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Statement of the Scientific Committee on Food on a Report on 2-alkylcyclobutanones

(expressed on 3 July 2002)

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http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

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The Committee was asked to assess the results of a recent report¹ prepared within the framework of the Interregio Program research project to evaluate the toxicological properties of 2-alkylcyclobutanones (2-ACB), known to arise from irradiation-induced scission of triglycerides in irradiated fat-containing foods.

Various 2-alkylcyclobutanones were identified as specific markers of irradiated fat-containing foods offering an option for identification of irradiated food as early as 1992. Within the project methods of synthesis were developed for these 2-ACBs to provide standards for GC-MS analysis of irradiated foods and to prepare adequate amounts of pure substances for carrying out certain toxicological tests. The latter included reverse mutation tests in standard strains of *Salmonella typhimurium*, comet assays in cultured human colon tumour cells for single DNA-strand breaks, assays for oxidative damage to DNA-bases in cultured HeLa cells, assays for cytotoxicity in human colon tumour cells, an *in vivo* assay for promoter activity in rat colonic mucosa and some preliminary studies on the metabolic fate of two 2-ACBs.

The nature of the 2-ACBs formed depends on the precursor fatty acids irradiated. The results showed that promoter activity was seen after 23 weeks following administration of a colonic carcinogen to rats in relation to colonic tumour incidence. In some cases in the *in vitro* studies cytotoxic concentrations were needed to produce other adverse reactions. 2-ACBs were not genotoxic in the standard bacterial reverse mutation assay but were not tested for gene mutation or the induction of chromosomal aberrations in mammalian cells *in vitro*. No standard animal feeding tests were carried out with these 2-ACBs.

In summary, as the adverse effects noted refer almost entirely to *in vitro* studies, it is not appropriate, on the basis of these results, to make a risk assessment for human health associated with the consumption of 2-ACBs present in irradiated fat-containing foods. The genotoxicity of 2-ACBs has not been established by the standard genotoxicity assays nor are there any adequate animal feeding studies in existence to determine no-observed-adverse-effect levels (NOAELs) for various alkylcyclobutanones. Reassurance as to the safety of irradiated fat-containing foods can be based on the results of the large number of feeding studies carried out with irradiated foods which formed the basis for the wholesomeness assessments of irradiated foods published hitherto by WHO/FAO/IAEA² and the acceptance of the safety of the technology under appropriate conditions by the Committee in its Report on Food Irradiation³.

¹ Burnouf D, Delincée H, Hartwig A, Marchioni E, Miesch M, Raul F, Werner D (2001). "Etude toxicologique transfrontalière destinée à évaluer le risque encouru lors de la consommation d'aliments gras ionisés / Toxikologische Untersuchung zur Risikobewertung beim Verzehr von bestrahlten fetthaltigen Lebensmitteln – Eine französisch-deutsche Studie im Grenzraum Oberrhein." Rapport final / Schlussbericht Interreg II. Project / Projekt N° 3171 (submitted to the Commission by the authors in confidence). A summary of the report is available on Internet at: <http://www.iaea.org/programmes/rifa/icgfi/documents/summary-press.pdf>

² WHO (World Health Organisation) (1981). Wholesomeness of irradiated food. Report of a Joint WHO/FAO/IAEA Expert Committee. Geneva. WHO Technical Report Series, No 659.

³ European Commission (1986). Report of the Scientific Committee for Food on the irradiation of food. Opinion adopted on 13 March 1986. Reports of the Scientific Committee for Food, eighteenth series.