GUIDANCE DOCUMENT

Guidance for Industry: Submitting Requests under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food-Contact Articles

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Center for Food Safety and Applied Nutrition

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For questions regarding the use or interpretation of this guidance, or to obtain printed copies of this document, contact the Office of Food Additive Safety at premarkt@fda.hhs.gov (mailto:premarkt@fda.hhs.gov).

Introduction

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

Listed below is guidance for submitting a request to FDA for consideration under the threshold of regulation process established by 21 CFR 170.39 (Final rule published on July 17, 1995; 60 FR 36582). Requests should be limited to only those substances used in food-packaging or food processing equipment that are not designed to have a technical effect on the food itself.

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Procedures

Four copies of the request should be submitted. The request should contain the following information:

1. The chemical composition of the substance for which the request is made,including,whenever possible, the name of the chemical in accordance with current Chemical Abstract Service (CAS), https://www.cas.org/, nomenclature guidelines and a CAS Registry Number, if available [1];
2. The intended technical effect of the substance in the food-contact article (e.g., stabilizer, catalyst, defoamer);
3. Detailed information on the conditions of use of the substance (e.g., temperature, type of food with which the substance will come into contact, the duration of the contact, and whether the food-contact article will be for repeated or single use applications);
4. A clear statement as to whether the request for exemption from regulation as a food additive is based on the fact that the use of the substance in the food-contact article results in a dietary concentration at or below 0.5 ppb, or on the fact that it involves the use of a regulated direct food additive for which the dietary exposure is at or below 1 percent of the acceptable dietary intake (ADI);
5. Data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, except in those cases where FDA has historically not requested such data. (For example, FDA has not asked for such data when the substance is an alloy that is resistant to corrosion and abrasion. Instead, the agency has requested information on the properties of the alloy (e.g., hardness) that enable it to resist corrosion and abrasion. However, if the alloy is relatively soft, or contains active metals, or there is reason to suspect the presence of heavy metal contaminants (e.g., Pb, Cd, and Hg), the requestor should consult FDA for specific advice on the types of information that will be required.)
    a. These data should be either in the form of:
        i. Validated migration data obtained under worst-case (time/temperature) intended use conditions utilizing appropriate food simulating solvents as discussed in "Recommendations for Chemistry Data for Indirect Food Additive Petitions" or
        ii. Level of the substance used in the manufacture of the food contact article or the residual level of the substance present in the finished food-contact article. These data should be used to estimate a worst-case dietary concentration level assuming 100% migration to food. The agency recognizes that there may be cases in which mitigating circumstances make it highly unlikely that all of the substance would migrate to food. In such cases, submissions should include a

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detailed discussion of any factors that are likely to significantly decrease the extent of migration of the substance to food.

b. The submission should also include a detailed description of the analytical method used to quantify the substance along with data used to validate the method. In cases where there is no detectable migration into food or food simulants, or when no residual level of a substance is detected in the food-contact article by a suitable analytical method, the validated detection limit of the method used to analyze for the substance should be considered in estimating the dietary concentration. Submissions, in such cases, should include the data used to validate the method's detection limit.

c. For repeat-use articles, the submission should include an estimate of the amount of food that contacts a specific unit of surface area over the lifetime of the article.

d. A detailed discussion of how to estimate the dietary concentration resulting from the intended use of a substance in a food-contact article can be found in "Recommendations for Chemistry Data for Indirect Food Additive Petitions". Interested persons are also encouraged to obtain specific guidance from FDA's Office of Food Additive Safety (HFS-200), 5001 Campus Drive, College Park, MD 20744) on the appropriate protocols to be used for obtaining migration data, on the validation of the analytical methods used to quantify migration levels, on the procedures used to relate migration data to dietary exposures, and on any other issue not specifically covered in these guidelines, (see Exemptions for Houseware Articles)

6. The results of a literature search of existing toxicological information on the substance and its impurities. This information is needed to determine whether an animal carcinogen bioassay has been carried out, or whether there is some other basis for suspecting that the substance is a carcinogen or potent toxin. This information on the impurities is needed to determine whether any of them are carcinogenic and, if carcinogenic, whether their TD50 values are greater than 6.25 mg/kg bodyweight per day, in accordance with § 170.39(a)(1).

7. TOR submissions are agency actions that are subject to NEPA. Therefore, a TOR submission must contain either a claim of categorical exclusion, as specified under 21 CFR 25.15, or an environmental assessment (EA) as specified under 21 CFR 25.15 and 40.

    1. Claims of categorical exclusions that may apply to TOR submissions are 21 CFR 25.32(i), (j), or (q).

        - To qualify for an exclusion under 21 CFR 25.32(i), the substance must be present in the finished food-contact article at not greater that 5 percent-by-weight and must be expected to remain with the finished food-contact article through use by consumers or when the substance is a component of a coating of a finished food-packaging material

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- To qualify for an exclusion exemption under 21 CFR 25.32(j), the substance must be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.
- To qualify for an exclusion under 21 CFR 25.32(q), the substance must be registered by the Environmental Protection Agency under FIFRA for the same use as requested in the request for exemption.
- An adequate claim of categorical exclusion submitted under 21 CFR 25.15 should:
    - Cite the section of the CFR under which the categorical exclusion is claimed,
    - Include a statement of compliance with the categorical exclusion criteria, and
    - Include a statement that, to the submitter's knowledge, no extraordinary circumstances exist that require the submission of an EA.

2. If the TOR submission does not qualify for categorical exclusion, then it must contain an EA. The EA should include information that will enable FDA to determine whether to prepare a finding of no significant impact or an environmental impact statement.

   Guidance on how to prepare a claim of categorical exclusion or an environmental assessment is found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan). You can also find examples of extraordinary circumstances on that site.

Exemptions for Houseware Articles

In the past, FDA typically has not required food additive petitions containing the data described in item 5 above for food-contact articles used exclusively in the home or in restaurants. Although components of houseware articles that are reasonably expected to become components of food are food additives subject to premarket approval, in most cases, the use of such articles results in trivial levels of migration to food either because of short contact times or because the articles are manufactured using materials (e.g., alloys and ceramics) that pose little likelihood of migration to food. Therefore, the agency, because of limited resources, has not enforced the food additive provisions of the FD&C Act for such cases unless there is evidence of a potential health hazard. However, FDA cannot issue a binding "exemption from regulation" under 21 CFR 170.39 for houseware articles in the absence of information to show that the use of

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such articles would result in, or would reasonably be expected to result in, dietary concentrations below the "threshold". FDA is particularly concerned with single-service houseware articles that contain components that have the potential for migrating to food in significant amounts (i.e., would result in dietary concentrations above the threshold of regulatory concern). Therefore, the data described in item 5 above will also be required for any submission requesting an exemption for the use of a substance in a single-service houseware article. For repeat-use articles, the submission may need to include an estimate of the amount of food that contacts a specific unit of surface area over the lifetime of the article. The requestor should consult FDA as to whether such data will be needed for a specific repeat-use houseware article.

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[1] If the chemical formulation that is the subject of the exemption request involves a chemical(s) that is purchased from a manufacturer that considers its identity as trade secret, the requestor will need to contact the supplier(s) and have them send the applicable identity information (compositional information if this chemical is itself part of a chemical formulation) directly to FDA. If FDA determines that one or more components of the supplier's formulation is not regulated for the intended conditions of use, FDA will contact that supplier(s) and inform him of that fact. FDA would also inform the supplier that if the request qualifies for an exemption under 21 CFR 170.39, the identity of those chemical(s) that are the subject of the exemption (as well as appropriate limitations (e.g., use level)) would be put on public display at FDA's Docket Management Branch. (It would be emphasized that the identity of only those chemicals that are the subject of the exemption would be made publicly available. The remaining chemicals and composition of the formulation (i.e., weight percent of each chemical) would not be released to the public.) For FDA to proceed with its review of the exemption request, the supplier would need to agree that this identity information could be released in the event that these substances qualified for an exemption. If this potential release of information is acceptable, the supplier working in conjunction with the requestor would need to provide all of the information on these substances needed by FDA to complete its review.

If the supplier does not agree that the identity of the substance(s) can be released in the event that an exemption is issued by FDA, the requestor would be informed by FDA that this part of the request cannot be processed and the applicable chemical(s) would have to be either be eliminated from the formulation or replaced with chemicals that meet the regulations for the intended conditions of use or can be purchased from suppliers who do not regard their identities as trade secret.

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This document updates and supercedes the 1996 version of the Guidance for Submitting Requests Under 21 CFR 170.39 Threshold of Regulations for Substances Used in Food-Contact Articles.

Related Information

- Ingredients, Additives, GRAS & Packaging Guidance Documents & Regulatory Information (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/ingredients-additives-gras-packaging-guidance-documents-regulatory-information)

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You can submit online or written comments on any guidance at any time (see 21 CFR 10.115(g)(5))

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All written comments should be identified with this document's docket number: FDA-2013-N-0730 (https://www.regulations.gov/docket/FDA-2013-N-0730).

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