RECOMMENDATIONS FOR THE EARLY FOOD SAFETY EVALUATION OF NEW NON-PESTICIDAL PROTEINS PRODUCED BY NEW PLANT VARIETIES INTENDED FOR FOOD USE

OMB No. 0910-0583

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (57 FR 22984, May 29, 1992), the Food and Drug Administration (FDA) has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA early in the development process to discuss possible scientific and regulatory issues that might arise. The guidance titled, "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety. FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. FDA seeks extension of approval of the information collection provisions of the guidance.

2. Purpose and Use of the Information Collection

The guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

3. Use of Improved Information Technology and Burden Reduction

The new protein guidance does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by developers. Developers are free to use whatever forms of information technology may best assist them in voluntarily conducting the scientific evaluation and submitting it to the agency. Information for early food safety evaluations may be collected electronically. If the evaluation is submitted to FDA as an electronic file, one paper copy is also requested.

4. Efforts to Identify Duplication and Use of Similar Information

FDA plans to avoid duplicative collection of this information. If a protein has been evaluated in an early food safety evaluation and no safety concerns are identified, we would not expect an additional early food safety evaluation to be submitted if the same protein is introduced into another

plant species. Also, if a protein has previously been reviewed as part of a biotechnology consultation and there were no safety concerns identified, we would not expect the submission of an early food safety evaluation for such a protein.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.), the U.S. Environmental Protection Agency (EPA) has authority to regulate all pesticides, regardless of how they are made or their mode of action. This early food safety evaluation guidance applies to non-pesticidal proteins and is not duplicative with EPA responsibilities.

Many plants developed using recombinant DNA (rDNA) technology are considered "regulated articles" under regulations of USDA's Animal and Plant Health Inspection Service (APHIS) (7 CFR Part 340), which regulates the introduction of certain "genetically engineered" plants into the environment. A developer must obtain authorization from APHIS to field test such crops and, depending on the nature of the crop, a developer files either a permit application or a notification. In contrast, FDA requests a submission of data and information concerning the food safety of a specific new protein produced in a new plant variety. Therefore, although a submission to APHIS would include some information, such as the name of the company and the identity of the protein, that would be included in the information requested under FDA's guidance for the early food safety evaluation of new proteins, the submission is not duplicative.

5. Impact on Small Businesses or Other Small Entities

In the guidance, the agency has established criteria as to the type of information necessary for these submissions. The New Protein Guidance minimizes the reporting burden on all businesses, including small businesses, by providing that the developer submit a summary of data and information, rather than the data and information itself. There is no known way to minimize the burdens on a small business wishing to submit a request for action to the agency.

Further, submitting an early food safety evaluation to the agency for comment is voluntary. There would not be additional burden to the developer for developing the data and information that underlie the new protein evaluation because they would have already generated such data and information to insure that the protein is safe and is in compliance with all applicable requirements of the FFDCA.

6. Consequences of Collecting the Information Less Frequently

The data in an early food safety evaluation are submitted only once and therefore cannot be collected less frequently.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Allowing developers to submit an early food safety evaluation to the agency for comment does not involve submission of information more than quarterly to the agency, written responses to the agency in less than 30 days, submission of multiple copies, retention of records for more than three years, or the use of statistical methods.

With regard to the confidentiality of the information or the submission of trade secrets or proprietary information, the agency expects that it may receive submissions containing confidential

commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Consistent with confidentiality requirements, FDA will make submissions of early food safety evaluations for new proteins, and FDA's responses thereto, easily accessible to the public via the Internet. FDA believes this is consistent with the goal of enhancing public confidence in the regulatory oversight of bioengineered plants.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of January 9, 2009 (74 FR 906). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection will be used only to aid developers of new non-pesticidal proteins determine the safety of their new protein. Consistent with confidentiality requirements, FDA will make submissions of early food safety evaluations for new proteins, and FDA's responses thereto, easily accessible to the public via the Internet.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
First four data components	20	1	20	4	80
Two other data components	20	1	20	16	320
Total					400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates the annual total hour burden for this collection of information to be 400 hours. This estimate is based on early food safety evaluations submitted in the past three years. FDA's estimate of the time that it would take a respondent to prepare the data components of the early food safety evaluation submission is based on the agency's experience with similar submissions.

Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Based on its experience over the past three years, FDA estimates that approximately 20 developers will choose to complete an early food safety evaluation for their new plant protein. Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (e.g., on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with FDA about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. FDA estimates that completing these data components will take about 4 hours per evaluation. In table 1 of this document, row 1 shows that for 20 evaluations, the total burden for these 4 data components is 80 hours.

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves "wet" lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components to submit to FDA. We estimate that these two data components will take 16 hours to complete (8 hours for each component). In Table 1 of this document, row 2 shows that for 20 evaluations, the total burden for these two data components is 320 hours.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $28,024. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2009, which makes the annual wage cost for completion and submission approximately $14,012 (400 hours x $35.03 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $28,024.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to Federal Government

FDA estimates that the staffing burden for review of early food safety evaluations will be 80 hours per submission. We estimate that we will receive approximately 20 submissions annually. Thus, we estimate 1,600 hours will be needed to review early food safety evaluation submissions. The cost to the Federal government is estimated as being equivalent to the number of hours of review per year at an average hourly salary rate of $54.15, which is the hourly salary rate for a GS-13/Step 10 for the Washington-Baltimore locality pay area for year 2009 (1,600 hours x $54.15/hour = $86,640). This estimate also presumes that overhead will be equal to salary for a total cost to the

Federal government of approximately $173,280 per year ($86,640 x 2 = 173,280).

15. Explanation for Program Changes or Adjustments

There is no change in the estimated burden of this information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA plans to assign a number to each submission and create a list of the submissions for posting on the Internet. The information on the Internet will include a hyperlink to the text of each submission (other than confidential commercial information) and a hyperlink to FDA's response.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A