, June 1997.

The SCF last considered the human toxicology of aflatoxins in its opinion on aflatoxins, ochratoxin A and patulin expressed on 23 September 1994 (35th Report Series). At that time the SCF concluded, *inter alia*,

"Aflatoxins are genotoxic carcinogens. For this type of carcinogen, it is generally felt that there is no threshold dose below which no tumour formation would occur. In other words, only a zero level of exposure will result in no risk.

It agreed with the recent evaluations of IARC (1) (1993) with respect to the carcinogenicity and genotoxicity of the aflatoxins. From the many reports on risk assessment, it can be concluded that even very low levels of exposure to aflatoxins, i.e. 1 ng/kg b.w./day or less contribute to the risk of liver cancer."

At the 49th meeting, held in Rome, Italy from 17 to 26 June 1997, the JECFA (2) reviewed a wide range of studies in both animals and humans that provided qualitative and quantitative information on the hepatocarcinogenicity of aflatoxins.

The SCF discussed this recent JECFA evaluation merely on the basis of the summary report of the meeting. It noted that the background documentation which served as a basis for the JECFA evaluation has not been published yet and was not available for the SCF. The SCF therefore felt that it was not in the position to give a complete appraisal of the JECFA evaluation.

1. International Agency for Research on Cancer
2. Joint FAO/WHO Expert Committee on Food Additives

In the JECFA evaluation it is stated that the Committee (JECFA) considered that the weight of scientific evidence, which includes epidemiological data, laboratory animal studies and *in vivo* and *in vitro* metabolism studies, supports a conclusion that aflatoxins should be treated as carcinogenic food contaminants, the intake of which should be reduced to levels as low as reasonably achievable.

JECFA concluded, *inter alia*, that

- "Aflatoxins are considered to be liver carcinogens. Aflatoxin B₁ is the most potent carcinogen of the aflatoxins; most of the toxicological data available are related to aflatoxin B₁. Aflatoxin M₁, the hydroxylated metabolite of B₁, has a potency approximately one order of magnitude less than that of B₁."
- "The Committee (JECFA) has previously noted that reductions can be achieved through avoidance measures such as improved farming and proper storage practices and/or through enforcing standards for food or feed within countries and across borders (WHO Technical Report Series N° 759, 1987)."

These statements are not incompatible with the SCF's opinion expressed in 1994, which remains valid.

The SCF recognises the great effort made by JECFA to perform a quantitative risk assessment by combining carcinogenic potencies and human exposure data, but noted also the several limitations and assumptions, inherent in this approach, which were clearly set out in the report.

The SCF concluded that, given its present state of knowledge in this area, it was not possible to assess the degree of

uncertainty, arising from these limitations and assumptions, in the quantitative risk assessment and felt therefore that it was premature for it to draw definitive conclusions on this issue.