Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

0910-NEW

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 (the 1992 policy) (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 during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, FDA explained that, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), developers of new foods **(in this document food refers to both human food and animal feed)** have a responsibility to ensure that the foods they offer to consumers are safe and are in compliance with all requirements of the FD&C Act (57 FR 22984 at 22985). FDA has long regarded it to be a prudent practice for producers who use biotechnology in the manufacture or development of foods and food ingredients to work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements. Consequently, FDA instituted a voluntary consultation process with industry. The Guidance on Consultation Procedures: Food Derived From New Plant Varieties (originally published in 1996 and revised October 1997; the updated version is available on FDA's Web site at http://www.fda.gov/FoodGuidances) fosters communication by encouraging developers to submit to FDA their evaluation of the food safety of their new plant variety. Such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the FD&C Act.

FDA issued its 1992 policy statement and its guidance on consultation procedures under the broad statutory authority of the FDA to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled found in section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 393), as well as the authority found in the food additive provisions in sections 201(s) and 409 of the act (21 U.S.C. Sections 321(s) and 348) and in the adulterated food provisions in section 402(a)(1) of the act (21 U.S.C. Section 342(a)(1)).

We request OMB approval of the information collection provisions associated with consultations described in the 1992 policy statement and detailed in “Guidance on

Consultation Procedures: Foods Derived from New Plant Varieties" (1996 and revised 1997; the consultation procedures); and, Form FDA 3665.

2. Purpose and Use of the Information Collection

Under the consultation procedures, any person who is responsible for the development, distribution, importation, or sale of a food derived from a bioengineered plant variety may voluntarily consult with FDA and eventually submit summary safety and nutritional analysis which would form the basis of a biotechnology notification file (BNF). Based on the agency's experience, FDA expects that it ordinarily will be the seed developers and purveyors who notify the agency about such a bioengineered food.

Under the consultation procedures as described in the 1992 policy statement and the 1996 (1997) guidance that are the subject of this information collection request, a notifier submits a request for consultation to FDA through FDA's Center for Food Safety and Applied Nutrition (CFSAN). CFSAN receives the requests for final consultation and shares all BNF submissions with CVM. The two centers jointly review all notifications as a single review team. Thus, FDA has a single point of contact for industry. Depending on the plant and how it will be used as food for humans or animals, either CFSAN or the Center for Veterinary Medicine (CVM) may take a leadership role in the consultation. CVM reviews all notifications with animal feed uses. CFSAN reviews all notifications with human food uses. The majority of notifications have both food and feed uses. Files are established and records are maintained by CFSAN. At some stage after a consultation has been initiated, the developer submits a summary of its safety and nutritional assessment in support of its product (final consultation). After reviewing this submission, FDA may, as needed, request information to clarify particular points. When FDA has no further questions about the safety or regulatory status of the new plant variety, FDA sends a letter to that effect to the developer and the consultation is completed.

In FDA's experience, there has been a considerable interest, from a broad segment of the public, including members of the regulated industry, other federal, state, and local government agencies, international government agencies, and public interest groups, in BNFs evaluated under the policy. FDA has prepared a list of completed consultations (BNFs) and has made the text of the letter issued by the agency in response to each BNF and the text of the agency memo summarizing the completed evaluation of each BNF easily accessible to the public on FDA's Internet site (http://www.fda.gov/Food/Biotechnology/Submissions/default.htm).

Description of Respondents: Respondents to this collection of information include developers of new plant varieties intended for food use. Respondents are from the private sector (for-profit businesses, as well as not-for-profit institutions such as university and other U.S. government-supported researchers) and from the Federal Government.

3. Use of Improved Information Technology and Burden Reduction

Consultation submissions contain summaries of data and narrative text. FDA currently accepts this information electronically via the Electronic Submission Gateway (ESG) or electronic media (such as: CD ROM, DVD). The agency estimates that about fifty percent (50%) of the notifications will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

Many plants developed using 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. A developer's submission to APHIS includes information on the plant from which the food is derived, and details of the genetic changes to the plant. APHIS considers issues of agricultural and environmental safety during field trials, such as whether the crop could cause harm to plants or plant products, non-target organisms, or threatened and endangered species. After a period of research and development to gather safety data, a developer may request that APHIS grant "non-regulated" status to the genetically engineered plant, meaning that the agency has determined that the plant is as safe as similar conventionally bred varieties and as such will no longer be subject to APHIS oversight. In contrast, FDA's consultation procedure requests the submission only of data and information about food derived from the plant. FDA considers issues of food and feed safety, as well as any other food regulatory issues including labeling. Therefore, although a submission to APHIS would include some information that would be included under FDA's voluntary consultation procedures (e.g., the identity of the parent plant), the submission is not duplicative.

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. Thus, a plant bioengineered to contain a pesticide will also be reviewed by EPA. No person may sell or distribute a pesticide in the United States that is not registered, except under certain circumstances; EPA also has the authority to regulate unregistered pesticides, e.g., in field testing. EPA can establish conditions for use as part of the registration and for uses of unregistered pesticides. The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA; the act). Under the FFDCA, FDA has authority to regulate a non-pesticidal substance that may be introduced into a new plant variety and that is expected to become a component of food. Any food safety questions beyond those associated with the pesticide, such as those raised by unintended compositional changes, are under FDA's jurisdiction (57 FR 22984 at 23005). As such, FDA's consultation procedures apply to those non-pesticidal aspects of

bioengineered foods derived from a new plant variety modified to contain a pesticidal substance.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that five percent (5 %) of respondents are small businesses. The policy statement has been in place since 1992 and the food biotechnology industry has actively consulted with FDA since 1994. In 1996, FDA provided guidance to industry on procedures for these consultations. At least 25 companies and universities have completed over 80 biotechnology consultations with FDA. Most of these companies are multinationals with hundreds of millions of dollars in annual sales and do not meet the criteria for a small business. However, at least one of the companies that have consulted with FDA would meet the small entity definitions.

The consultation procedure minimizes the reporting burden on all businesses, including small businesses, by providing that the notifier submit a summary of data and information, rather than the data and information itself. There is no burden to the notifier for developing the data and information that underlie the BNF because they would have already generated such data and information to ensure that the bioengineered food is as safe as comparable food and is otherwise in compliance with all applicable requirements of the act. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The current voluntary consultation policy has been functioning since the 1992 policy statement. As discussed, over 80 consultations have been completed. If the information collection being considered here was not conducted, businesses would not have the opportunity to consult with FDA. It has been the experience of FDA that industry welcomes the opportunity to consult with FDA, especially if the process is transparent to public scrutiny, because the outcome of the consultation process will support their business interests by improving public and customer confidence in their product.

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

There are no special circumstances associated with this collection of information.

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

In the Federal Register of February 18, 2010 (75 FR 7274), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter, containing multiple comments, in response to the notice. One comment expressed strong support for the consultation procedures, generally.

(Comment 1) One comment noted with appreciation that Form FDA 3665 will provide a standardized format and an ability to provide electronic information.

(Response) FDA agrees. As discussed elsewhere in this document, the new form will prompt developers to submit to FDA certain information in a standard format. In addition, the form and attachments can be submitted in an electronic format. FDA believes that use of the form and electronic submission will facilitate both the preparation and review of the submission because it organizes the information necessary to support the safety of the food derived from the new plant variety. FDA also expects that use of the form will decrease the overall paperwork burden on respondents.

(Comment 2) Another comment noted that the use of the new form and electronic submission of data and information for FDA's use should assure the protection of proprietary data and information submitted to FDA.

(Response) The submission to FDA may contain trade secret and commercial confidential information. Only information that is releasable under 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act (21 U.S.C. 331(j)) and would be protected from disclosure under sections 552(a) and (b) of the Freedom of Information Act (5 U.S.C. 552(a) and (b)).

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA believes that, in most cases, neither the existence of a BNF, nor most or all of its content, would satisfy the criteria for exemption from disclosure. At this time, we do not proactively disclose evidence of a developer’s submission until after subject completes the consultation procedure. After the consultation is complete, we place on the FDA Internet site an electronic version of the agency response to the company and a memorandum summarizing the submission (http://www.fda.gov/Food/Biotechnology/Submissions/default.htm). Information submitted to FDA in a BNF may contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Form FDA 3665, its instructions, and related guidance, provide instructions for assisting FDA with protecting confidential information. A submitter may choose to provide a redacted copy of the submission, identifying that information that the submitter views as trade secret or as

confidential commercial or financial information. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: Respondents to this collection of information include developers of new plant varieties intended for food use. As noted above, in this document food refers to both human food and animal feed.

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

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

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Initial consultation	None	20	2	40	4	160
Final consultation	FDA 3665	12	1	12	150	1,800
Total						1,960

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

Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in its guidance to industry, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, firms developing a new bioengineered plant variety intended for food use have generally initiated consultation with FDA early in the process of developing such a variety, even though there is no legal obligation for such consultation. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the Agency in exercising their mutual responsibilities under the FD&C Act.

Generally, for an initial consultation, a developer requests a meeting by sending FDA a letter with an agenda. A mutually convenient time is arranged and the developer comes to discuss their product. In preparation for a meeting, a developer might prepare written materials or a slide presentation to discuss their product under development. A meeting between the developer and FDA typically lasts between 1 and 2 hours. As a result of such a meeting, FDA establishes a file called a biotechnology notification file, or BNF, to collect all documentation and communication regarding the bioengineered plant. For example, FDA typically places information such as the developer's letter, agenda, and any written materials (such as copies of a slide presentation) in a BNF, as well as any memorandum FDA prepares as a record of the meeting. FDA has not issued any recommendations as to the format for these types of materials (e.g., there is no form associated with requesting a meeting).

Depending on the introduced trait, the experience the developer has had with the kind of modification being considered, and their familiarity with the consultation procedures, a developer might choose to do a final consultation without an initial consultation.

FDA estimates that CVM and CFSAN jointly received, on average, 40 initial consultations per year in the last three years via telephone, e-mail or written letter. Based on this information, we expect to receive no more than 40 annually in the next three years, as shown in Table 1.

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 FD&C 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. FDA has recently developed a form that prompts a developer to include certain elements in the final consultation in a standard format. New Form FDA 3665 is entitled "Final Consultation for Food Derived From a New Plant Variety (Biotechnology Final Consultation)." The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format.

The summary information of the safety and nutritional assessment for a new plant variety submitted to FDA (on the form and in attachments to the form) 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 5 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 estimated that the average time to prepare a submission for final consultation under the 1996 procedures is 150 hours (69 FR 68381, November 24, 2004). The availability of FDA Form 3665, and the opportunity to provide the information in electronic format, could reduce this estimate. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the form and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission for final consultation under the 1996 procedures.

Jointly, CVM and CFSAN received 2 final consultations in 2008, 7 final consultations in 2009, and 4 final consultations in 2010. Based on this information, we expect to receive no more than 12 annually in the next three years, as shown in Table 1.

As requested in part III of Form 3665, section 5, this submission may incorporate by reference information from a previous submission to FDA (biotechnology notification file (BNF), new protein consultation (NPC), generally recognized as safe (GRAS) notice,

GRAS affirmation petition, food additive petition, and food master file). These collections of information have been approved by OMB under the following control numbers: new protein consultations are approved under OMB Control No. 0910-0583; GRAS notices and affirmation petitions are approved under OMB Control No. 0910-0342; and, food additive petitions and food master files are approved under OMB Control No. 0910-0016.

12b. Annualized Cost Burden Estimate

Gathering the information discussed here and providing it to the agency may be done by a professional employee such as a scientist. FDA estimates that the average hourly wage for this employee would be equivalent to a GS-14/Step-1 level in the locality pay area of Washington-Baltimore in 2011, approximately $50.41/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $100.82/hour. The overall estimated cost incurred by the respondents is $197,607.20 (1,960 burden hours x $100.82/hr = $197,607.20). In addition, while FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure (PKI) certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20-$30.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA estimates that CFSAN directs approximately four (4) full time equivalent positions (FTEs) to the notification procedure for human foods. CFSAN usually has the lead on BNFs, and thus assigns more reviewers and devotes more resources to developing the agency's record of the consultation than CVM. FDA estimates that CVM will direct two (2) FTEs to processing the notification procedure for animal foods. Based on an average cost of $110,000 per fully supported position, the cost of processing consultations would be $660,000 per year.

15. Explanation for Program Changes or Adjustments

This is an existing collection without an OMB control number, thus a change due to a violation. The estimated reporting burdens reflect our estimate of the number of BNF submissions the agency expects to receive annually over the next three years.

16. Plans for Tabulation and Publication and Project Time Schedule

No statistics from the information obtained from this data collection will be published. However, as noted above in Section 10, we do not proactively disclose evidence of a developer's submission until after subject completes the consultation procedure. After the consultation is complete, we place on the FDA Internet site an electronic version of the agency response to the company and a memorandum summarizing the submission.

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

There are no exceptions to the certification.