

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT**

**WORKING GROUP ON PHYTOESTROGENS**

**Submission from Mr Richard James (received 19/02/01)**

**Background**

1. The Working Group has received 4 submissions from Mr James (Soy on line service, New Zealand). Mr James contacted the Food Standards Agency and requested financial support to commission a report on the adverse effects of phytoestrogens. The Food Standards Agency replied to Mr James outlining the remit and terms of reference of the Working Group. Mr James has enclosed a copy of a submission made to the US FDA in opposition to claims by Protein Technologies International (PTI) that soy protein is generally recognised as safe (GRAS).

**Submission**

1. Dr Fitzpatrick disputes the PTI's claim that soy should be granted GRAS status. Dr Fitzpatrick outlines the health concerns associated with consumption of soy protein; in particular those associated with isoflavone intake. Dr Fitzpatrick comments that by recommending intake of between 25-100g soy protein/day PTI is advocating the ingestion of up to 600mg isoflavones/day. This value is much higher than that which resulted in changes to menstrual cycle length and hormone disturbance (45mg isoflavones) in a study by Cassidy *et al* (1994). Dr Fitzpatrick concludes that to maintain a level of no more than 45mg isoflavones it is advisable for women to consume no more than 18g soy protein isolate/day.

2. Dr Fitzpatrick comments that contrary to PTI's claims, reproductive and developmental toxicity has been demonstrated in a number of animal species. The articles to support these claims have been discussed in PEG/2001/3 and PEG/2001/7. Dr Fitzpatrick also discusses the goitrogenic effects of isoflavones and concludes that high exposure to these compounds, irrespective of iodine intake, has the potential to induce thyroid disease (Hill *et al*, 1989).

3. Dr Fitzpatrick concludes that the evidence to claim GRAS status for soy protein is unavailable and that there is evidence of a risk of toxicity from isoflavones.