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ORGANIZACIÓN DE LAS NACIONES
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PROGRAMA CONJUNTO FAO/OMS SOBRE NORMAS ALIMENTARIAS

COMITÉ DEL CODEX SOBRE ADITIVOS ALIMENTARIOS Y CONTAMINANTES DE LOS ALIMENTOS

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POSICION SOBRE LOS CLOROPROPANOLS

AUSTRALIA (English only)

In reference to CCX/ FAC 02/28, - Position Paper on Chloropropanols, Australia wishes to provide the following comments.

BACKGROUND

The 33rd Session of the CCFAC requested the United Kingdom, with assistance provided by Canada and the US, to revise the position Paper on Chloropropanols presented at the 33rd Session (CX/FAC 01/31) for circulation, comment and consideration at the 34th Session of the CCFAC. The paper was revised in light of comments submitted on the earlier paper and the re-evaluation of chloropropanols at the 57th JECFA meeting in June 2001 (ALINORM 01/12A, paras. 181-182).

COMMENT ON THE POSITION PAPER ON CHLOROPROPANOLS

Australia notes that several scientific bodies, including the UK Food Standards Agency (FSA), the European Commission's Scientific Committee on Food (SCF) and the FAO/WHO Joint Expert Committee on Food Additives (JECFA) have reassessed the toxicity of 3-MCPD and concluded that this contaminant is not genotoxic *in vivo*. Australia also notes the JECFA recommendation of a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 µg/kg bw and the conclusion that the establishment of a tolerable intake for 1,3-DCP is inappropriate because of the nature of toxicity for this contaminant (genotoxic *in vitro*, hepatotoxic, and induced a variety of tumours in various organs in rats).

Australia supports the argument presented in the Position Paper that chloropropanol contamination is a food safety issue that has international implications, and therefore a harmonised approach to control chloropropanol levels in foods is desirable to protect consumers.

During 2001, Australia and New Zealand introduced emergency measures to establish maximum levels for chloropropanols in soy and oyster sauces (0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP). In doing so, the Australia New Zealand Food Authority (ANZFA) and the Australia New Zealand Food Standards Council (ANZSC) took into account the following considerations:

- The reassessment of the toxicity data for 3-MCPD and 1,3-DCP by scientific bodies such as UK FSA, SCF and JECFA, demonstrating that 3-MCPD is not a genotoxic carcinogen and the reconfirmation that 1,3-DCP was genotoxic *in vitro*;
- The results of surveys on samples of soy and oyster sauces conducted in the UK, Australia and New Zealand in 2001;
- The dietary modelling results carried out by the Australia New Zealand Food Authority (ANZFA) on the UK survey data and Australian and New Zealand data;
- The margin of safety available from the dietary modelling data and information on what was reasonably achievable for industry.

While there is some evidence that controlling the level of 3-MCPD will control the level of 1,3-DCP, the evidence is not conclusive. In order to minimise exposure to 1,3-DCP (i.e. 0.005 mg/kg), based on a level of 0.2 mg/kg for 3-MCPD only, the ratio for 3-MCPD:1,3-DCP would have to be 40:1. The relationship between levels of 3-MCPD and 1,3-DCP is not constant at all concentrations and the ratio has been reported to vary widely. Thus reliance upon the level of 3-MCPD to control levels of 1,3-DCP is an indirect measure.

Australia considered that regulatory control of 3-MCPD was not adequate from a regulatory point of view to obviate the need for specific controls on 1,3-DCP and, given the toxicity profile of this contaminant, decided to set a specific level for 1,3-DCP at the limit of detection of the assay methodology for 1,3-DCP (0.005 mg/kg).

Based on the PTDI (0.002 mg/kg bw) for 3-MCPD, dietary exposure assessment using Australian food consumption data indicates that soy sauce products containing a 3-MCPD level above 3.5 mg/kg will exceed the PTDI. Of the 172 retail soy sauce products sampled and tested in Australia and New Zealand surveys, 16 products (9%) were found to contain greater than 3.5 mg/kg of 3-MCPD. These products were removed from the market in Australia.

Data on the Australian surveys can be found on the ANZFA website at www.anzfa.gov.au (search for 'Chloropropanols').