CFSAN/Office of Food Additive Safety
August 2003

Guidance for Industry

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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Draft released for comment August 2003.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions on the content of the draft document contact Center for Food Safety and Applied Nutrition, Layla Batarseh at (202)418-3016 or (202) 418-3005, E-Mail: erg@cfsan.fda.gov. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

Additional contact information

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
August 2003

030-0379 GDL

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 Non-binding Recommendations

Draft-Not for Implementation

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This draft guidance , when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 can use an alternative approach if the approach satisfies the requirement of applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible of implementing this guidance. If you can not identify the appropriate staff, call the appropriate number listed on the title page of the 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. FDA's regulation in 21 *CFR* 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 21 *CFR* 170.39, allowing notifications for food contact substances submitted under 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 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

II. Categorically Excluded Actions

A category of actions that has been found not to individually or cumulatively have a significant affect 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 categorical exclusion?

The following 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 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 facially 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.

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 the 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)).

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. (Return to text)

(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. (Return to text)

(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%. (Return to text)

(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. (Return to text)

(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. (Return to text)

(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. (Return to text)

(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. (Return to text)

(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. 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. (Return to text)

(10) The OECD's Guidelines for the Testing of Chemicals are available on the Internet. (Return to text)

(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). (Return to text)

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FDA U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Food Additive Safety
August 2003

Attachment 1

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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4.12	Earthworm Subacute Toxicity
5.00	**TECHNICAL ASSISTANCE DOCUMENTS--CALCULATIONS**
5.01	Acute Toxicity Calculations
5.02	Analysis of Variance and Tests of Differences Between Group Means

This Environmental Assessment Technical Handbook is available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161. The telephone number is (703) 605-6000. The NTIS order number is PB 87-175345/AS. Price codes are A17 for paper copy and A01 for microfiche; call for the current prices.

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Attachment 2

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Sample Data Summary Table

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Physical/chemical characterization	
Water Solubility	
Dissociation Constant(s)	
Octanol/Water Partition Coefficient (Log K_{ow})	
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Sorption/Desorption (K_{oc})	
Hydrolysis	
Aerobic Biodegradation	
Soil Biodegradation	
Photolysis	
Metabolism	
Environmental effects[1]	
Microbial Inhibition	
Acute Toxicity	
Chronic Toxicity	

[1]Identify organism(s) and report results, *e.g.*, NOEL, MIC, EC_{50}, LC_{50}.

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FDA U.S. Food and Drug Administration Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Food Additive Safety
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Appendix A

Guidance for Preparing an Environmental Assessment for Substances that are Macronutrient Replacements

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Below are recommendations for the suggested format and types of information to submit to the agency in an environmental assessment. An alternative approach may be used if the approach satisfies the requirements of the applicable statutes and regulations.

1. **Date:** The environmental assessment (EA) should provide the date the EA was prepared.

2. **Name of submitter:** The EA should identify the submitter.

3. **Address:** The EA should provide the business address for the submitter.

4. **Description of the proposed action:** FDA recommends that the EA describe the proposed action by addressing the following:

    a. **Requested approval:** The EA should describe the requested approval by naming the substance that is the subject of the action, by describing the proposed use of the substance, including any limitations, and by providing the use level. The EA should identify the proposed regulation by providing the section(s) of the *Code of Federal Regulations* (*CFR*) to be amended, if known. FDA recommends that the description of the proposed use in the EA is consistent with the use requested and described in other sections of the petition.

    b. **Need for action:** The EA must include brief discussions of the need for the proposal (21 *CFR* 25.40). The description of the proposed action, e.g., the intended technical effect of the food additive, should be consistent with other sections of the petition.

    c. **Locations of use:** (1) The EA should describe briefly the locations where the substance will be used. FDA recommends that you describe the sites where the substance will be incorporated into food products, *e.g.*, food-processing plants. For locations where consumers prepare and ingest food products, usually in homes and

restaurants, FDA recommends that you state, if applicable, that the product will be consumed as a component of the human diet in patterns corresponding to national population density.

d. **Locations of disposal:** The EA should describe disposal sites for the substance. If appropriate, the following sentence may be used in the EA to describe disposal sites: "Disposal is expected to occur nationwide with the substance, or its excretion products, entering publicly owned treatment works (POTW) or septic tanks following consumption."

5. **Identification of substances that are the subject of the proposed action:** FDA recommends that the EA should identify fully the substance by providing sufficient information to locate accurately data about the substance in the scientific literature and to closely identify related substances. Information presented elsewhere in the petition may be repeated here so that the EA is a complete and independent document. FDA recommends that the EA contain:

   - Complete nomenclature
   - Chemical Abstracts Service (CAS) registry number (if available)
   - Molecular weight
   - Molecular formula
   - Structural (graphic) formula
   - Physical description (*e.g.*, triglyceride, solid at room temperature, etc.)

6. **Introduction of substances into the environment:**

   a. **Introduction of substances into the environment as a result of manufacture:** FDA does not ask routinely that information about environmental introductions resulting from the production of an FDA-regulated article be included in an EA. (2) However, the preparer of an EA should determine if any extraordinary circumstances pertain to the manufacture of the article. Extraordinary circumstances include situations where 1) unique emission circumstances 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; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 *CFR* 1508.27 (b) (10)); and 3) production associated with a proposed action may affect adversely 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. If extraordinary circumstances apply to the manufacture of the macronutrient replacement substance, such as those outlined above, the EA must discuss any reasonable alternative course of action that offers less environmental risk or that is preferable environmentally to the

proposed action (21 *CFR* 25.40(a)). If no extraordinary circumstances apply to the manufacture of the substance, FDA recommends that the EA includes a statement to that effect.

b. **Introductions of substances into the environment as a result of use:** The EA should discuss any introductions into the environment resulting from the use of the substance. CFSAN believes that, in general, introductions of macronutrient replacements into the environment as a result of their use will be minimal. Macronutrient substitutes are intended to be incorporated into food and to remain with food until ingestion by consumers. You may consider using the following statement in the EA, if appropriate: "There will be little or no introduction of (insert name of substance) into the environment as a result of its use because it is incorporated almost completely into food and remains with food through ingestion by consumers." If this statement does not apply, FDA recommends that the EA include an estimate of the quantity and concentration of substances introduced into the environment resulting from the use of the macronutrient replacement. Such substances may include the macronutrient replacement substance, its degradation products, and/or any other substance resulting from the use of the food additive.

c. **Introductions of substances into the environment as a result of disposal:** We recommend that the focus of the environmental review of macronutrient replacements be on the disposal of human waste products containing the substance and/or its products of digestion and metabolism.

> **NOTE: FDA does not believe that further analysis under Format Items 6, 7, and 8 would be necessary if human metabolism data show that the excretion products that result from the ingestion and metabolism of the substance are the same as the metabolic products resulting from the ingestion of human food. If this is the case, FDA recommends that you make a statement to this effect and provide information to support your statement. If this is not the case, FDA recommends that you address these format items as indicated.**

The EA should include an estimate for 1) the maximum yearly market volume of the substance for the proposed use based on total fifth year production estimates, and 2) the expected introduction concentration (EIC) of the substance and its degradation products present in wastewater effluents and in sewage sludge generated in POTWs. These estimates should consider the volumes of wastewater effluent and the amount of sewage sludge generated in POTWs. FDA recommends that you state all assumptions, provide the basis for the calculations, and show all calculations. If your calculations and the basis for those calculations are protected from disclosure under 18 U.S.C. 1905, 21 U.S.C. 331(j) or 360j(c), such data and information must be submitted separately in a confidential section of the petition and must be summarized, to the extent possible, in the EA (21 *CFR* 25.51(a)). Specific guidance that you may consider for calculating the EICs for the substance in the aquatic, terrestrial, and atmospheric environments is provided below.

i. **Calculating the EIC for the substance in the aquatic environment:** FDA

believes that a conservative calculation of the EIC for the substance in the aquatic environment is based on the following assumptions: a) even distribution of the food substance throughout the U.S. per day, b) total consumption of the food substance, and c) no metabolism and depletion mechanisms. An option for calculating the EIC is as follows:

EIC--Aquatic (ppm) = A x B x C x D, where

A = kg/year production volume of the substance

B = 1/liters per day entering POTWs (3)

C = year/365 days

D = 10^6 mg/kg (conversion factor)

FDA believes that a more realistic calculation of the EIC for the substance in the aquatic environment would consider human metabolism and environmental depletion mechanisms that occur in the wastewater treatment process (*e.g.*, adsorption, biodegradation, and hydrolysis) if such information is available. If you use a different method to calculate the EIC, FDA recommends that you state clearly your assumptions, show your calculations, and provide the basis for these calculations.

ii. **Calculating the EIC for the substance in the terrestrial environment:** The substance may enter the terrestrial environment when sewage sludge from a POTW is applied to land. Substances with an adsorption coefficient (K_{oc}) $\geq$ 1000 might adsorb significantly to sewage sludge. FDA based the sample calculation of the EIC for the terrestrial environment on the following assumptions: a) even distribution of the food substance throughout the U.S. per day, b) total consumption of the food substance, c) no degradation of the substance, and d) all of the substance adsorbs to sewage sludge.

EIC--Terrestrial (ppm) = A x B x C x D, where

A = kg/year production volume of the substance

B = 1/6.4 x 10^9 kg sewage sludge/year (4)

C = 0.555 (5)

D = 10^6 mg/kg (conversion factor)

FDA believes that a more realistic calculation of the EIC for the terrestrial environment would consider human metabolism and environmental depletion mechanisms that occur in the wastewater treatment process (*e.g.*, adsorption, biodegradation and hydrolysis), if such information is available. If you use a different method to calculate the EIC, FDA recommends that you state

clearly your assumptions, show your calculations, and provide the basis for these calculations.

Of the 44.5% of sewage sludge that is not land applied, 22% is incinerated, 14% is landfilled, 7.5% is put to other beneficial uses such as daily landfill covers, and 1% is disposed of by other means.(4) Introductions into the environment from these routes of disposal are expected to be minimal and therefore FDA does not generally recommend they be considered.

iii. **Calculating the EIC for the substance in the atmospheric environment:** The concentration expected in the atmospheric environment should be considered for substances that are likely to volatilize significantly from the aquatic or terrestrial environments. We generally do not expect macronutrient replacement substances to be volatile.

FDA recommends that the EIC(s) will be used to calculate the expected environmental concentrations (EEC(s)) (6) of the substances under Format Item 7 and, in combination with information provided under Format Item 8, to determine whether the proposed action has potential for significant environmental effects.

7. **Fate of substances released into the environment:** FDA recommends using the EIC(s) calculated above in Format Item 6, and available information regarding the fate parameters for the substance when estimating the expected environmental concentration (s) (EEC(s)) for the substance and its degradation products. (7) Environmental fate parameters may include the following:

   a. **Physical/chemical properties** such as water solubility, dissociation constants in water, *n*-octanol/water partition coefficient (K_{ow}), and vapor pressure or Henry's Law constant.

   b. **Environmental depletion mechanisms** such as adsorption coefficient (K_{oc}), aerobic and anaerobic biodegradation, hydrolysis, and photolysis. (8)

   When you estimate the EEC in various environmental compartments, FDA recommends that you also consider dilution by water in receiving streams or by soil mixed with sewage sludge. If the chemical has a high K_{ow}, it may persist in the environment, therefore, you should consider its potential to bioaccumulate. You may want to use FDA's *Environmental Assessment Technical Handbook* (Table of Contents as Attachment 1) that contains technical assistance documents as guidance for environmental fate testing (Sections 3.01-3.12). You also may want to consider using environmental fate test protocols based on scientifically validated methods issued by other organizations, *e.g.*, the Environmental Protection Agency (EPA; 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) and the Organization for Economic Co-operation and Development (OECD; the OECD's Guidelines for the

Testing of Chemicals, Section 1--PHYSICAL-CHEMICAL PROPERTIES and Section 3--DEGRADATION AND ACCUMULATION are available on the Internet.)

We suggest that you use a table, such as the Sample Data Summary Table (Attachment 2), to summarize environmental fate data.

8. **Environmental effects of released substances:** FDA recommends that the EA compare the EEC of the substance and its degradation products to the relevant toxicity endpoints (*i.e.* LC_{50}. EC_{50}, NOEL) so that the potential for adverse environmental effects may be determined. The EA should report, or incorporate by reference, existing data relating to the environmental effects of the substance and its degradation products. The EA should report the toxicity of the substance or its degradation products to organisms that may be exposed in the environment, *e.g.*, vertebrates, invertebrates, plants, fungi, and bacteria. FDA recommends that you consider environmental testing if no effects data are available, or are available only for species not representative of those found in environments predicted to have significant concentrations of the substance or its degradation products. Chronic toxicity testing should be considered for compounds that persist in the environment and have the potential to bioaccumulate or are introduced continuously into the environment. You may want to use FDA's *Environmental Assessment Technical Handbook* (Table of Contents as Attachment 1) that contains protocols (Sections 4.01-4.12) that may be used for conducting environmental effects tests. You also may want to consider using environmental toxicity test protocols based on scientifically validated methods used by other organizations, *e.g.*, EPA (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) and OECD (the OECD's Guidelines for the Testing of Chemicals, Section 1--PHYSICAL-CHEMICAL PROPERTIES and Section 3--DEGRADATION AND ACCUMULATION are available on the Internet).

   We suggest that you use a table, such as the Sample Data Summary Table (Attachment 2), to summarize environmental effects data. FDA believes that adverse environmental effects may occur if a comparison of the EECs with the toxicity endpoints shows that an EEC exceeds the toxicity endpoint after taking appropriate safety factors into consideration.

   The EA should discuss the potential effects of the substance on the efficient operation of POTWs or individual household disposal systems (primarily septic tanks). FDA recommends that you consider, as part of such a discussion, fate information provided under Format Item 7, and, if applicable, any testing undertaken to evaluate this issue, *e.g.*, studies on primary or secondary wastewater treatment processes.

   If a significant percentage of the substance is expected to remain with sewage sludge and subsequently be applied to agricultural or forestry lands, FDA recommends that you discuss the potential effects of the substance on the physical/chemical properties of the soil (*e.g.*, soil structure, pore size, water holding capacity, water percolation, cation exchange capacity).

   Existing laws and regulations may apply to introductions resulting from use and disposal

of the substance. If this is the case, FDA recommends that the EA cite the specific laws or regulations and discuss how such laws or regulations will control the introduction of substances into the environment and prevent adverse environmental impacts. FDA recommends that such a discussion consider, based on the environmental fate and effects information provided under Format Items 7 and 8, whether the proposed use presents unique emissions circumstances that would threaten a violation of such laws and regulations.

If you think that there are uncertainties about the potential for, or significance of, environmental effects, we recommend that you consult CFSAN for specific guidance.

9. **Use of resources and energy:** FDA recommends that the EA state whether the petitioned substance is intended to compete with and replace another food component already in use such that there is essentially no effect on the use of natural resources and energy. If so, the EA should contain a brief justification for this conclusion and identify the substance (s) being replaced. Otherwise, FDA recommends that the EA specify the natural resources, including land use, minerals, and energy, required to produce, transport, use, and/or dispose of wastes generated from production, use, and/or disposal of the petitioned substance. If the substance is derived from a plant or animal, the EA must specifically state whether extraordinary circumstances exist, such as when the action may 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 (21 *CFR* 25.21(b)).

10. **Mitigation measures:** The EA must describe mitigation measures, which are not included in the proposed action or alternatives, for the purpose of avoiding or mitigating potential adverse environmental impacts associated with the proposed action (40 *CFR* 1502.14(f) and 1502.16(h); 21 *CFR* 25.40(a)). The EA must include the environmental impacts of the proposed action (21 *CFR* 25.40(a)). Thus if, based upon a review of adequate and complete data and information, no adverse environmental effects have been identified, you need to state that in the EA.

11. **Alternatives to the proposed action:** If potential adverse environmental impacts have been identified for the proposed action, the EA must describe the environmental impact of reasonable alternatives to the proposed action (including no action, and including measures that FDA or another government agency could undertake as well as those the petitioner could undertake) (40 *CFR* 1502.14 and 1502.16). The EA must describe any reasonable course of action that offers less environmental risk or that is environmentally preferable to the proposed action (21 *CFR* 25.40(a)). The EA should discuss the environmental benefits and risks of the proposed action and of each alternative.

12. **List of preparers:** The EA should list the name, job title, and qualifications (*e.g.*, educational background or professional discipline) for each person preparing the EA. The EA must identify any persons or agencies consulted (21 *CFR* 25.40(a)).

13. **Certification:** FDA recommends that the EA provide a signed and dated statement such as the following:

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of (insert company name)."

_____
(Date)

_____
(Signature of responsible official)

_____
(Name and title of responsible official, printed)

14. **References:** The EA should provide complete citations for all material referenced in the EA either in footnotes within the EA or as endnotes under this format item.

15. **Attachments:** The EA should provide a list of any materials that are attached to the EA. Confidential materials must not be attached to the EA, but must be provided in a separate section of the petition, as provided in 21 *CFR* 25.51(a).

Notes

(1) The term "Locations of use" refers to the sites of use of the manufactured substance, not the locations where the substance itself is produced or manufactured. If the suggested descriptions of use and disposal sites provided in subsections 4.c. and 4.d. are not applicable for the substance, FDA recommends that you provide the appropriate descriptions. (Return to text)

(2) After reviewing hundreds of EAs, the agency found that FDA-regulated articles produced in compliance with applicable emission and occupational safety requirements do not affect the environment significantly. Therefore, as provided in 21 *CFR* 25.40(a), the EA must focus on relevant environmental issues relating to the use and disposal from the use of FDA-regulated articles. (Return to text)

(3) The total flow of wastewater to POTWs in the United States is 32,175 million gallons per day (1.22×10^{11} liters per day). Table C-3, Appendix C, *1996 Clean Water Needs Survey*, U.S. Environmental Protection Agency, viewed on the Internet at: http://www.epa.gov/owm/mtb/cwns/1996rtc/append-c.htm on August 4, 2003. (Return to text)

(4) The volume of biosolids from POTWs was projected to be 7.1 million tons, or about 6.4×10^9 kg, for the year 2000 (*Biosolids Generation, Use, and Disposal in the United States*. EPA 530-R99-009; September 1999, p. 30). (Return to text)

(5) The proportion of biosolids from POTWs projected to be land applied or composted was estimated to be 55.5% for the year 2000. (*Biosolids Generation, Use, and Disposal in the United States*. EPA 530-R99-009; September 1999, p. 35). (Return to text)

(6) The EEC is the expected concentration of a substance that organisms would be exposed to in the environment after consideration of fate parameters. The EEC usually is lower than the EIC.

(Return to text)

(7) If the degradation products of the substance are persistent in the environment, the EA should identify these products and provide any available fate data. (Return to text)

(8) If a depletion mechanism is being used to claim a reduction in the expected introduction and/or environmental concentrations, FDA recommends that you provide an analysis of the depletion mechanism (*e.g.*, according to a standard test method, analysis of expected exposure time in the environment, test protocols and test data). (Return to text)

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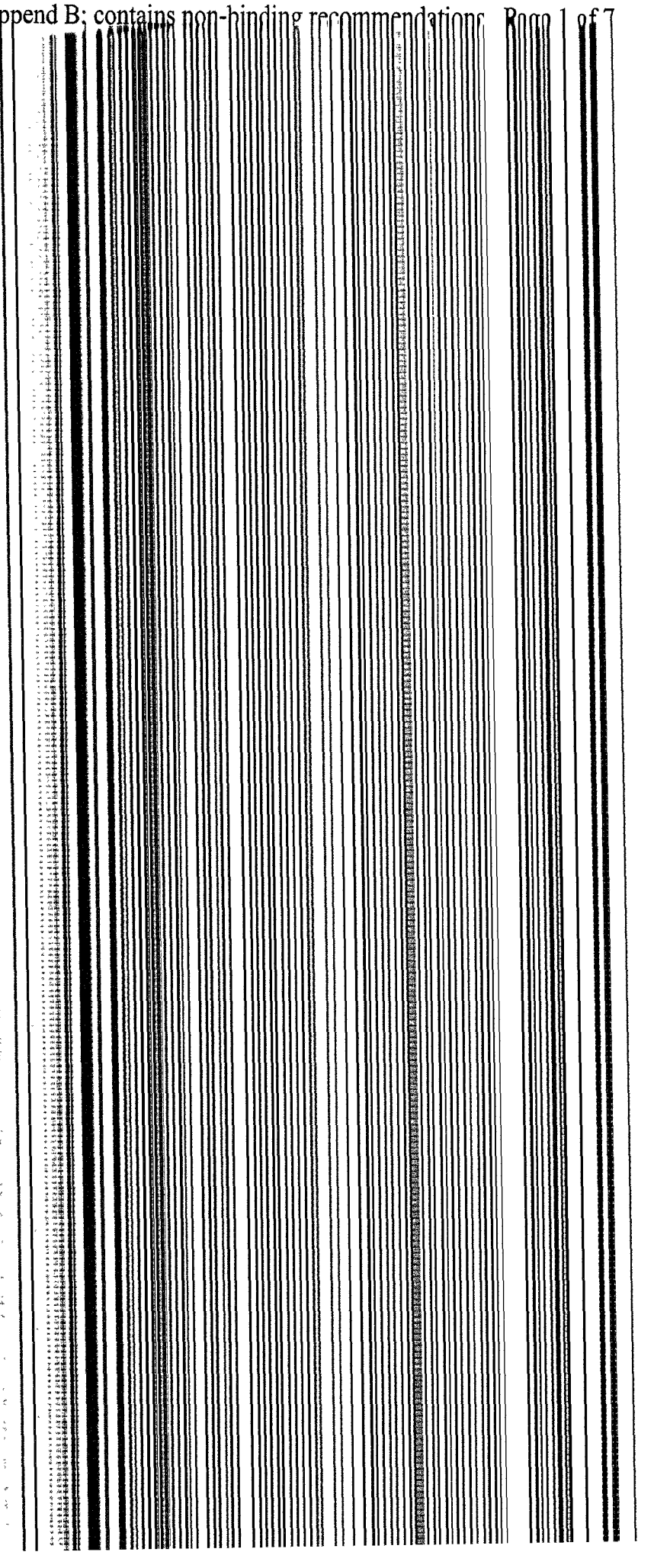

U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Food Additive Safety
August 2003

Appendix B

Guidance for Preparing an Environmental Assessment for Secondary Direct Food Additives and Food Contact Substances Used in the Production of Food that are Not Intended to Remain with Food

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Below are recommendations for the suggested format and types of information to submit to the agency in an environmental assessment. An alternative approach may be used if the approach satisfies the requirements of the applicable statutes and regulations.

1. **Date:** The environmental assessment (EA) should provide the date the EA was prepared.

2. **Name of submitter:** The EA should identify the submitter.

3. **Address:** The EA should provide the business address for the submitter.

4. **Description of the proposed action:** FDA recommends that the EA describe the proposed action by addressing the following:

    a. **Requested action:** The EA should describe the requested action by naming the secondary direct food additive (hereinafter "food additive") or the food contact substance that is the subject of the action, by describing the proposed use of the food additive or food contact substance, including any limitations, and by providing the use level. For food additive petitions, the EA should identify the proposed regulation by providing the section(s) of the *Code of Federal Regulations* (*CFR*) to be amended, if known. FDA recommends that the description of the proposed use in the EA is consistent with the use requested and described in other sections of the submission.

    b. **Need for action:** The EA must include brief discussions of the need for the proposal (21 *CFR* 25.40). The description of the proposal, e.g., the intended technical effect of the food additive or food contact substance, should be consistent with other sections of the submission.

c. **Locations of use/disposal:**[1] The EA should describe briefly the locations where the food additive or food contact substance will be used in the processing/manufacturing of food. FDA recommends that you describe these sites in general terms, *e.g.*, potato slicing plant. In addition, the EA should describe, to the extent possible, the types of environments that might be affected such as the workplace, waters receiving liquid production wastes, and areas subject to air emissions.

5. **Identification of substances that are the subject of the proposed action:** FDA recommends that the EA identify fully the food additive or food contact substance by providing sufficient information to accurately locate data about the food additive or food contact substance in the scientific literature, to identify closely related substances, and to use structure-activity relationships (SAR) programs to predict the fate and effects of the food additive or food contact substance. FDA recommends that the information presented elsewhere in the submission be repeated here so that the EA is a complete and independent document. FDA recommends that the EA contain:

   - Complete nomenclature
   - Chemical Abstracts Service (CAS) registration number (if available)
   - Molecular weight
   - Molecular formula
   - Structural (graphic) formula
   - Physical description; for example, white solid, powder.

6. **Introduction of substances into the environment:**

   a. **Introduction of substances into the environment as a result of manufacture:** FDA routinely does not ask that information about environmental introductions resulting from the production of an FDA-regulated article be included in an EA.[2] However, the preparer of an EA should determine if any extraordinary circumstances pertain to the manufacture of the article. Extraordinary circumstances include situations where 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a proposed action may 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. If extraordinary circumstances apply to the manufacture of the food additive or food contact substance, such as those outlined above, the EA must discuss any reasonable alternative course of action that offers less environmental risk or that is preferable environmentally to

the proposed action (21 *CFR* 25.40(a)). If no extraordinary circumstances apply to the manufacture of the food additive or food contact substance, FDA recommends that the EA include a statement to that effect.

b. **Introduction of substances into the environment as a result of use/disposal:** The EA should discuss any introductions of substances into the environment resulting from the use and disposal of the food additive or food contact substance. Such substances may include the food additive or food contact substance, its degradation products, and/or any other substance resulting from the use and disposal of the food additive or food contact substance. CFSAN believes that, in general, introductions of substances into the environment occur as a result of disposal of the food additive or food contact substance after its use in the production/processing of food. To discuss the introduction of substances into the environment, FDA recommends that the EA should include 1) an estimate of the maximum yearly market volume of the food additive or food contact substance for the proposed use based on total fifth year production estimates; 2) the percent of that amount that will enter the waste stream at the site where the food additive or food contact substance is used to produce/process food; (3) 3) the mode by which the substances are introduced into the environment, *e.g.*, continuous or intermittent (batch) and at what frequency if it is intermittent, *e.g.*, once a week; 4) the expected concentration of substances introduced into the environment at these sites (EIC), (4) *e.g.*, concentrations in air emissions, wastewater effluents, solid waste (including sewage sludge), and the workplace; and 5) the material safety data sheets (MSDSs) for substances to which workers are expected to be exposed. Since food producing/processing plants vary in production capacity, FDA recommends that you calculate the most conservative estimate of the EIC(s). You should state all assumptions, show all calculations, and provide the basis for the calculations. If your calculations and the basis for those calculations are protected from disclosure under 18 U.S.C. 1905, 21 U.S.C. 331(j) or 360j(c), such data and information must be submitted separately in a confidential section of the submission and must be summarized, to the extent possible, in the EA (21 *CFR* 25.51(a)). FDA recommends that the EIC(s) be used to calculate the expected environmental concentrations (EEC(s)) (5) of the substances under Format Item 7 and, in combination with information provided under Format Item 8, to determine whether the proposed action has potential for significant environmental effects.

7. **Fate of substances released into the environment:** FDA recommends using the EIC(s) calculated above in Format Item 6 and available information regarding the fate parameters for substances introduced into the environment, when estimating the EEC(s) for these substances.(6) Environmental fate parameters may include the following:

   a. **Physical/chemical properties** such as water solubility, dissociation constants in water, *n*-octanol/ water partition coefficient (K_{ow}), and vapor pressure or Henry's Law constant.

   b. **Environmental depletion mechanisms** such as adsorption coefficient (K_{oc}), aerobic and anaerobic biodegradation, hydrolysis, and photolysis. (7)

You may want to use FDA's *Environmental Assessment Technical Handbook* (Table of Contents as Attachment 1) that contains technical assistance documents as guidance for environmental fate testing (Sections 3.01-3.12). You also may want to consider using environmental fate test protocols based on scientifically validated methods issued by other organizations, *e.g.*, the Environmental Protection Agency (EPA; 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) and the Organization for Economic Co-operation and Development (OECD; the OECD's Guidelines for the Testing of Chemicals, Section 1--PHYSICAL-CHEMICAL PROPERTIES and Section 3--DEGRADATION AND ACCUMULATION are available on the Internet.) Actual experimental data regarding physical/chemical properties and environmental depletion mechanisms generally are preferable to computer modeling; however, you may use fate prediction models such as the structure-activity relationships (SAR) programs when data about substances are not available. CFSAN will evaluate your modeling predictions and the applicability of the SAR program you used to the substance (s) in question. If CFSAN determines that a predicted value is not applicable to a substance, it may recommend testing. The estimate(s) of the EEC(s) in various environmental compartments (air, water, soil, workplace) should also consider dilution, *e.g.*, the water in receiving streams will dilute entering effluents; the soil with which sewage sludge is mixed will dilute the sludge. If a substance has a high K_{ow}, it may persist in the environment, therefore, you should consider its potential to bioaccumulate. We suggest that you use a table, such as the Sample Data Summary Table (Attachment 2), to summarize environmental fate data.

8. **Environmental effects of released substances:** FDA recommends that the EA compare the EEC(s) of the substances to the relevant toxicity endpoints (*e.g.*, EC_{50}, LC_{50}) so that the potential for adverse environmental effects may be determined. The EA should report, or incorporate by reference, existing data relating to the environmental effects of the substance(s) introduced into the environment as a result of the use and disposal of the food additive or food contact substance in the production/processing of food. The EA should report the toxicity of these substances to laboratory animals (submitted to satisfy human safety requirements) and their toxicity to organisms that may be exposed in the environment, *e.g.*, vertebrates, invertebrates, plants, fungi, and bacteria. FDA recommends that you consider environmental testing if no effects data are available, or if the data are available only for species not representative of those found in environments predicted to have significant concentrations of the substances. Chronic toxicity testing should be considered for substances that persist in the environment and have the potential to bioaccumulate or are continuously introduced into the environment. You may want to use FDA's *Environmental Assessment Technical Handbook* (Table of Contents as Attachment 1) that contains protocols that may be used for conducting environmental effects tests (Sections 4.01-4.12). You also may want to consider using environmental toxicity test protocols based on scientifically validated methods issued by other organizations, *e.g.*, EPA (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) and OECD (the OECD's Guidelines for the Testing of Chemicals, Section 2--EFFECTS ON BIOTIC SYSTEMS are available on the Internet.). Actual experimental data regarding environmental effects are generally preferable to computer modeling; however, you may consider using effects

prediction models such as the structure-activity relationships (SAR) programs when data about substances are not available. CFSAN will evaluate your modeling predictions and the applicability of the program you use to the substance(s) in question. If CFSAN determines that a predicted value is not applicable to a substance, it may recommend testing. We suggest that you use a table, such as the Sample Data Summary Table (Attachment 2), to summarize environmental effects data. If your comparison of the EECs with the toxicity endpoints shows that an EEC exceeds a toxicity endpoint, after taking appropriate safety factors into consideration, then adverse environmental effects may occur.

Existing laws and regulations may apply to introductions resulting from use and disposal of the food additive or food contact substance. If this is the case, FDA recommends that the EA cite the specific laws and regulations and discuss how such laws and regulations will control the introduction of substances into the environment and prevent adverse environmental impacts. FDA recommends that this discussion consider, based on the environmental fate and effects information provided under Format Items 7 and 8, whether the proposed use presents unique emissions circumstances that would threaten a violation of such laws and regulations.

If you think that there are uncertainties about the potential for, or significance of, environmental effects, we recommend that you consult CFSAN for specific guidance.

9. **Use of resources and energy:** FDA recommends that the EA state whether the use of the food additive or food contact substance is intended to compete with and replace another substance already used in the production/processing of food such that there is essentially no effect on the use of natural resources and energy. If so, FDA recommends that the EA should contain a brief justification for this conclusion and identify the substance(s) being replaced. Otherwise, FDA recommends that the EA specify the natural resources, including land use, minerals, and energy, required to produce, transport, use, and/or dispose of wastes generated from production, use, and/or disposal of the food additive or food contact substance.

10. **Mitigation measures:** The EA must describe mitigation measures, which are not included in the proposed action or alternatives, for the purpose of avoiding or mitigating potential adverse environmental impacts associated with the proposed action (40 *CFR* 1502.14(f) and 1502.16(h); 21 *CFR* 25.40(a)). The EA must include the environmental impacts of the proposed action (21 *CFR* 25,40(a)). Thus, if, based upon a review of adequate and complete data and information, no adverse environmental effects have been identified, you need to state that in the EA.

11. **Alternatives to the proposed action:** If potential adverse environmental impacts have been identified for the proposed action, the EA must describe the environmental impact of reasonable alternatives to the proposed action (including no action, and including measures that FDA or another government agency could undertake as well as those the submitter could undertake) (40 *CFR* 1502.14 and 1502.16). The EA must describe any reasonable course of action that offers less environmental risk or that is preferable environmentally to the proposed action (21 *CFR* 25.40(a)). The EA should discuss the environmental benefits and risks of the proposed action and of each alternative.

12. **List of preparers:** The EA should list the name, job title, and qualifications (*e.g.*, educational background or professional discipline) for each person preparing the EA. The EA must identify any persons or agencies consulted (21 *CFR* 25.40(a)).

13. **Certification:** FDA recommends that the EA provide a signed and dated statement such as the following:

    "The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of (insert company name)."

    _____
    (Date)

    _____
    (Signature of responsible official)

    _____
    (Name and title of responsible official, printed)

14. **References:** The EA should provide complete citations for all materials referenced in the EA either in footnotes within the EA or as endnotes under this format item.

15. **Attachments:** The EA should provide a list of any materials that are attached to the EA. Confidential materials must not be attached to the EA, but must be provided in a separate section of the submission, as provided in 21 *CFR* 25.51(a).

Notes

(1) The term "locations of use/disposal" refers to the sites of use of the food additive or food contact substance, not the locations where the substance itself is produced or manufactured. If the suggested descriptions of use/disposal sites provided in subsection 4.c. are not applicable for the food additive or food contact substance, FDA recommends that you provide the appropriate descriptions. (Return to text)

(2) After reviewing hundreds of EAs, the agency found that FDA-regulated articles produced in compliance with applicable emission and occupational safety requirements do not affect the environment significantly. Therefore, as provided in 21 *CFR* 25.40(a), the EA must focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles. (Return to text)

(3) For example, assume that 100,000 kilograms (kg) of the food additive or food contact substance is the maximum yearly market volume for the proposed use. If 90,000 kg of this amount enters the waste stream at a food production/processing site and if 10,000 kg stays with food, then the percentage of the market volume of the food additive or food contact substance that enters the environment at the site(s) of production/processing of food will be 90%. (Return to text)

(4) The EIC is the expected introduction concentration as a result of use of the food additive or

food contact substance. For substances that do not stay with the food, the EICs would be pertinent to the use sites (*e.g.*, food production/processing plants). Your estimates should consider any emissions control devices (*e.g.*, scrubbers that control air emissions) or pre-release treatment processes (*e.g.*, on-site primary, secondary, or tertiary wastewater treatment), along with any relevant environmental fate processes reported under Format Item 7. Please note that if you claim environmental introductions are limited because of pre-release wastewater treatment processes, FDA recommends that the claim be supported by appropriate biodegradation data under Format Item 7. All calculations used in making your estimates should be included. (Return to text)

(5) The EEC is the expected concentration of a substance that organisms would be exposed to in the environment after consideration of fate parameters. The EEC is usually lower than the EIC. (Return to text)

(6) If the degradation products are persistent in the environment, the EA should identify these products and provide any available fate data about them. (Return to text)

(7) If a depletion mechanism is being used to claim a reduction in the expected introduction and/or environmental concentrations, FDA recommends that you provide an analysis of the depletion mechanism (*e.g.*, according to a standard test method, analysis of expected exposure time in the environment, test protocols and test data). (Return to text)

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U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Food Additive Safety
August 2003

Appendix C

Guidance for Preparing an Environmental Assessment for Processing Aids Used in the Production of Food-Packaging Materials but that Are Not Intended to Remain as Components of Finished Food-Packaging Materials

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Below are recommendations for the suggested format and types of information to submit to the agency in an environmental assessment. An alternative approach may be used if the approach satisfies the requirements of the applicable statutes and regulations.

1. **Date:** The environmental assessment (EA) should provide the date the EA was prepared.

2. **Name of submitter:** The EA should identify the submitter.

3. **Address:** The EA should provide the business address for the submitter.

4. **Description of the proposed action:** FDA recommends that the EA describe the proposed action by addressing the following:

    a. **Requested action:** FDA recommends that the EA describe the requested action by naming the processing aid that is the subject of the action, by describing the proposed use of the processing aid, including any limitations, and by providing the use level. For food additive petitions, the EA should identify the proposed regulation by providing the section(s) of the *Code of Federal Regulations* (*CFR*) to be amended, if known. FDA recommends that the description of the proposed use in the EA is consistent with the use requested and described in other sections of the submission.

    b. **Need for action:** The EA must include brief discussions of the need for the proposal (21 *CFR* 25.40). The description of the proposal, e.g., the intended technical effect of the food additive or food contact substance, should be consistent with other sections of the submission.

c. **Locations of use/disposal:** (1) The EA should describe briefly the locations where the processing aid will be used in the processing/manufacturing of food-packaging material. FDA recommends that you describe these sites in general terms, *e.g.*, polymer production plants, paper mills. In addition, the EA should describe, to the extent possible, the types of environments that might be affected such as the workplace, surface waters receiving liquid production wastes, and areas subject to air emissions.

5. **Identification of substances that are the subject of the proposed action:** FDA recommends that the EA identify fully the processing aid by providing sufficient information to locate accurately data about the processing aid in the scientific literature, to identify closely related substances, and to use structure-activity relationships (SAR) programs to predict the fate and effects of the processing aid. Information presented elsewhere in the submission may be repeated here so that the EA is a complete and independent document. The EA should contain:

   - Complete nomenclature
   - Chemical Abstracts Service (CAS) registration number (if available)
   - Molecular weight
   - Molecular formula
   - Structural (graphic) formula
   - Physical description; for example, white solid; powder.

6. **Introduction of substances into the environment**

   a. **Introduction of substances into the environment as a result of manufacture:** FDA routinely does not ask that information about environmental introductions resulting from the production of an FDA-regulated articles be included in an EA. (2) However, the preparer of an EA should determine if any extraordinary circumstances pertain to the manufacture of the substance. Extraordinary circumstances include situations where 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a proposed action may affect adversely 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. If extraordinary circumstances apply to the manufacture of the processing aid, such as those outlined above, the EA must discuss any reasonable alternative course of action that offers less environmental risk or that is preferable environmentally to the proposed action (21 *CFR* 25.40(a)). If no extraordinary circumstances apply to the manufacture of the

processing aid, FDA recommends that the EA include a statement to that effect.

b. **Introduction of substances into the environment as a result of use/disposal:** The EA should discuss any introductions of substances into the environment resulting from the use and disposal of the processing aid. Such substances may include the processing aid, its degradation products, and/or any other substance resulting from the use of the processing aid. CFSAN believes that, in general, introductions of substances into the environment occur as a result of the disposal of the processing aid after its use in manufacturing/processing of food-packaging material. FDA recommends that you discuss the introduction of substances into the environment, and include 1) an estimate of the maximum yearly market volume of the processing aid for the proposed use based on total fifth year production estimates; 2) the percent of that amount that will enter the waste stream at the site where the processing aid is used to manufacture/process food-packaging material; (3) 3) the mode by which the substances are introduced into the environment; *e.g.*, continuous or intermittent (batch) and at what frequency if it is intermittent, *e.g.*, once a week; 4) the expected concentration of the substances introduced into the environment at these sites (EIC), (4) *e.g.*, concentrations in air emissions, wastewater effluents, solid waste (including sewage sludge), and the workplace; and 5) the material safety data sheets (MSDSs) for substances to which workers are expected to be exposed. Since food-packaging manufacturing/processing plants vary in production capacity, FDA recommends that you calculate the most conservative estimate of the EIC(s). You should state all assumptions, show all calculations, and provide the basis for the calculations. If your calculations and the basis for those calculations are protected from disclosure under 18 U.S.C. 1905, 21 U.S.C. 331(j) or 360j(c), such data and information must be submitted separately in a confidential section of the submission and must be summarized, to the extent possible, in the EA (21 *CFR* 25.51(a)). FDA recommends that the EIC(s) be used to calculate the expected environmental concentrations (EEC(s)) (5) of the substances under Format Item 7 and, in combination with information provided under Format Item 8, to determine whether the proposed action has potential for significant environmental effects.

7. **Fate of substances released into the environment:** FDA recommends using the EIC(s) calculated above in Format Item 6 and available information regarding the fate parameters for substances introduced into the environment, when estimating the EEC(s) for these substances. (6) Environmental fate may include the following:

   a. **Physical/chemical properties** such as water solubility, dissociation constants in water, *n*-octanol/ water partition coefficient (K_{ow}), and vapor pressure or Henry's Law constant.

   b. **Environmental depletion mechanisms** such as adsorption coefficient (K_{oc}), aerobic and anaerobic biodegradation, hydrolysis, and photolysis. (7)

   You may want to use FDA's *Environmental Assessment Technical Handbook* (Table of Contents as Attachment 1) that contains technical assistance documents as guidance for environmental fate testing (Sections 3.01-3.12). You also may want to consider using

environmental fate test protocols based on scientifically validated methods issued by other organizations, *e.g.*, the Environmental Protection Agency (EPA; 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) and the Organization for Economic Co-operation and Development (OECD; the OECD's Guidelines for the Testing of Chemicals, Section 1--PHYSICAL-CHEMICAL PROPERTIES and Section 3--DEGRADATION AND ACCUMULATION are available on the Internet). Actual experimental data regarding physical/chemical properties and environmental depletion mechanisms are generally preferable to computer modeling; however, you may consider using fate prediction models such as the structure-activity relationships (SAR) programs when data about substances are not available. CFSAN will evaluate your modeling predictions and the applicability of the program you use to the substance(s) in question. If CFSAN determines that a predicted value is not applicable to a substance, it may recommend testing. The estimate(s) of the EEC(s) in various environmental compartments (air, water, soil, workplace) should also consider dilution, *e.g.*, the water in receiving streams will dilute entering effluents; the soil with which sewage sludge is mixed will dilute the sludge. If a substance has a high K_{ow}, it may persist in the environment, therefore, you should consider its potential to bioaccumulate. We suggest that you use a table, such as the Sample Data Summary Table (Attachment 2) to summarize environmental fate data.

8. **Environmental effects of released substances:** FDA recommends that the EA compare the EEC(s) of the substances to the relevant toxicity endpoints (*e.g.*, EC_{50}, LC_{50}) so that the potential for adverse environmental effects may be determined. The EA should report, or incorporate by reference, existing data relating to the environmental effects of the substance(s) introduced into the environment as a result of the use of the processing aid to manufacture/process food-packaging materials. The EA should report the toxicity of these substances to laboratory animals (submitted to satisfy human safety requirements) and their toxicity to organisms that may be exposed in the environment, *e.g.*, vertebrates, invertebrates, plants, fungi, and bacteria. FDA recommends that you consider environmental testing if no effects data are available, or if the data are available only for species not representative of those found in environments predicted to have significant concentrations of the substances. Chronic toxicity testing should be considered for substances that persist in the environment and have the potential to bioaccumulate. You may want to consider using FDA's *Environmental Assessment Technical Handbook* (Table of Contents as Attachment 1) that contains protocols (Sections 4.01-4.12) that may be used for conducting environmental effects tests. You also may want to consider using environmental toxicity test protocols based on scientifically validated methods used by other organizations, *e.g.*, EPA (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) and OECD (the OECD's Guidelines for the Testing of Chemicals, Section 1--PHYSICAL-CHEMICAL PROPERTIES and Section 3--DEGRADATION AND ACCUMULATION are available on the Internet). Actual experimental data regarding environmental effects are generally preferable to computer modeling; however, you may consider using effects prediction models such as the structure-activity relationships (SAR) programs when data about substances are not available. CFSAN will evaluate your modeling predictions and the applicability of the program you use to the substance(s) in question. If CFSAN

determines that a predicted value is not applicable to a substance, it may recommend testing. We suggest that you use a table, such as the Sample Data Summary Table (Attachment 2) to summarize environmental effects data. If your comparison of the EECs with the toxicity endpoints shows that an EEC exceeds a toxicity endpoint after taking appropriate safety factors into consideration, then adverse environmental effects may occur.

Existing laws and regulations may apply to introductions resulting from use and disposal of the processing aid. If this is the case, FDA recommends that the EA cite the specific laws and regulations and discuss how such laws and regulations will control the introduction of substances into the environment and prevent adverse environmental impacts. FDA recommends that such a discussion consider, based on the environmental fate and effects information provided under Format Items 7 and 8, whether the proposed use presents unique emissions circumstances that would threaten a violation of such laws and regulations.

If you think that there are uncertainties about the potential for, or significance of, environmental effects, we recommend that you consult CFSAN for specific guidance.

9. **Use of resources and energy:** FDA recommends that the EA state whether the requested use of the processing aid is intended to compete with and replace another processing aid already used in the manufacturing/processing of food-packaging material such that there is essentially no effect on the use of natural resources and energy. If so, the EA should contain a brief justification for this conclusion and identify the processing aid(s) being replaced. Otherwise, FDA recommends that the EA specify the natural resources, including land use, minerals, and energy, required to produce, transport, use, and/or dispose of wastes generated from production, use, and/or disposal of the processing aid.

10. **Mitigation measures:** The EA must describe mitigation measures, which are not included in the proposed action or alternatives, for the purpose of avoiding or mitigating potential adverse environmental impacts associated with the proposed action (40 *CFR* 1502.14(f) and 1502.16(h); 21 *CFR* 25.40(a)). The EA must include environmental impacts of the proposed action (21 *CFR* 25.40(a)). Thus, if, based upon a review of adequate and complete data and information, no adverse environmental effects have been identified, you need to state that in the EA.

11. **Alternatives to the proposed action:** If potential adverse environmental impacts have been identified for the proposed action, the EA must describe the environmental impact of reasonable alternatives to the proposed action (including no action, and including measures that FDA or another government agency could undertake as well as those the submitter could undertake) (40 *CFR* 1502.14 and 1502.16). The EA must describe any reasonable course of action that offers less environmental risk or that is preferable environmentally to the proposed action (21 *CFR* 25.40(a)). The EA should discuss the environmental benefits and risks of the proposed action and of each alternative.

12. **List of preparers:** The EA should list the name, job title, and qualifications (*e.g.*, educational background or professional discipline) for each person preparing the EA. The EA must identify any persons or agencies consulted (21 *CFR* 25.40(a)).

13. **Certification:** FDA recommends that the EA provide a signed and dated statement such as the following:

    "The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of (insert company name)."

    _____
    (Date)

    _____
    (Signature of responsible official)

    _____
    (Name and title of responsible official, printed)

14. **References:** The EA should provide complete citations for all materials referenced in the EA either in footnotes within the EA or as endnotes under this format item.

15. **Attachments:** The EA should provide a list of any materials that are attached to the EA. Confidential materials must not be attached to the EA, but must be provided in a separate section of the submission, as provided in 21 *CFR* 25.51(a).

Notes

(1) The term "Locations of use/disposal" refers to the sites of use of the processing aid, not the locations where the processing aid itself is produced or manufactured. If the suggested descriptions of use/disposal sites provided in subsection 4.c are not applicable for the processing aid, FDA recommends that you provide the appropriate descriptions. (Return to text)

(2) After reviewing hundreds of EAs, the agency found that FDA-regulated articles produced in compliance with applicable emission and occupational safety requirements do not affect the environment significantly. Therefore, as provided in 21 *CFR* 25.40(a), the EA must focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles. (Return to text)

(3) For example, assume that 100,000 kilograms (kg) of the processing aid is the maximum yearly market volume for the proposed use. If 90,000 kg of this amount enters the waste stream at a food packaging production/processing site and if 10,000 kg stays with food-packaging, then the percentage of the market volume of the processing aid that enters the environment at the site (s) of production/processing of food packaging material will be 90%. (Return to text)

(4) The EIC is the expected introduction concentration as a result of use of the processing aid. For processing aids that do not stay with the food-packaging material, the EIC would be pertinent to the use sites of the processing aid (*e.g.*, food-packaging production/processing plants). FDA recommends that your estimates consider any emissions control devices (*e.g.*, scrubbers that control air emissions) or pre-release treatment processes (*e.g.*, on-site primary, secondary, or tertiary wastewater treatment), along with any relevant environmental fate processes reported under Format Item 7. Please note that if you claim environmental

introductions are limited because of pre-release wastewater treatment processes, FDA recommends that the claim be supported by appropriate biodegradation data for the processing aid under Format Item 7. All calculations used in making your estimates should be included. (Return to text)

(5) The EEC is the expected concentration of a substance that organisms would be exposed to in the environment after consideration of fate parameters. The EEC is usually lower than the EIC. (Return to text)

(6) If the degradation products are persistent in the environment, the EA should identity these products and provide any available fate data about them. (Return to text)

(7) If a depletion mechanism is being used to claim a reduction in the expected introduction and/or environmental concentrations, FDA recommends that you provide an analysis of the depletion mechanism (*e.g.*, according to a standard test method, analysis of expected exposure time in the environment, test protocols and test data). (Return to text)

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CFSAN/Office of Food Additive Safety
August 2003

Appendix D

Guidance for Preparing an Environmental Assessment for Components of Finished Food-Packaging Material Present at Greater than 5-Percent-by-Weight

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Below are recommendations for the suggested format and the types of information to submit to the agency in an environmental assessment. An alternative aproach may be used if the approach satisfies the requirements of the applicable statutes and regulations.

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.

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Additional Contact Information

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CFSAN/Office of Food Additive Safety
August 2003

Appendix E

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

40 *CFR* 1508.27

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§ 1508.27 Significantly

"Significantly" as used in NEPA requires considerations of both context and intensity:

(a) *Context.* This means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality. Significance varies with the setting of the proposed action. For instance, in the case of a site-specific action, significance usually would depend upon the effects in the locale rather than in the world as a whole. Both short- and long-term effects are relevant.

(b) *Intensity.* This refers to the severity of impact. Responsible officials must bear in mind that more than one agency may make decisions about partial aspects of a major action.The following should be considered in evaluating intensity:

(1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that, on balance, the effect will be beneficial.

(2) The degree to which the proposed action affects public health or safety.

(3) Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

(4) The degree to which the effects on the quality of the human environment are likely to be highly controversial.

(5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.

(6) The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.

(7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts.

(8) The degree to which the action may affect adversely districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.

(9) The degree to which the action may affect adversely an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.

(10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

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Hypertext updated by pcd/emw/msl August 14, 2003