Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

Contains Nonbinding Recommendations

May 2006

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
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See Additional PRA statement in Section IV of this guidance

Contains Nonbinding Recommendations

Guidance for Industry
Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

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This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternative approach, please contact the FDA staff responsible for implementing this guidance. If you cannot

identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The National Environmental Policy Act of 1969 (NEPA) requires each Federal agency to assess, as an integral part of its decisionmaking process, the environmental impacts of its actions and to ensure that the interested and affected public is informed of environmental analyses. FDA's regulations in part 25 (21 CFR part 25) set forth procedures to supplement the regulations of the Council on Environmental Quality (CEQ) under 40 CFR parts 1500-1508. The agency amended part 25 on July 29, 1997 (62 FR 40570) (hereinafter "the 1997 final rule") to increase the efficiency of FDA's implementation of NEPA and to reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant affect on the human environment and for which, therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. Section 25.20 specifies the types of actions that ordinarily require at least the preparation of an environmental assessment. Such actions include approval of food additive petitions and color additive petitions, granting of requests for exemption from regulation as a food additive under §170.39 (21 CFR 170.39), allowing notifications for food contact substances submitted under section 409 (h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 348 (h)) to become effective, affirmation of a food substance as Generally Recognized as Safe (GRAS), and establishment by regulation of food labeling requirements, unless the action qualifies for a categorical exclusion under § 25.30 or § 25.32. Interested parties may request agency actions by submitting to the agency any of the petitions, requests for exemption, or notifications listed here. These requests for action will be collectively referred to in this document as "submissions" and the parties making the submissions as the "submitters."

This guidance is intended to assist submitters by offering suggestions for information that may be included in categorical exclusion and EA submissions. The guidance refers to some of the requirements in part 25 in addition to suggesting types of information that would be helpful to the agency's review of submissions. The following topics are included: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion; (2) What must a claim of categorical exclusion include by regulation; (3) What is an EA; (4) When is an EA required by regulation and what format should be used; (5) What are extraordinary circumstances; and (6) What suggestions does CFSAN have for preparing an EA? If a proposed action is not covered in this document, a submitter may contact CFSAN for guidance on how to assess the potential environmental effects.

Under § 25.15(a), all submissions requesting agency action must be accompanied by either a claim of categorical exclusion or an adequate EA. An adequate EA is one that addresses the relevant environmental issues and contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment. For actions that may significantly affect the quality of the human environment, the agency must prepare an environmental impact statement (EIS) in accordance with § 25.22.

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

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II. Categorically Excluded Actions

A category of actions that has been found not to individually or cumulatively have a significant effect on the human environment is subject to a categorical exclusion and, therefore, ordinarily does not require the preparation of an EA or an EIS. However, as required under 21 CFR 25.21 and 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment. See **Section III.C** for additional information regarding extraordinary circumstances. The categorical exclusions that apply to CFSAN actions are listed in §§ 25.30 and 25.32.

A. What types of industry-initiated actions are subject to a claim of categorical exclusion?

The following claims of categorical exclusions in §§ 25.30 and 25.32 apply to industry requests for CFSAN actions including approval of food additive petitions and color additive petitions, requests for exemption, allowing a food contact substance (FCS) notification to become effective, affirmation of GRAS status, and petitions for certain food labeling regulations:

1. Corrections and technical changes in regulations (§ 25.30(i));
2. Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes (§ 25.30(k));
3. Issuance, amendment, or repeal of a food standard (§ 25.32(a));
4. Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics (§ 25.32(c));
5. Affirmation of a food substance as GRAS for humans or animals on FDA's initiative or in response to a petition under 21 CFR parts 182, 184, 186, or 582, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in 21 CFR 170.3(1) and 181.5(a), if the substance or food ingredient is marketed already in the United States for the proposed use (§ 25.32 (f));
6. Approval of a food additive petition, GRAS affirmation petition, the granting of a request for exemption, or allowing a notification to become effective, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material (§25.32(i));
7. Approval of a food additive petition, GRAS affirmation petition, the granting of a request for exemption, or allowing a notification to become effective, when the substance is to be used as a component of a food-contact surface of permanent or semi-permanent equipment or of another food-contact article intended for repeated use (§ 25.32(j));
8. Approval of a food additive, color additive, or GRAS affirmation petition, or allowing a notification to become effective, for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food (§ 25.32(k));
9. Approval of a petition for color additives used in contact lenses, sutures, filaments used as supporting haptics in intraocular lenses, bone cement, and in other FDA-regulated products having similarly low levels of use (§ 25.32(l));
10. Approval of a food additive petition for the intended expression product(s) present in food derived from new plant varieties (§ 25.32(o));
11. Approval of a food additive petition, the granting of a request for exemption, or allowing a notification to become effective, for a substance registered by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for the same use requested in the petition (§ 25.32 (q));
12. Approval of a food additive, color additive, or GRAS affirmation petition, or allowing a notification to become effective, for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment (§ 25.32(r)). [(1)]
13. Issuance, amendment, or revocation of a regulation in response to a reference amount citizen petition as described in 21 CFR 101.12(h), a nutrient content claim petition as described in 21 CFR 101.69, or a health claim petition as described in 21 CFR 101.70 (§ 25.32(p)). [(2)]

A submitter need only submit a claim for one categorical exclusion, even though more than one exclusion may apply for a particular action.

B. What must a claim of categorical exclusion include by regulation?

If a submitter elects to request a categorical exclusion for a proposed action, a claim of categorical exclusion must be submitted, as required by § 25.15. Section 25.15 requires that the claim of categorical exclusion (1) cite the section of the CFR under which the categorical exclusion is claimed, (2) include a statement of compliance with the categorical exclusion criteria, and (3) include a statement that, to the submitter's knowledge, no extraordinary circumstances exist that require submission of an EA.

The FDA has formulated its categorical exclusions to include specific criteria so that in most instances a categorical exclusion can either be easily determined or confirmed by review of other information submitted as part of the request for action. This approach is consistent with CEQ's view in that the information submitted in a request for categorical exclusion is usually sufficient. In the limited instances when it may be necessary, CFSAN may request additional information to establish to the agency's satisfaction that the criteria for a categorical exclusion have been met, particularly for exclusions claimed under § 25.32(i), § 25.32(o), and § 25.32(q). Such information may assist CFSAN in determining whether an exclusion applies, as discussed below.

Submissions for substances that are present in finished food-packaging material at not greater than 5 percent-by-weight and are expected to remain with finished food-packaging material through use by consumers are excluded under § 25.32(i). When claiming this categorical exclusion, the agency anticipates that simply stating that the claim applies would be sufficient for substances that remain with, and function in, finished food-packaging materials. For substances that have no function in finished food-packaging materials, *i.e.*, processing aids, but that do become incorporated into packaging and remain with the finished packaging through use by consumers, FDA recommends that you provide an estimate of the percentage of the amount of the substance used that is incorporated into packaging. [3] The exclusion may apply when 1) the processing aid is present in finished food packaging at no greater than 5 percent-by-weight; 2) the processing aid is expected to remain with finished food-packaging material through use by consumers; and 3) the percentage of the processing aid that is incorporated into the finished food-packaging material is high, *e.g.*, > 95%.

The exclusion under § 25.32(o) applies to an action to approve a food additive petition for the intended expression product(s) present in food derived from new plant varieties. As discussed in the preamble to the proposed rule to amend part 25 (61 FR 19476 at 19483, May 1, 1996), the FDA established this exclusion based on the determination that the United States Department of Agriculture (USDA), under the authority of the Federal Plant Pest Act, addresses the potential of new plant varieties to pose a plant pest risk in accordance with NEPA. FDA recommends that you provide in the claim of categorical exclusion for actions in this class the status of USDA's review under the Federal Plant Pest Act. If the USDA has made a determination of nonregulated status for an organism that has been subject to USDA oversight because it was considered to present a potential risk of being a plant pest, the claim of categorical exclusion should cite the Federal Register notice for that determination.

The exclusion under § 25.32(q) applies to an action that involves a substance registered by the EPA under FIFRA for the same use requested in the submission to FDA. The preamble to the 1997 final rule provides guidance for applying this exclusion (62 *FR* 40570 at 40582-83). The phrase "same use" means that, when comparing the food additive use to the pesticide use, the purpose of the use, any components used with the substance for the requested use, and the amount of the substance and the amounts of any components used with it are substantially identical. For this class of actions, the agency recommends that submitters include in any claim of categorical exclusion 1) a copy of the current FIFRA registration label for the substance that has the same use requested in the submission, and 2) a copy of the proposed FIFRA registration label that includes the FDA-regulated non-pesticide use of the substance for which the sponsor intends to request an amendment from EPA after FDA approval.

Submitters are encouraged to contact CFSAN for questions about whether a categorical exclusion may apply to a particular action.

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III. Preparing an Environmental Assessment (EA)

A. What is an EA?

As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for determining whether to prepare an EIS or a Finding of No Significant Impact (FONSI). The EA must include brief discussions of the need for the proposed action, the alternatives as required by section 102(2)(E) of NEPA, the environmental impacts of the proposed action and its alternatives, and a list of agencies and persons consulted (40 CFR 1508.9 and 21 CFR 25.40). The EA must focus on environmental issues relating to the use and disposal from use of FDA-regulated substances and be a concise, objective, and well-balanced document that allows the public to understand the basis for the

agency's decision to prepare an EIS (§§ 25.22 and 25.42) or a FONSI (§ 25.41). If potentially adverse environmental impacts are identified for an action or group of related actions, the EA must discuss any reasonable alternative courses of action that offer less environmental risk or that are environmentally preferable to the proposed action (§ 25.40(a)).

Before FDA amended part 25, the regulations provided standard EA formats for various classes of actions. After consulting CEQ, FDA decided that sample formats for preparing EAs should be provided in guidance documents rather than in the amended rule. Because guidance documents, which do not bind the agency or the public, are more easily revised, their use will give FDA greater flexibility to tailor environmental documents to reflect state-of-the-art developments in environmental analysis and will assist submitters in focusing on important environmental issues. Actions requiring an EA are specified in Section B below, and the recommended formats for these actions are provided in Appendices A-D of this document.

B. When is an EA required by regulation and what format should be used?

Suggested EA formats are provided for the following substances that are the subject of a submission to the agency and that are not otherwise subject to a categorical exclusion in § 25.30 or § 25.32:

1. Substances added directly to food that are intended to remain in food through ingestion by consumers, that are intended to replace macronutrients in food, and that do not qualify for exclusion under § 25.32(r) (see EA format in Appendix A). [(4)]
2. Secondary direct food additives and food contact substances used in the production of food that are not intended to remain with food and that do not qualify for exclusion under § 25.32(j), (q), or (r) (see EA format in Appendix B). [(5)]
3. Processing aids used in producing food-packaging materials that are not intended to remain as components of finished food-packaging material and that do not qualify for categorical exclusion under § 25.32(i), (q), or (r) (see EA format in Appendix C). [(6)]
4. Components of finished food-packaging material present at greater than 5 percent-by-weight except for components of a coating of a finished food-packaging material (see EA format in Appendix D). [(7)] (Appendix D is still under development and will be issued at a later date. In the interim, we recommend that you contact the Office of Food Additive Safety for assistance in submitting the necessary information.)

C. What are extraordinary circumstances?

In accordance with 40 CFR 1508.4 and 21 CFR 25.21, FDA will require at least an EA for any normally excluded action if extraordinary circumstances indicate that the proposed action may have a significant environmental affect. An extraordinary circumstance may be shown by data available to either the agency or industry sponsor and may be based on production, use, or disposal from use of a substance. Data available to the agency include public information, information in the submission, and information the agency has received in other submissions for the same or similar substances. **(Return to Section II)**

The CEQ has defined "significantly" to aid in determining if an action may affect significantly the quality of the human environment. This definition should be considered when evaluating whether extraordinary circumstances exist that may warrant the submission of at least an EA (see Appendix E). Examples of extraordinary circumstances that may apply to CFSAN actions include, but are not limited to, the following:

1. Actions for which existing data establish that, at the expected level of exposure, there is the potential for serious harm to the environment (§ 25.21(a));
2. Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law (§ 25.21(b));
3. Actions that threaten a violation of Federal, State, or local law or requirements imposed for the protection of the environment (40 CFR 1508.27(b)(10));
4. Unique emission circumstances that are not addressed adequately by general or specific emission requirements (including occupational) promulgated by Federal,

State or local environmental agencies and the emissions may harm the environment;

5. Actions that may have significant effects on solid waste management, *e.g.*, source reduction, recycling, composting, incineration, and landfilling; and
6. Actions involving substances derived from a plant or animal that could affect the sustainability of the source organism or the surrounding ecosystem, *e.g.*, potentially significant effects on resources resulting from changes in agricultural practices for a cultivated crop, such as changes in water, energy, agrochemical or land use; or significant effects resulting from the harvesting of wild specimens.

If FDA determines that extraordinary circumstances apply to a proposed action that would otherwise be subject to a categorical exclusion, the agency will provide the submitter with guidance on what information that the agency recommends be included in an EA.

D. What suggestions does CFSAN have for preparing an EA?

1. Consult CFSAN early in the process to determine the EA format best suited for your proposed action and to discuss the nature and extent of information that may be necessary. It is particularly important to consult CFSAN before conducting any environmental tests to determine if testing should be considered and, if so, what tests to consider. In many cases, existing information can be used to establish the environmental record to support the proposed action.
2. When environmental tests are done, the use of test-sequencing procedures, called tiered testing, is recommended (§ 25.40(a)). FDA recommends the use of the environmental fate and effects test protocols in the FDA's *Environmental Assessment Technical Handbook* [(8)] or protocols based on scientifically validated methods issued by other organizations, *e.g.*, EPA [(9)] and the Organization for Economic Co-operation and Development (OECD). [(10)]
3. You should not leave any items blank. FDA recommends that, for any particular item you think is not applicable, you provide a statement to that effect and explain why it is not applicable.
4. FDA recommends that you provide a level of analysis commensurate with the potential for environmental impact. For example, if the use and disposal of a substance are expected to result in very limited environmental exposures, you may elect to include less information on the environmental fate and effects of the substance.
5. You should make sure that the action described in the EA is consistent with the action requested in other sections of the submission, and that it includes the range of uses permitted by the proposed action.
6. You should support the claims and conclusions in your EA by providing relevant data from sources such as the scientific literature, databases, or company files. [(11)] You should not make claims that are not supported, or that virtually are impossible to support. In accordance with 40 CFR 1500.4 and 1502.21, relevant publicly available documents should be incorporated by reference into the EA. The incorporated materials should be cited in the EA and briefly described. Material that is not reasonably available for inspection by potentially interested persons within the time allowed for comment may not be incorporated by reference (40 CFR 1502.21).
7. If the analysis indicates uncertainty as to whether the agency's action will have environmental effects or whether potential environmental effects could be significant, FDA recommends that you state this and identify the uncertainties. You are encouraged to contact CFSAN for additional guidance about how to proceed in the event that such uncertainties exist.

When preparing an EA, consider that the EA must be a concise, objective, and well-balanced document that will enable the agency to decide whether a FONSI or an EIS is necessary and that will permit the public to understand the basis for the agency's decision. Finally, note that the FDA is responsible for the scope and content of an EA (40 CFR 1506.5 and 21 CFR 25.40(b)). Therefore, FDA will review carefully an EA and will request that it be revised or supplemented if it is not adequate. An adequate EA is one that contains sufficient information to enable the agency to determine whether the proposed action may affect significantly the quality of the human environment (§ 25.15(a)).

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IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:
Office of Food Additive Safety, HFS-265
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this infomation collection is 0910-0541 (expires 12/31/2013 (Note: Expiration date updated 12/08/2010)).

Notes

(1) Substances that occur naturally in the environment are obtained from a natural resource or biological system and exist in the environment in the same form as substances found naturally in the environment. Synthetic substances also may be considered naturally occurring if they are identical to substances found naturally in the environment.

(2) Section 25.32(p) refers to a petition pertaining to the label declaration of ingredients as described in § 101.103 (21 *CFR* 101.103). However, FDA revoked § 101.103 on June 3, 1996 (61 *FR* 27779) because it duplicated the procedures in 21 CFR 10.30 for citizen petitions. The agency intends to correct § 25.32(p) by removing the reference to § 101.103.

(3) For example, assume that 100,000 kilograms (kg) of the substance is the maximum yearly market volume for the proposed use. If 2,000 kg of the substance enters the waste stream at the food-packaging production site, and if 98,000 kg will become a component of the finished food-packaging material, then the percentage of the amount of the substance used that is incorporated into packaging will be 98%.

(4) Certain actions in this class may qualify for exclusion under § 25.32(r) because they involve substances that occur naturally in the environment and do not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(5) Actions on certain substances used in the production of food may qualify for exclusion under § 25.32(j), (q), or (r) because they are used as components of the food-contact surface of permanent or semi-permanent equipment or of another food-contact article intended for repeated use, are registered by the EPA under FIFRA for the same use requested in the submission, or are substances that occur naturally in the environment, and the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(6) Actions on certain processing aids used in the production of food-packaging materials may qualify for exclusion under § 25.32 (i), (q), or (r) because the substances are present in finished food packaging at no greater than 5 percent-by-weight and remain with finished food-packaging material through use by consumers, are registered by the EPA under FIFRA for the same use requested in the submission, or are substances that occur naturally in the environment and the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(7) Action on components of coatings of finished food-packaging material may qualify for categorical exclusion under § 25.32 (i). **(Return to text)**

(8) Available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (Telephone 703-605-6000), Order Number PB-87 175345/AS.

(9) See 40 CFR part 796 for EPA's Chemical Fate Testing Guidelines, or EPA's Office of Pollution Prevention and Toxic Substances (OPPTS) Harmonized Test Guidelines: 835 - Fate, Transport and Transformation Test Guidelines at **http://www.epa.gov/opptsfrs/home/guidelin.htm (http://www.epa.gov/opptsfrs/home/guidelin.htm)**. See 40 CFR part 797 for EPA's Environmental Effects Testing Guidelines, or EPA's OPPTS Harmonized Test Guidelines: 850 - Ecological Effects Test Guidelines at **http://www.epa.gov/opptsfrs/home/guidelin.htm (http://www.epa.gov/opptsfrs/home/guidelin.htm)**.

(10) The **OECD's Guidelines for the Testing of Chemicals (http://www.oecd.org)** are available on the Internet.

(11) Data and information that are protected from disclosure under 18 U.S.C. 1905, 21 U.S.C. 331(j) or 360j(c) shall be submitted separately in a confidential section of the submission and shall be summarized, to the extent possible, in the EA (21 CFR 25.51).

The above guidance document supersedes the draft version dated September 2003.

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*The FDA web links cited in this article are now out of date. The new FDA websites can be accessed from the Food Ingredients and Packaging section under the Food topic of www.fda.gov.

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