

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Consideration of the Belgian Competent Authority's Initial Opinion on an application from Belovo SO. for the placing on the market of Iodine-Enriched Wild-Type Eggs

Issue

1. On 1st July 2002, the Belgian Competent Authority received the above application from Belovo SO (a copy of the summary is attached at Annex 1). The Belgian Competent Authority (CA) Initial Opinion for the application was forwarded to the Commission on the 27th August 2002, and subsequently received by the UK on 27th September 2002. A copy of the Belgian CA Initial Opinion is attached at Annex 2. As we are considering this application under the 60-day rule, the UK opinion is required by the 26th November 2002. The Secretariat has a copy of the application dossier, which is available on request.
2. After receiving a copy of the summary document for this application, the Secretariat raised a number of concerns to the Commission regarding the status of the product (Attached at Annex 3). However, as we are now in receipt of an initial opinion, under Article 6 of the Novel Foods Regulation (EC) 258/97, the UK CA is obliged to forward comments or reasoned objections within 60 days.

Background

3. The applicant seeks approval to market eggs that are enriched with iodine. The source of the enrichment is the chicken feed. As the production process applied results in a change in the chemical composition of this food that affects its nutritional value, it is covered by category 6 of the Commission Guidelines for the Safety Assessment of Novel Foods.
4. The chicken feed contains 100ppm "feed grade iodine salt 'iodine equivalent'" which exceeds the maximum authorised levels of iodine in feed (10ppm) as stipulated in Directive 70/524/EEC.
5. The level of iodine enrichment is 650µg (+/- 50µg) per egg. The Joint Expert Committee on Food Additives, (JECFA) has recommended a Provisional Maximum Tolerable Daily Intake (PMTDI) of 0.017mg/kg bw/day (equivalent to 1mg per day for a 60kg Adult.)

6. There are a number of European countries (including Belgium) that do not operate a universal salt iodination programme, the UK is not one of them, and the issue of iodine deficiency does not occur within the general UK population.
7. In the UK there are concerns of overexposure to iodine in the diet. In view of this, the Committee on Toxicology (COT) has looked at levels of iodine in the diet, and specifically those obtained from cows' milk. Survey data reviewed by the COT in 1999 indicated that the PMTDI could potentially be exceeded particularly by children who consume high quantities of milk, although the committee was reassured by a scientific study looking at the effect of iodide consumption in children.
8. Following the review of these data, the COT issued a statement on iodine in cows' milk (January 2000) and instructed the COT Expert Committee on Vitamins and Minerals to review the toxicity of iodine. The conclusions of the EVM were that although there was insufficient data to establish a safe upper limit for iodine, they were able to set a guidance intake limit of 0.94mg/day which is similar to the JECFA figure. The COT concerns about differing effects of different chemical forms of iodine persist and a recent (October 2002) meeting of COT concluded that additional work to identify predominant iodine species in milk should be undertaken.
9. A draft Scientific Committee on Food document on the Tolerable Upper Intake Level of Iodine, is due for discussion at a forthcoming Plenary Meeting, will set the upper limit for iodine in foods. Members should be mindful of these levels in their consideration of this application.

Belgian CA Opinion

9. In their consideration of this novel food the Belgian CA have restricted their assessment to levels of iodine enrichment only, and conclude that on the basis of available nutritional and medical data, an unfavourable opinion should be given for this product. The Belgian CA conclude that this product risks moving the (small) subgroup of the Belgian population who currently are iodine deficient, to a state of excessive iodine consumption, which is could trigger a range of undesirable effects such as hypothyroidism, hyperthyroidism and auto-immune thyroiditis.

10. This opinion is based on the fact that consumption of very low quantities of the novel food would lead to consumption of levels of iodine that are beyond those recognised as safe by the WHO/UNICEF International Council for Control of Iodine Deficiency Disorders (ICCIDD) whose recommended levels of iodine are lower than those recommended by JECFA and the SCF. The ICCIDD is of the opinion that a daily level of 100-200µg / day is sufficient and that levels in excess of 1000µg are considered to be potentially toxic.
11. The Belgian CA also conclude that although the issue of iodine deficiency needs to be looked at in countries where there is no unilateral iodine fortification programme, this novel food is not a product that should be considered as a basis for correcting such deficiency.
12. Although the Belgian CA state that the safety assessment was on the basis of iodine over-consumption only, they are of the opinion that a ten-fold reduction in iodine levels would have been a more suitable level of fortification for such a product.

Committee Action Required

11. The Committee is asked if it has any comments or reasoned objections to raise or whether it is content to agree with the Initial Opinion of the Belgian Competent Authority. In particular:
 - (a) does the Committee accept that given the levels of iodine in the NF are unacceptable for Member States that have a problem of iodine deficiency, the product presents an unnecessary risk for the UK population?
 - (b) In view of the negative Initial Opinion by the Belgian CA for this product, is the Committee content with the text of the letter to the Commission, drafted by the Secretariat and attached at Annex 4.

**ACNFP Secretariat
November 2002**