

## MINUTE STATEMENT ON PATULIN

**Expressed by the Scientific Committee on Food during the plenary meeting on 8 March 2000.**

Patulin is a mycotoxin produced by fungi belonging to several genera, including *Penicillium*, *Aspergillus* and *Byssochlamys* species. Although patulin can occur in many mouldy fruits, grains and other foods, the major sources of patulin contamination are apples and apple products.

The Committee expressed an Opinion on patulin in 1994 in which it stated: "The Committee agrees for the time being with the JECFA and IARC conclusions. It proposes to reconsider its opinion in the light of new information." (SCF 1996).

The background for this opinion was (1) the JECFA evaluation of 1990 when a provisional tolerable weekly intake (PTWI) of 7 ug/kg bw was established, based on a no-effect level (NOEL) of 0.1 mg/kg bw/day in a combined reproductive toxicity/long term toxicity/carcinogenicity study in rats, and (2) the IARC conclusion that no evaluation could be made of the carcinogenicity of patulin to humans and that there is inadequate evidence in experimental animals (JECFA, 1990, IARC, 1986).

Patulin was reviewed by JECFA in 1995 and it appeared that, although several more studies were incorporated, the above mentioned study was still the most sensitive. Since it became apparent that patulin was administered only three times per week during 24 months, the NOEL in this study was recalculated to be 43ug/kg bw/day. As patulin does not accumulate in the body and in the light of the consumption pattern, the PTWI was changed to a provisional maximum tolerable daily intake (PMTDI). Based on a NOEL of 43 ug/kg bw/day and a safety factor of 100, a PMTDI of 0.4 ug/kg bw was established (JECFA, 1995).

A recent literature survey from 1995 onwards revealed many publications on patulin, dealing primarily with chemical analyses and in vitro studies and only a few with in vivo studies. However, none of these studies would change the assessment made by JECFA in 1995.

The Committee, therefore, endorses the PMTDI of 0.4 ug/kg bw for patulin.

### References

- SCF 1996: Reports of the Scientific Committee for Food(Thirty-fifth series),1996
- JECFA 1990: Evaluation of certain food additives and contaminants.WHO Technical Report Series,No.789,1990, and corrigenda
- IARC 1986: IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans,Vol.40,1986
- JECFA 1995: Evaluations of certain food additives and contaminants.WHO Technical Report Series,No.859,1995