

Guidelines for MAFMA Final Report

Final Reports due 45 days after completion of project
(4-5 pages)

Project Title Determination of the Minimal Eliciting Dose for Soy in Soy-Allergic Individuals

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Co-PI (s) None

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Award Date September 2005

Please complete all questions below and attached form

1. Objective Summary (1-2 sentence summary)

The objective of this study is to determine the no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) for soy protein by challenging soy-allergic individuals in a double blind, placebo controlled food challenge format.

2. Objective Accomplishments

(If objectives were not met, what extenuating circumstances contributed to that factor?)

Convey all of your progress on this project including that obtained with the industry and other matching funds.

A baked granola challenge vehicle was developed and subjected to sensory evaluations. The granola vehicle containing 1000 mg soy protein (in soy flour) was not distinguishable from the granola with no soy protein in a sensory triangle test. The blinded doses of 0.1, 1, 10, 100 and 1000 milligrams soy protein in 20 grams of granola (a range of 5-50,000 parts per million) were given to soy allergic individuals in a double blind format, with a positive challenge day and a separate placebo day. The blinded challenges were followed by one open challenge of 8 ounces of soy milk, containing 7 grams of soy protein. This challenge was given on Day 2 of the challenge if no objective symptoms were observed on either day of the challenge.

Clinical collaborators have been identified – Dr. Barbara Ballmer-Weber (Zurich, Switzerland), Dr. Michael Levy (Milwaukee WI), Dr. Motohiro Ebisawa (Kanagawa, Japan), Dr. Fabienne Rancé (Toulouse, France), and Dr. Anthony Dubois (Groningen, Netherlands). Institutional Review Board (IRB)/ethics board approvals have been obtained for all except the Groningen group which will be resubmitting the proposal that does not include children as subjects. Only Dr. Ballmer-Weber has actually completed challenges. Ten subjects have completed the challenge. Only two subjects reacted with objective symptoms at doses at or below the top dose of the blinded challenge of 1000 mg – one subject at 10 mg and the other at 1000 mg. Six additional subjects experienced reactions on the open challenge phase with 8 oz of soy milk containing 7 grams of soy protein (although one of these only consumed 20% of this open challenge dose). Thus, these subjects appear to be soy-allergic with individual

minimum eliciting doses (MEDs) of >1000 mg. Two subjects reacted to placebo and were not given the open challenge; we cannot be sure that these two subjects are soy-allergic. These preliminary results tend to indicate that the threshold dose for soybeans is comparatively high for most subjects. We will continue with our collaborators to complete challenges of a total of 29 soy-allergic subjects.

3. Unexpected findings, if any: There were no unexpected findings.
4. Practical impacts of research efforts. Include: implementation of accomplishments by industry partners (if any), identification of economic impacts, and any further pursuit by PI of research in area of this project whether MAFMA or not.
 - a. Short Term Impacts
No short term impacts are likely as this study remains incomplete.
 - b. Long Term Impacts
The results of this study will assist the food industry and regulatory agencies in starting to assess risk for the inadvertent ingestion of food allergens by the food-allergic consumer, and will contribute to a knowledge base that is extremely lacking. Information on threshold levels for allergens would enable regulatory agencies to establish a level below which they can feel confident that the risk to a food-allergic individual meets the “reasonable certainly of no harm” principle. This will impact and affect the area of food product recalls due to allergens, the number one reason for recalls in the United States, and will affect enforcement of food allergen labeling regulations in the future, not only in the US but in other countries, as well.
5. If you are also making reports to other funding agencies in the course of this research work, please include a copy of that report.
6. a. If any publications resulted from the research, a copy must be included. Please note we were notified by the USDA/CSREES National Program Leader for the Midwest Advance Food Manufacturing Alliance (MAFMA) that all publications resulting from research that was funded by MAFMA must include the following wording **“The project was supported by the USDA Cooperative State Research, Education and Extension Service, special research grant number 200X-34328-xxxxx.**
- b. **If any patents (pending or granted) resulted from the research, please include the patent information.**