

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

Draft report on FSA funded project (T01057). A possible blind placebo controlled parallel trial of soy phytoestrogens in patients with compensated hypogonadism

Background

1. Phytoestrogens are naturally occurring compounds found in some plant-based foods, notably soya. These compounds, as their name suggests, have structural similarities to the female sex hormone oestradiol. As a result, concern has been expressed that consuming phytoestrogens might have oestrogenic, anti-oestrogenic and/or other effects in humans. These effects could be either adverse or beneficial and could affect particular subgroups of the population. This work would extend the aims of the T05 research programme's goal of improving the assessment of the human health implications (risks and benefits) of dietary phytoestrogens.
2. The 2003 COT report on Phytoestrogens and Health¹ noted that there had been some speculation that phytoestrogens may adversely affect the fertility of men by reducing testosterone levels and sperm counts. However the COT concluded that reports of hormonal effects in men from dietary soy or isoflavone supplementation were inconsistent, showing no or weak hormonal effects. The FSA has subsequently funded research in this area.
3. This project investigated the effects of consumption of phytoestrogen-containing products in individuals with low testosterone levels. This is an area of emerging scientific interest: for example, a recent case report reports an incident of a man regularly consuming a large volume of soy milk developed gynecomastia (Martinez J, Lewi J E; 1: Endocr Pract. 2008 14:415-8) and another study an association between reduced sperm count and consumption of soy containing food (Chavarro J E, Toth T L, Sadio S M and Hauser R; Hum. Reprod. Advance Access published online on July 23, 2008).

Project.

4. The study was commissioned to investigate whether phytoestrogens had adverse effects on male fertility. It was not feasible to undertake a study in the normal population since this would have required a very large sample size to obtain adequate power. The use of a sub-population suffering from

¹ <http://cot.food.gov.uk/pdfs/phytoreport0503>

hypogonadism allowed a sufficiently powered study to be carried out in a population where any effect would be magnified.

5. The study was a double blind placebo controlled cross over study. The intervention was a bar containing soy isoflavones and soy protein whereas the control arm only received soy protein. An interim report is at Annex A.

Questions on which the views of the Committee are sought

6. Members are invited to comment on the results of this research and its significance. In particular, Members are asked whether:

- i. The use of individuals with hypogonadism was an appropriate population.
- ii. Using alterations in testosterone was a suitable and sensitive indicator for effects on fertility
- iii. The effects seen on testosterone levels following soy isoflavones were likely to be biologically relevant
- iv. The potential that other hormonal problems in the patients might confound these data and whether this was sufficiently accounted for
- v. The implications of the findings for risk assessment

7. Members are asked to comment and make recommendations on whether these results require additional follow up.

**Secretariat
June 2013**

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Note: The Committee were provided with a version of this report. A finalised version will be published on the FSA website after the results have been published in the peer-reviewed literature.

**Secretariat
June 2013**