SUPPORTING STATEMENT

THRESHOLD OF REGULATION POLICY FOR FOOD-CONTACT ARTICLES

OMB No. 0910-0298

A. JUSTIFICATION

1. Need and Legal Basis

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) (Attachment 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) (Attachment B) 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 extension of OMB's 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. Information Users

FDA uses this information to determine whether a 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.

3. Improved Information Technology

In a **Federal Register** notice of August 31, 1994 (59 FR 45160), FDA proposed regulations that would, under certain circumstances, permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These proposed regulations would apply to threshold of regulation exemption requests submitted under 21 CFR 170.39.

The agency currently has a working local area network (LAN) and optical scanning system in operation. Current paper files are optically scanned and placed on the LAN. This is a preliminary step that will complement the long-range goal of electronic submission of threshold of regulation exemption requests. Guidance for electronic submission of food and color additive petitions as well as food contact notifications are currently being prepared. Submitters of threshold of regulation exemption requests will be able to use these guidance documents to help them submit exemption requests electronically.

The availability of computerized indexing services such as Med-Line and Tox-line permits requestors to search the scientific literature to determine if a component of a food-contact article has been the subject of an animal carcinogen bioassay. These data bases can also be used to determine whether any significant impurities present in the component of the food-contact article have been shown to be carcinogens in humans or animals and whether their TD_{50} values (i.e., the feeding dose that causes cancer in 50 percent of the test animals when corrected for tumors found in control animals) are below 6.25 mg/kg bodyweight/day. FDA has also instituted a computerized indexing system (SIREN: Scientific Information Retrieval and Exchange Network) to permit FDA personnel to easily locate data previously submitted to the agency.

4. Duplication 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. 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. Less Frequent Collection

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

The submission of requests under FDA's Threshold of Regulation Policy is voluntary. Any manufacturer or supplier who submits a request would do so only one time for the specific use of a substance in a food-contact article. Additional submissions would be needed only if the requestor seeks to obtain an additional exemption for the use of the same substance under significantly different conditions. These additional submissions would be needed because the extent of migration of a component of a food-contact article into food can vary significantly depending on the conditions of use (i.e., 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).

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), in the Federal Register of January 8, 2007 (72 FR 792), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

9. Payment/Gift to Respondent

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

10. Confidentiality

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. Sensitive Questions

There are no questions of a sensitive nature in the data requirements for requests for exemptions under the FDA's Threshold of Regulation Policy.

12. Burden Estimate (Total Hours and Wages)

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	15	1	15	48	720

[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 15 requests per year will be submitted under the threshold of regulation exemption process of § 170.39. 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.

Costs to Respondents. 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. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

FDA estimates that it will receive an average of 15 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.

Based on an average cost of $188,000 annually per fully supported position ($90/hr), the cost of processing a request under the Threshold of Regulation Policy would be $2,250 ($90/hr x 25 hrs = $2,250). Therefore, the annualized cost to the federal government is estimated to be $33,750 (i.e., $2,250/request x 15 requests = $33,750)

15. Program or Burden Changes

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

16. Publication and Tabulation Dates

The agency has no plans for publication of information from this information collection.

17. Display of OMB Approval Date

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