

codex alimentarius commission

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Agenda Item 4(b)

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOOD**

First Session

Beijing, China, 16 - 20 April 2007

**MATTERS OF INTEREST OF THE 67TH MEETING OF THE
JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)**

1. This document highlights main discussions and conclusions resulting from the 67th JECFA meeting.

Aluminium

2. The Committee established a Provisional Tolerable Weekly Intake (PTWI) for Al of 1 mg/kg bw, which applies to all aluminium compounds in food, including additives. The previously established ADIs and PTWI for aluminium compounds were withdrawn.
3. The Committee concluded that aluminium compounds have the potential to affect the reproductive system and developing nervous system at doses lower than those used in establishing the previous PTWI and therefore revised the PTWI. The available studies have many limitations and are not adequate for defining the dose-response relationships. The Committee therefore based its evaluation on the combined evidence from several studies. The lowest LOELs for Al in a range of different dietary studies in mice, rats and dogs were in the range of 50–75 mg/kg bw per day. The Committee applied an uncertainty factor of 100 to the lower end of this range of LOELs (50 mg Al/kg bw per day) to allow for inter- and intra-species differences. There are deficiencies in the database, notably the absence of NOELs in the majority of the studies evaluated and the absence of long-term studies on the relevant toxicological end-points. These deficiencies are counterbalanced by the probable lower bioavailability of the less soluble aluminium compounds present in food. Overall, it was considered appropriate to apply an additional uncertainty factor of 3. The Committee confirmed that the resulting health-based guidance value should be expressed as a PTWI, because of the potential for bioaccumulation.
4. The Committee noted that the PTWI is likely to be exceeded to a large extent by some population groups, particularly children, who regularly consume foods that include aluminium-containing additives. The Committee also noted that dietary exposure to Al is expected to be very high for infants fed on soya-based formula.
5. The Committee recommended to the Codex Alimentarius Commission that provisions for aluminium-containing additives included in the Codex GSFA should be compatible with the newly established PTWI for Al of 1 mg/kg bw. The Committee noted in particular that provisions for such additives used at levels consistent with GMP in staple foods may lead to high exposure in the general population and in particular in children.

3-chloro-1,2-propanediol (3-MCPD)

6. As no new pivotal toxicological studies had become available the Committee retained the previously established PMTDI of 2 µg/kg bw for 3-chloro-1,2-propanediol.
7. Estimated exposures at the national level considered a wide range of foods, including soy sauce and soy-sauce related products, ranged from 1% to 35% of the PMTDI for average exposure in the general population. For the consumers at the high percentile (95th), the estimated intakes ranged from 3% to 85% and up to 115% of the PMTDI in young children. These estimates are based on concentrations of 3-chloro-1,2-propanediol derived before any remedial action had been taken by government or industry.
8. The Committee noted that reduction in the concentration of 3-chloro-1,2-propanediol in soy sauce and related products made with acid-HVP could substantially reduce the intake of this contaminant by certain consumers of this condiment.

1,3-dichloro-2-propanol (DCP)

9. The Committee concluded that the critical effect of 1,3-dichloro-2-propanol is carcinogenicity and that a genotoxic mode of action could not be excluded. According to the recommendations of the 64th JECFA meeting a Margin of Exposure (MoE) analysis was performed by applying dose-response modelling to the cancer data, and comparing the results to the estimated mean intake for the general population of 0.051 µg/kg bw per day and an estimated high-level intake (young children included) of 0.136 µg/kg bw per day.
10. Based on the resulting margins of exposure of approximately 65 000 and 24 000, respectively, the Committee concluded that the estimated intakes of 1,3-dichloro-2-propanol were of low concern for human health.
11. Regarding the co-occurrence of 3-MCPD and DCP, the available evidence suggests that 1,3-dichloro-2-propanol occurs at lower levels than 3-chloro-1,2-propanediol in soy sauce and related products, and also in acid-HVP food ingredients. However, in meat products the concentrations of 1,3-dichloro-2-propanol are generally higher than the levels of 3-chloro-1,2-propanediol.

Methylmercury

12. The Committee made it clear that the previous PTWI of 3.3 µg/kg bw had, in fact, been withdrawn in 2003. The Committee confirmed the existing PTWI of 1.6 µg/kg bw, set in 2003, based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans). However, the Committee noted that life-stages other than the embryo and fetus may be less sensitive to the adverse effects of methyl mercury.
13. In the case of adults, the Committee considered that intakes of up to about two times higher than the existing PTWI of 1.6 µg/kg bw would not pose any risk of neurotoxicity in adults, although in the case of women of childbearing age, it should be borne in mind that intake should not exceed the PTWI, in order to protect the embryo and fetus.
14. Concerning infants and children aged up to about 17 years, the data do not allow firm conclusions to be drawn regarding their sensitivity compared to that of adults. While it is clear that they are not more sensitive than the embryo or fetus, they may be more sensitive than adults because significant development of the brain continues in infancy and childhood. Therefore, the Committee could not identify a level of intake higher than the existing PTWI that would not pose a risk of developmental neurotoxicity for infants and children.
15. The Committee has previously noted that fish makes an important contribution to nutrition, especially in certain regional and ethnic diets. The present Committee recommends that the known benefits of fish consumption need to be taken into consideration in any advice aimed at different subpopulations. Risk managers may wish to consider whether specific advice should be given concerning children and adults, after weighing the potential risks and benefits.
16. The Committee concluded that the setting of guideline levels for methyl mercury in fish may not be an effective way of reducing exposure for the general population. The Committee noted that advice targeted at population subgroups that may be at risk from methyl mercury exposure may provide an effective method for lowering the number of individuals with exposures greater than the PTWI.