B. Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed.

Summary information of the safety and nutritional assessment for a new plant variety submitted to FDA includes the following information:

- The name of the bioengineered food and the crop from which it is derived;
- A description of the various applications or uses of the bioengineered food, including animal feed uses;
- Information concerning the sources, identities, and functions of introduced genetic material;
- Information on the purpose or intended technical effect of the modification, and its expected effect on the composition or characteristic properties of the food or feed;
- Information concerning the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or food derived therefrom;
- Information regarding any known or suspected allergenicity and toxicity of expression products and the basis for concluding that foods containing the expression products can be safely consumed;
- Information comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties of the same crop with special emphasis on important nutrients, and toxicants that occur naturally in the food;
- A discussion of the available information that addresses whether the potential for the food derived from a bioengineered plant to induce an allergic response has been altered by the genetic modification; and
- Any other information relevant to the safety and nutritional assessment of the bioengineered food.

In 2001 FDA contacted five firms that had made one or more biotechnology consultation submissions under the 1996 procedures. FDA asked each of these firms for an estimate of the hourly burden to prepare a submission under the voluntary biotechnology consultation process. Three of these firms subsequently provided the requested information. Based on this information, FDA is estimating that the average time to prepare a submission for final consultation under the 1996 procedures is 150 hours.

Dated: November 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26048 Filed 11–19–04; 1:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0369]

Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.'' The draft guidance, when finalized, is intended to provide recommendations to developers of new plant varieties, in particular bioengineered plants, on the early food safety evaluation of new non-pesticidal proteins. The draft guidance describes procedures for submitting an early food safety evaluation of such proteins to the agency.

DATES: Submit written or electronic comments concerning the draft guidance and the collection of information provisions by January 24, 2005.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' to Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1165. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments concerning the draft guidance and the collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1165, FAX 301–436–2965, e-mail: *mditto@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In a document in the **Federal Register** of August 2, 2002 (67 FR 50578), the U.S. Office of Science and Technology Policy (OSTP) proposed Federal actions to update field test requirements and to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and diversity of bioengineered crops. As the number and diversity of field tests for bioengineered plants increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced during field tests with commercial seeds or grain may also increase. This could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA's voluntary consultation procedures for foods derived from new plant varieties (referred to as ''biotechnology consultation'' in the case of bioengineered plants).[1] FDA is issuing a draft guidance document to address this possibility.

This draft guidance describes the procedure for early food safety evaluation of new proteins produced by new plant varieties that are under

[1] Guidance on Consultation Procedures: Foods Derived from New Plant Varieties can be found at *http://www.cfsan.fda.gov/~lrd/consulpr.html*.

development. While this guidance is focused on new proteins in bioengineered plants, these procedures may, of course, be used for new proteins in non-bioengineered foods as well. This draft guidance also provides information to sponsors and developers about submitting their evaluation to FDA.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the early food safety assessment of new proteins produced by new plant varieties intended for food use. It does not create or confer any rights, for or on any person, and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing the guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed in the title page of the guidance.

II. Paperwork Reduction Act of 1995

This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Elsewhere, in this issue of the **Federal Register**, FDA is publishing a notice announcing an opportunity for public comment on the information collection, entitled ''Guidance on Consultation Procedures; Foods Derived from New Plant Varieties.''

Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (57 FR 22984, May 29, 1992), 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 current guidance 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. This 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.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Operating and Maintenance Costs	Total Hours
First four data components	20	1	20	4	$0	80
Two other data components	20	1	20	16	$0	320
Annual one-time burden hours						400

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

Burden:

Hour Burden Estimate

One Time Burden

Completing an early food safety evaluation for a new protein from a new plant variety will be a one-time burden (one evaluation per new protein). FDA cannot know how many developers will choose to complete an early food safety evaluation for their new plant protein. Some plant developers may choose not to complete an evaluation because of the uncertainty of the new plant variety's future viability in the marketplace. Other developers may have previously communicated with FDA about the food safety of a new protein, for example, when the same protein was expressed in a different crop. Still other developers may test a new plant variety under such

conditions that those developers have no concerns that the new protein could enter the food supply.

FDA scientists predict that this draft guidance will generate about 20 to 150 early food safety evaluations yearly. While there is uncertainty as to the number of developers who will choose to submit an evaluation, FDA estimates that the annual number of early food safety evaluations will be closer to the lower bound estimate of 20 evaluations rather than the upper bound estimate of 150 evaluations. This estimation is supported by the fact that on average there have been nine initial biotechnology consultations per year; an initial biotechnology consultation has traditionally been the first discussion between a developer and FDA about a bioengineered food.

Evaluation Components

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 put together 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). Table 1, row 2, shows that for 20 evaluations, the total burden for these two data components is 320 hours.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the collection of information provisions. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance is available on the Internet at *http://www.cfsan.fda.gov/guidance.html* and *http://www.fda.gov/cvm*.

Dated: November 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26049 Filed 11–19–04; 1:52 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0481]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry.'' This guidance document describes a means by which newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry may comply with the requirements of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry into class II (special controls). This guidance document is immediately in effect as the special control for newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidances are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol C. Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, ext. 144.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for newborn screening test systems for amino acids, free carnitine, and acylcarnitines that utilize tandem mass spectrometry. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving written notice classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1)