IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
1138 Pearson Hall
Ames, Iowa 50011-2207
515 294-4566
FAX 515 294-4267

Date: 8/20/2014

To: Dr. Wendy S White
1111 Human Nutritional Sciences Bldg

CC:

From: Office for Responsible Research

Title: Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas

IRB ID: 13-376

Approval Date:	8/19/2014	**Date for Continuing Review:**	8/19/2015
Submission Type:	Continuing Review	**Review Type:**	Full Committee

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, **including the recruitment materials and informed consent documents that have the IRB approval stamp.**
- **Retain signed informed consent documents for 3 years after the close of the study**, when documented consent is required.
- **Obtain IRB approval prior to implementing any changes** to the study by submitting a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form, as necessary.
- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.
- **Stop all research activity if IRB approval lapses,** unless continuation is necessary to prevent harm to research participants. Research activity can resume once IRB approval is reestablished.
- **Complete a new continuing review form** at least three to four weeks prior to the **date for continuing review** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please be aware that IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g. student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

Upon completion of the project, please submit a Project Closure Form to the Office for Responsible Research, 1138 Pearson Hall, to officially close the project.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

Assigned IRB ID: **13-376**

INSTITUTIONAL REVIEW BOARD (IRB)
Continuing Review Form

Title of Project: Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas			
Principal Investigator (PI): **Wendy S. White**			Degrees: Ph.D., R.D.
University ID:	Phone: 4-3447	Email Address: wswhite@iastate.edu	
Department: Food Science and Human Nutrition			

FOR STUDENT PROJECTS (*Required when the principal investigator is a student*)			
Name of Major Professor/Supervising Faculty:			
University ID:	Phone:	Email Address: @iastate.edu	

RECEIVED
JUL 31 2014
By IRB

Alternate Contact Person:	Email Address:
Correspondence Address:	Phone:

Please notify the IRB Office if your contact information has changed since the last review.

ASSURANCE

- I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted to external funding agencies. Misrepresentation of the research described in this or any other IRB application may constitute non-compliance with federal regulations and/or academic misconduct.
- I agree to provide proper surveillance of this project to ensure that the rights and welfare of the human subjects are protected. I will report any problems to the IRB. See Reporting Adverse Events and Unanticipated Problems for details.
- I agree that modifications to the approved project will not take place without prior review and approval by the IRB.
- I agree that the research will not take place without the receipt of permission from any cooperating institutions when applicable.
- I agree to obtain approval from other appropriate committees as needed for this project, such as the IACUC (if the research includes animals), the IBC (if the research involves biohazards), the Radiation Safety Committee (if the research involves x-rays or other radiation producing devices or procedures), etc., and to obtain background checks for staff when necessary.
- I understand that IRB approval of this project does not grant access to any facilities, materials, or data on which this research may depend. Such access must be granted by the unit with the relevant custodial authority.
- I agree that all activities will be performed in accordance with all applicable federal, state, local, and Iowa State University policies.

WSWhite 7/29/14

Signature of Principal Investigator Date

Signature of Major Professor/Supervising Faculty Date
(*Required when the principal investigator is a student*)

For IRB Use Only	Full Committee Review: ☑	Review Date: August 19, 2014
	EXPEDITED per 45 CFR 46.110(b): Category Letter	Approval/Determination Date: August 19, 2014
		Approval Expiration Date: August 19, 2015
	OTHER:	Risk: Minimal ☑ More than Minimal ☐
IRB Reviewer's Signature	Kerry A Agnitsch	August 20, 2014

Continuing Review Information

Please provide answers to all questions, except as specified. The fields will expand as you type. Incomplete forms will be returned without review.

Part A: Status of the Research: Please respond to the following statements to describe the current status of your research.

☐ Yes ☒ No	1. The remaining research activities are limited **solely** to data analysis (i.e., all contact with participants has ended and no additional data about participants will be collected).
☐ Yes ☐ No	**1.a.** If *Yes*, have the data been de-identified, such that it is no longer possible to link the data with the identities of the persons to whom the data pertain?
If **both** 1 and 1.a are *Yes*, **STOP**! IRB oversight of your study is no longer required. Please complete the Project Closure Form and send it to the IRB Office, 1138 Pearson. If one or both are *No,* proceed to Question 2.	

☒ Yes ☐ No	2. Recruitment and enrollment of new participants has begun and is ongoing.
If *No,* proceed to Question 3. If *Yes,* proceed to Part B. A current copy of the informed consent document(s) and recruitment materials must be submitted with the application.	

☐ Yes ☐ No	3. Recruitment and enrollment of new participants (or collection of private and identifiable data) has ended; no additional participants will be sought.
If *Yes*, proceed to Question 4. If *No*, proceed to Part B.	

☐ Yes ☐ No	4. All research activities involving participants (including collection of private and identifiable data about participants) have been completed; **OR** Only long-term follow-up activities will continue, such as • follow-up interactions that involve no more than minimal risk (e.g., "member checking") or • follow-up interventions that would normally be performed for non-research purposes (e.g., blood draws at a routine physical exam, routine clinical monitoring for disease progression, routine cholesterol screening, etc.).
Please proceed to Part B.	

Part B: Progress Report

Please provide a brief summary of your progress to date in conducting the research and what activities remain.
The study has been substantially delayed due to delays in shipping the needed bananas from Australia. We distributed an electronic recruitment notice, but have not yet begun the screening of study applicants. We will begin screening when the students return for the new semester at the end of August.

Part C: New Information

☐ Yes ☒ No 1. Is there any new information available relevant to the risks or potential benefits of the research, such as the following? (Check all that apply.)

- ☐ Results from other relevant studies (published or unpublished)
- ☐ Interim findings
- ☐ Data safety monitoring board (DSMB) reports
- ☐ Multi-center trial reports
- ☐ Other information that suggests a change, either positive or negative, in the risk to participants
- ☐ Other information that suggests a change, either positive or negative, in the expected benefits of the research

1.a. If any of the above are checked, please provide the following:

(i) a detailed description of the new information and how it is relevant to your study:

(ii) a complete description of any related changes to the research procedures or materials (including the informed consent process) that are needed to safeguard the rights and welfare of participants:

If none are checked, please proceed to Part D.

Part D: Protocol Changes

☐ Yes ☒ No 1. Do you wish to make any changes to research procedures, study materials, or key personnel with this application for *implementation in the future*?

If *Yes*, please complete and attach a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form as applicable.

☐ Yes ☒ No	2.	Have there been any changes to the research procedures (e.g., methods of collecting data, sources of data, experimental design, interventions, stimuli, confidentiality measures, inclusion/exclusion criteria, consent process, etc.) *implemented since the last IRB review*?
		If *Yes*, please provide a detailed description of these changes, including when each change was implemented:

☐ Yes ☒ No	3.	Have there been any changes to study materials (e.g., informed consent documents, data collection instruments, recruitment materials, etc.) *implemented since the last IRB review*?
		If *Yes*, please provide a detailed description of these changes, including when each change was implemented:

☐ Yes ☒ No	4.	Have there been any changes to key personnel since the last IRB review?
		If *Yes*, please provide a detailed description of these changes, including when each change was implemented:

Part E: Enrollment

Please complete the following table related to the enrollment of participants in your study. For definitions and guidance on how to determine enrollment, please see the document entitled Enrollment and Accrual of Study Participants.

Number of participants approved by the IRB:	
Total number of participants enrolled in the study to date: 0	
Estimated percent of the total enrolled by sex/gender (if known): Males:	Females: 100 Unknown: ☐
Number of screen failures (participants who were screened and deemed ineligible) to date: 0	
Check if any enrolled participants are: ☐ Minors (under 18) | Age range of minors: ☐ Pregnant women/fetuses ☐ Cognitively impaired ☐ Prisoners	
List below the estimated percent of the total enrolled that are minorities (if known)	Unknown: ☒
American Indians:	Alaskan Native:
Asian or Pacific Islander:	African American:
Black (not of Hispanic origin):	Hispanic:

☐ Yes ☒ No	1. Have any participants withdrawn or have you asked any participants to withdraw from the study?
	If *Yes*, describe the reason(s) for the withdrawal(s):

Part F: Problems or Concerns

☐ Yes ☒ No	1. Have there been any adverse events or unanticipated problems involving risks to subjects or others associated with the study? See guidance entitled Reporting Adverse Events and Unanticipated Problems for definitions and reporting requirements.	
If *Yes*, please describe the event(s)/problem(s) as follows:		
Brief summary of adverse event(s) or unanticipated problem(s)	Approximate date incident occurred	Was a report submitted to the IRB?

☒ Yes ☐ No	2. Have there been any complaints from participants or others about the study?
If *Yes*, please describe the event(s)/problem(s) as follows:	
Brief summary of complaint(s) and how each was handled by research staff	Approximate date complaint occurred
A Des Moines Register reporter was contacted by a "GMO-skeptic" who was questioning whether a study of this type can be safe. The basis for the question was a story about our study which appeared on the National Public Radio (NPR) web site. The NPR story did not provide specific information about the study or the genetic engineering of the bananas. I am currently working with Annette Hacker to draft a response for the Des Moines Register.	7/29/14

Part G: Submission Requirements

Unless enrollment is permanently closed and/or all remaining activities are limited to data analysis, please:

☒ Attached
☐ N/A

Submit an unstamped copy of the informed consent document or informational letter so a current IRB approval stamp can be added. If you would like to modify these materials, please complete and attach a Modification Form for Non-Exempt Research.

☒ Attached
☐ N/A

Submit an unstamped copy of all recruitment materials so that a current IRB approval stamp can be added. If you would like to modify these materials, please complete and attach a Modification Form for Non-Exempt Research.

Please Note: *Any changes to the protocol, procedures, or other study materials (e.g., survey instruments, interview questions, flyers, posters, etc.) must be described in detail as requested in* **Modification Form for Non-Exempt Research.**

If you have any questions or feedback, please contact the IRB office at IRB@iastate.edu or 515-294-4566.

ISU IRB # 1	13-376
Approved Date:	19 August 2014
Expiration Date:	19 August 2015

Human Subjects Needed

Introduction

Cooked bananas are a major component of diets in Uganda and other parts of East Africa. To alleviate widespread vitamin A deficiency in East Africa, scientists at Queensland University of Technology, Brisbane, Australia developed transgenic bananas which have been genetically modified to produce more beta-carotene in the fruit. Beta-carotene is converted in the body to vitamin A.

Purpose of the study:

To measure the vitamin A value of the beta-carotene in transgenic bananas which have been genetically modified to contain more beta-carotene.

Subject requirements

- Female, healthy, nonsmokers, 18-40 years
- Willing to eat a diet provided by the investigators for 4 days during each of 3 study periods
- Willing to donate blood samples
- Available during selected weeks (months to be specified)
- Participation is voluntary; subject information will be confidential.

Compensation

- Participants will receive up to $900 in compensation.

Contact: Vitamin A Study (VitaminAStudy@iastate.edu)

ISU IRB # 1	13-376
Approved Date:	19 August 2014
Expiration Date:	19 August 2015

INFORMED CONSENT DOCUMENT

Title of Study: "Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas"

Investigators: Wendy S. White, Ph.D., R.D., , M.S., , M.S.

This is a research study. Please take your time in deciding if you would like to participate. Please feel free to ask questions at any time.

INTRODUCTION

Cooked bananas are a major component of diets in Uganda and other parts of East Africa. To alleviate widespread vitamin A deficiency in East Africa, the Bill and Melinda Gates Foundation funded scientists at Queensland University of Technology, Brisbane, Australia to develop transgenic beta-carotene-biofortified bananas. These bananas are genetically modified to produce more beta-carotene. *The purpose of the current research is to determine the vitamin A value of the beta-carotene in these transgenic beta-carotene-biofortified bananas.*

Beta-carotene is a yellow-orange pigment that occurs naturally in many fruits and vegetables. Beta-carotene is converted to vitamin A in the body. Low amounts of beta-carotene are naturally present in conventional bananas; however, these amounts are too low to improve vitamin A nutrition.

This will help scientists to evaluate the value of the transgenic beta-carotene-biofortified bananas in combating vitamin A deficiency. You are being invited to participate in this study because you are a resident of Ames or the surrounding communities from which we are recruiting our study population.

DESCRIPTION OF PROCEDURES

To determine if you are eligible to participate in the study, a trained interviewer will collect relevant health and medical history information using a standardized questionnaire. If you remain eligible to participate, the interviewer will make an appointment for you to donate a small blood sample to be used for additional health screening.

If you are eligible and agree to participate in the study, your participation will involve 3 study periods

During each of 3 study periods, you will be asked to complete the following protocol:

RISKS

While participating in this study you may experience risks pertaining to insertion of a butterfly needle or syringe needle into a peripheral forearm vein for collection of blood samples. Risks accompanying the use of a needle for blood collection include infection and excessive blood loss. Infection is not expected to be a significant risk because the licensed medical technicians who will draw the blood are experienced and trained to follow safe procedures. The risk of anemia is considered to be minimal because only blood will be collected during each of the 3 study periods. As a safeguard, you will be tested for anemia as well as other blood indicators of good health before you are enrolled in the study; if found to be anemic, you will not be allowed to participate.

While participating in this study you may experience discomfort pertaining to the placement of a needle in a forearm vein. The discomforts involved are: slight pain during insertion of the butterfly needle and bruising caused by minor seepage of blood around the site of insertion. The discomfort is expected to be minor because the licensed medical technician who will place the needle and collect the blood samples will have extensive experience and be trained to minimize discomfort. If you have a psychological aversion to blood donation, you should not participate in the study.

Note:
The current study will be the first time that these transgenic bananas will be consumed by human subjects.

The FDA agreed with the biotechnology companies that the evidence indicated that the foods derived from these genetically-modified plants were as safe as the foods derived from conventional varieties.

Note:
The current study will be the first time that bananas containing the will be consumed by human subjects.

The transgenic bananas will contain more beta-carotene and related yellow-orange carotenoids when compared with conventional bananas. The maximum total amount of beta-carotene and other carotenoids in the single transgenic banana portion that you will consume will be about There is no known risk due to consuming this amount of beta-carotene and related carotenoids.

BENEFITS

If you decide to participate in this study there will be no direct benefit to you. It is hoped the information gained in this study will benefit society by developing a sustainable, cost-effective, agricultural solution to the problem of vitamin A deficiency; a solution that will be accessible to the rural poor in developing countries.

COSTS AND COMPENSATION

You will not have any costs from participating in this study. You will be compensated for participating in this study. You will be paid $300 at the end of each of the 3 study periods or a total of $900.

To meet governmental reporting requirements for the $300 payments, you will need to complete a University form that requires that you provide your social security number. The form will be kept in a locked cabinet until it is delivered to the Iowa State University Controller's Office where precautions are in place to keep the information secure. You may forego receipt of payment(s) and continue in the research study if you do not wish to provide your social security number and address. Information regarding documentation required for participant compensation may be obtained from the Controller's Department, 294-2555 or http://www.controller.iastate.edu.

Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payments you will receive.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate or may leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise

entitled. If you are found to have forearm veins that are not suitable for blood collection, if you develop a medical or other condition that would preclude your safe or appropriate participation, or if you are noncompliant with required study procedures, your participation may be terminated.

RESEARCH INJURY

Emergency treatment for any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity. Compensation for any injuries will be paid if it is determined under the Iowa Tort Claims Act, Chapter 669 Iowa Code. Claims for compensation should be submitted on approved forms to the State Appeals Board and are available from the Iowa State University Office of Risk Management and Insurance.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, the Food and Drug Administration, HarvestPlus (the research sponsor) and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken. Information collected as a result of your participation in the study will be shared only among the investigators involved. When personal identifiers such as your name or initials are used to record data, data sheets will be stored in a locked cabinet and will be accessible only to the investigators. Electronic data files containing personal identifiers will be stored in a password-protected computer. Identifier codes will be removed from data sheets within a 5-year period after publication of the results of the research project. When the results of the study are published, your identity will remain confidential.

CLINICAL TRIAL REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study contact Wendy S. White, Ph.D., Department of Food Science and Human Nutrition, 1111 Human Nutritional Sciences Building, (515) 294-3447.

If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566; IRB@iastate.edu, or Director, Office of Responsible Research, (515) 294-3115; 1138 Pearson Hall, Ames, IA 50011.

SUBJECT SIGNATURE

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. You will receive a copy of the signed and dated written informed consent prior to your participation in the study.

Subject's Name (printed) _____

_____ _____

(Subject's Signature) (Date)

INVESTIGATOR STATEMENT

I certify that the participant has been given adequate time to read and learn about the study and all of their questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits and the procedures that will be followed in this study and has voluntarily agreed to participate.

_____ _____

(Signature of Person Obtaining Informed Consent) (Date)

W.S. White
8/12/14

- *Safety of GM food crops*: The FDA has concluded that there is no scientific evidence to support the idea that genetically-modified (GM) foods pose any greater risk to human health than conventional foods. This point of view is supported by the World Health Organization (WHO): "The use of these [biotechnological techniques] does not result in food which is inherently less safe than that produced by conventional ones"(FAO/WHO. 1991. Strategies for assessing the safety of foods produced by biotechnology. Report of a Joint FAO/WHO Consultation).

- *Current consumption*: GM foods have been in our food supply for 17 years with no known adverse effects. Most Americans eat GM-derived foods nearly every day (Chrispeels MJ.Yes indeed, most Americans eat GMOs every day! J Integrative Plant Biology 2014;56:4-6). In the U.S., 94% of the soybean crop and 93% of the maize crop is GM (USDA Economic Research Service. Adoption of Genetically Engineered Crops in the U.S., 2014).

- *Generally Recognized as Safe:* FDA's policy for regulating biotech crops was established in 1992 (57 Federal Register 22983 May 29, 1992). The 1992 policy asserted that GM crops are usually the same as, or "substantially equivalent" to, the conventional non-GM crop. Thus, like their non-GM counterparts, they are considered "Generally Recognized as Safe" (GRAS) under the Federal Food, Drug, and Cosmetic Act and no pre-market approval is necessary.

- *Animal testing*: FDA regulations do not require whole food toxicity animal studies of GM food or feed. A recent review was conducted by the International Life Sciences Institute (ILSI) International Food Biotechnology Committee Task Force on the Use of Mammalian Toxicology Studies in the Safety Assessment of GM Foods (Bartholomaeus et al. The use of whole food animal studies in the safety assessment of genetically modified crops: Limitations and recommendations. Critical Reviews in Toxicology 2013;43:1-24). The task force found that animal testing is unnecessary due to the "improbability of *de novo* generation of toxic substances in crop plants using genetic engineering practices and due to the weakness of whole food toxicity studies in general." *The review concluded that "whole food animal toxicity studies are unnecessary and scientifically unjustifiable."*

- *Unintended changes:* The ILSI task force (above) also commented on the *"implausibility of a simple insertion of a transgene generating de novo production of toxic proteins or secondary metabolites unrelated to either the parent crop or the source of the transgene".* They further stated *"there is no evidence that the insertion of a transgene from a non-toxic source into a GM crop has any greater propensity to result in the de novo generation of novel toxic compounds than does the range of conventional plant breeding techniques that currently require no toxicity testing. Thus, it presents a considerable challenge to identify circumstances under which the conduct of a whole food [animal] study is scientifically and ethically justified."*

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- *Pregnant women:* During early pregnancy, either too little or too much vitamin A may cause birth defects (Underwood BA. Maternal vitamin A status and its importance in infancy and early childhood. Am J Clin Nutr 1994;59(suppl):517S-24S). Retinoic acid is the active hormone form of vitamin A. Retinoic acid is produced in tissues by tightly controlled oxidation of the retinol form of vitamin A according to the body's needs (Underwood BA. Maternal vitamin A status and its importance in infancy and early childhood. Am J Clin Nutr 1994;59(suppl):517S-24S). The body's conversion of beta-carotene to retinol and then to retinoic acid is also tightly regulated. As a result, beta-carotene does not cause vitamin A toxicity. When given as a high-dose supplement, retinoic acid may cause birth defects. *There is no documented evidence that beta-carotene may cause birth defects. There is no evidence that retinoic acid can be produced by plants.*

  Beta-carotene is viewed as a safe alternative to vitamin A supplements for pregnant women (Underwood BA. Maternal vitamin A status and its importance in infancy and early childhood. Am J Clin Nutr 1994;59(suppl):517S-24S). Poor pregnant women in low income countries rely upon dietary beta-carotene as their source of vitamin A because animal foods (which contain vitamin A) are scarce. The Hohenheim consensus conference recommended that at least 6 milligrams of beta-carotene per day be consumed when vitamin A intake is low (Grune et al., β-Carotene is an

important vitamin A source for humans. J Nutr 2010;140:2268S-2285S).

In preparing this written statement, I discovered a recently published "clinical medicine insight", which proposes that dietary beta-carotene be monitored during pregnancy as a potential source of excess 13-cis retinoic acid that could cause birth defects (Goldberg JS. Monitoring maternal beta carotene and retinol consumption may decrease the incidence of neurodevelopmental disorders in offspring. Clin Med Insights Reprod Health 2012;6:1-8). No original data are presented in this paper. The author theorizes that low beta-carotene concentrations in human fetal tissues indicate limited storage of beta-carotene by the fetus. (Previously, researchers have attributed low beta-carotene concentrations found in umbilical cord blood to poor placental transfer of maternal beta-carotene). The author then presupposes that limited fetal storage of beta-carotene must reflect its high conversion to retinoic acid. These conclusions are highly speculative. There are no documented reports that beta-carotene, even when ingested by the mother as a supplement in high doses, can produce excess retinoic acid or birth defects in the fetus. The author's recommendation regarding monitoring of dietary beta-carotene intake by pregnant women has not been adopted by any medical or health organization. *Regardless, the amount of beta-carotene that will be consumed by our subjects in the GM bananas is average daily beta-carotene intake in Western industrialized countries (3.9 milligrams)* (Weber and Grune. The contribution of β-carotene to vitamin A supply of humans. Mol Nutr Food Res 2012;56:25-58).