

SCIENTISTS DENOUNCE “UNETHICAL” USE OF CHILDREN IN GM FEEDING EXPERIMENTS

This formal letter of protest relating to a severe breach of medical ethics has been sent by 22 senior scientists to the Tufts University School of Medicine, together with a call for these GM feeding experiments to be terminated immediately.

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OPEN LETTER

Professor Robert Russell,
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Dear Professor Russell,

TUFTS UNIVERSITY INVOLVEMENT IN GOLDEN RICE FEEDING TRIALS

We are writing to express our shock and unequivocal denunciation of the experiments being conducted by your colleagues which involve the feeding of genetically modified Golden Rice to human subjects (adults and children.) We are all senior scientists / academics with a professional interest in the health and environmental effects of GMOs.

We refer to three trials described on the US Clinical Trials web site:

1. Project NCT 00680355.(10) Bioavailability of Golden Rice Carotenoids in Humans.
<http://clinicaltrials.gov/ct2/show/record/NCT00680355?term=golden+rice&rank=1>
2. Project NCT 00082420. Retinol Equivalence of Plant Carotenoids in Children.
<http://clinicaltrials.gov/archive/NCT00082420>
3. Project NCT 00680212. Vitamin A Equivalence of Plant Carotenoids in Children.
<http://clinicaltrials.gov/ct2/show/record/NCT00680212?term=golden+rice&rank=3>

We wish to remind you that the variety of Golden Rice used in these

experiments (GR2) is inadequately described in terms of biological and biochemical characterisation on the Clinical Trials web site and indeed anywhere else in the publicly available literature, and has woefully inadequate pre-clinical evaluation. It is a genetically modified product which has not been shown to be distinctive, uniform and stable over time. It has never been through a regulatory / approvals process anywhere in the world. There is now a large body of evidence that shows that GM crop/food production is highly prone to inadvertent and unpredictable pleiotropic effects, which can result in health damaging effects when GM food products are fed to animals (for reviews see Pusztai and Bardocz , 2006; Schubert, 2008; Dona and Arvanitoyannis, 2009). More specifically, our greatest concern is that this rice, which is engineered to overproduce beta carotene, has never been tested in animals, and there is an extensive medical literature showing that retinoids that can be derived from beta carotene are both toxic and cause birth defects.

In these circumstances the use of human subjects (including children who are already suffering illness as a result of Vitamin A deficiency) for GM feeding experiments is completely unacceptable. The three Projects listed breach the Nuremberg Code / medical ethics code on a number of counts, and we urge you to call them to a halt immediately. They should not be resumed unless and until the researchers can demonstrate that a full range of laboratory and animal feeding trials have been completed and published for the Golden Rice strain being used, and unless and until appropriate regulatory bodies have had an opportunity to come to a view on the health and safety issues about which we are very concerned.

We can assure you that such trials would not have been approved within the European Union in the absence of safety information, which highlights yet again the flaw of the USDA and FDA regulatory system in considering GM crops/foods as hypothetically “generally recognised as safe – GRAS” in the absence of hard experimental data.

References:

- (1) Pusztai A. and Bardocz S. (2006). GMO in animal nutrition: potential benefits and risks. In: *Biology of Nutrition in Growing Animals*, eds. R. Mosenthin, J. Zentek and T. Zebrowska, Elsevier Limited, pp. 513-540.
- (2) Schubert D.R. (2008) The problem with nutritionally enhanced plants. *J Med Food.*, 11: 601-605.
- (3) Dona A. and Arvanitoyannis I.S. (2009) Health Risks of Genetically Modified Foods. *Crit Rev Food Sci Nutr.*, 49: 164–175.

These unethical and potentially dangerous trials MUST be stopped, and we ask you to undertake a thorough review of why and how they were approved and funded in the first place. Please accept this letter as a formal protest, and please forward it to the relevant authorities at USDA, FDA, NIDDK, NIH and the US State Department.

We look forward to hearing from you.

Yours sincerely,

Prof Malcolm Hooper, Prof David Schubert, Professor Brian Goodwin, Dr Michael Antoniou, Dr Vandana Shiva, Dr Stanley W.B. Ewen, Dr Mira Shiva, Dr Brian John, Dr Phil Davies, Dr Irina Ermakova, Dr Judy Carman, Prof E R Orskov, Professor Leda Raptis, Dr Eva Novotny, Professor Peter T Saunders, Dr E. Ann Clark, Professor Carlo Leifert, Dr Mae-Wan Ho, Professor Ralph C. Martin, Prof. Joe Cummins, Prof David Suzuki

THIS LETTER IS ALSO SIGNED BY CHILDREN'S ADVOCATE JOAN KNOX

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