Threshold of Regulation Policy for Food-Contact Articles

OMB Control No. 0910-0298

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the act, (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA requests the extension of OMB approval of the information collection requirements in the following citation:

21 CFR 170.39 - Reporting

Specifies criteria that must be met to obtain an exemption from the food additive petition process for food-contact articles.

2. Purpose and Use of the Information Collection

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Requests for exemptions from the food additive listing regulation requirement are letter-type submissions from manufacturers of food packaging and food processing equipment. These submissions are reviewed by FDA personnel to ascertain if the substance(s) is adequately identified and if the proposed use meets the criteria specified in 21 CFR 170.39 for an exemption. If the data are sufficient to support an exemption under 21 CFR 170.39, the agency informs the requestor by letter that the intended use of the substance in a food-contact article is not required to be the subject of a food additive listing regulation or a food contact notification.

Description of Respondents: Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The agency is not equipped to receive these submissions electronically at this time. Therefore, this information collection will not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. FDA is working diligently to develop the necessary technology infrastructure to enable it to accept these submissions electronically in the future. The agency has made progress toward completion of a Public Key Infrastructure (PKI) capable system that we expect to enable us to accept these submissions electronically. Accordingly, FDA has carefully evaluated the nature and regulatory significance of the submission, in particular the significant legal consequences attendant to the signing and submitting of the request for exemption, and request that the agency be authorized to continue this information collection activity in non-electronic format.

The request for exemption must be signed by a responsible person, and in signing the request, that person is certifying that the information in it is accurate. The request for exemption carries legal implications for the firm and the signatory. Therefore, these documents carry significant risk of repudiation. For this reason, FDA believes that the significant legal consequences attendant to the signature warrant a level of authentication and signer non-repudiation that only digital signatures in a PKI model can currently provide. Because CFSAN lacks that model, but is working with other FDA units toward putting it in place, the agency believes that other forms of electronic submission that the agency might be able to accept present unacceptable risks that provide a basis to not accept these submissions electronically until an acceptable infrastructure is in place. FDA estimates that none of the respondents (0%) will use electronic means to submit the required information.

4. Efforts to Identify Duplication and Use of Similar Information

A critical element in FDA's Threshold of Regulation Policy is that the use of a substance exempted by the agency is not limited to only the manufacturer who submitted the request for an

exemption. Other manufacturers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and is also available on the Internet at http://www.cfsan.fda.gov. A list of exempted substances can also be obtained by contacting FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740. This list includes the name of the company that made the request, the chemical name of the exempted substance, and the specific use for which it has been exempted, as well as any appropriate limitations. Having the list of exempted substances publicly available also decreases the likelihood that a company would submit a food additive petition or a food contact substance notification for the use of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

To avoid unnecessary duplication, existing data are used whenever possible by FDA in evaluating requests for exemption of components of food-contact articles under 21 CFR 170.39. This includes data in FDA files as well as data available in the scientific literature. For example, existing data in FDA files on the migration of components of food-contact articles into food or food simulating solvents can often be used to predict the level of migration resulting from similar uses of other components of food-contact articles. However, because the extent of migration of a component of a food-contact article into food depends on a number of factors (e.g., the chemical nature of the substance, the temperature of use, the type of food contacted, the length of time in contact with food, the amount of food contacted over the lifetime of a repeat-use article), and because substances used in the manufacture of food-contact articles possess a wide range of chemical and physical properties and are used under a variety of conditions, additional information is often needed to determine whether a particular use of a specific substance results in a dietary concentration that is below the "threshold of regulation."

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately ten percent (10%) of the respondents are small businesses. FDA's threshold of regulation process minimizes the burden on all businesses by providing a procedure that is less burdensome than the current food additive petition process. Because agency reviews made under this process require significantly less resources than petition reviews, decisions authorizing the marketing of a product are issued relatively quickly (i.e., within 4- 5 months as opposed to the 1-4 years required for the review of a petition and the issuance of a regulation). As a result, components of food-contact articles that are found to be exempt from the food additive listing regulation requirement can be marketed sooner than those authorized by the petition process. Because the types of information needed for approval under the premarket notification process for those uses of food-contact articles involving dietary concentrations of 0.5 ppb or less is identical to that required under 21 CFR 170.39, the burden on industry for the preparation of a premarket notification would be similar to the burden for the preparation of a request submitted under the existing threshold of regulation process.

The agency has established the types of data necessary to demonstrate that the use of a component of a food-contact article meets the criteria for an exemption under 21 CFR 170.39. However, the agency does not have the resources to generate the data needed to support a request for an exemption under this policy. Whenever possible, assistance will be given to requestors to minimize the likelihood that unnecessary work is performed. FDA aids small businesses in dealing with the requirements through the Division of Education and Communication in the Center for Food Safety and Applied Nutrition (CFSAN) and through the scientific and administrative staffs of the agency.

Whenever possible, to reduce the burden on all businesses, FDA will provide assistance to requestors to minimize the likelihood that unnecessary work is performed. CFSAN's Division of Education and Communication will also aid small businesses in dealing with the submission requirements specified in 21 CFR 170.39. It should be emphasized that the Threshold of Regulation Policy itself is, in part, a response to representatives of the food packaging and processing industries who have proposed, both informally and formally (Petition submitted by the Society of Plastics Industries; Docket No. 77-0122) that FDA establish a Threshold of Regulation Policy for food-contact articles.

6. Consequences of Collecting the Information Less Frequently

Respondents will submit the required information on an occasional basis, as required by 21 CFR 170.39. Any restriction of the right to require certain types of data for requests submitted under this policy would significantly decrease the number of food contact substances exempted from the requirement that they be the subject of food additive petitions or food contact substance notifications. Exemptions would be restricted to those situations which involve substances which are generally recognized as safe (GRAS) substances whose use was sanctioned prior to January 1, 1958, and substances approved for investigational use under section 409(j) of the act. All other components of food-contact articles whose use results in or which may reasonably be expected to result in migration into food, even in trivial amounts, would require premarket approval via the food additive petition process or the notification process.

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 accordance with 5 CFR 1320.8(d), in the Federal Register of April 9, 2010 (75 FR 18209), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

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

Requests for exemptions of components of food-contact articles from the food additive listing regulation requirement often contain trade secret and commercial confidential information. Only information that is releasable under the agency's regulations (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)).

A list of substances exempted under 21 CFR 170.39 is placed on display at the Division of Dockets Management and is also available on the Internet at http://www.cfsan.fda.gov. This list includes the name of the company that made the request, the chemical name of the exempted substance and the specific use for which it has been exempted, as well as any appropriate limitations. It does not include any trade names or other confidential information. The agency's finding of no significant environmental impact and the evidence supporting that finding, contained in an environmental assessment, are also available for public inspection at the Division of Dockets Management.

11. Justification for Sensitive Questions

There are no questions of a personally sensitive nature in the data requirements for requests for

exemptions under the FDA's Threshold of Regulation Policy.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

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

Table 1: Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	7	1	7	48	336

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

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past 3 years. The annual hours per response reporting estimate is based on information received from representatives of the food packaging and processing industries and agency records.

FDA estimates that approximately 7 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910-0495) in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at http://www.cfsan.fda.gov. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

12 b. Annualized Cost Burden Estimate

Based on information provided to FDA, the annualized cost for the collection of information and preparation of a simple request for review under the proposed Threshold of Regulation Policy would range from $5,000-$25,000 depending on the complexity of the project. If analytical studies are required to show that the dietary exposure resulting from the proposed use is below the threshold of regulation, FDA estimates that the additional cost would vary from $10,000 to $75,000 depending on the complexity of the project (i.e., the number of substances and food simulating solvents involved, the method of analysis). Based on these estimates, the total cost to the respondent to submit requests under FDA's Threshold of Regulation Policy would vary from $5,000-$100,000.

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 it will receive an average of 7 requests per year for review under the Threshold of Regulation Policy. An abbreviated review of the chemistry, toxicology and environmental impact information requires an average 25 hours to review.

FDA estimates the hourly cost for review to be $46.93 per hour, the GS-13/Step-4 rate for the Washington-Baltimore locality pay area for the year 2010. To account for overhead, this cost is increased by 100 percent, making the total cost $93.86 per hour. FDA estimates the cost to the Federal Government for the review of records to be $2,346.50 per review ($93.86/hour x 25 hours). Thus, FDA estimates that the annual cost to the Federal Government would be $16,425.50 ($2,346.50 x 7 requests).

15. Explanation for Program Changes or Adjustments

The decrease in burden is due to the decrease in the estimated number of respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency does not publish information from this information collection other than, as noted above, by making available a list of substances exempted under 21 CFR 170.39 at the Division of Dockets Management and on the Internet at http://www.cfsan.fda.gov. This list includes the name of the company that made the request, the chemical name of the exempted substance and the specific use for which it has been exempted, as well as any appropriate limitations. It does not include any trade names or other confidential information. The agency's finding of no significant environmental impact and the evidence supporting that finding, contained in an environmental assessment, are also available for public inspection at the Division of Dockets Management.

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.