regulations in accordance with FDA's FOIA procedures as described in part 20. In particular, data and information that fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure in accordance with 21 CFR 20.61(c) (see comment 30 of this document).

(9) FDA is revising the language in § 170.39(g) to state that the agency plans to notify manufacturers by means of a notice published in the **Federal Register** of its decision to revoke an exemption issued for a specific use of a substance in a food-contact article (see comment 13 of this document).

(10) FDA is revising § 170.39(c) to state that three copies of a request for an exemption from regulation are to be submitted. If part of the submitted material is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate in accordance with § 10.20(c)(2) (see Section III. of this document: Other Actions). In addition to these changes, FDA is clarifying its definition of TD_{50} in § 170.39(a)(1). This minor change from the October 12, 1993, proposal ensures the scientific soundness of this definition.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Rulis, A., ''Threshold of Regulation: Options for Handling Minimal Risk Situations,'' in *Food Safety Assessment*, edited by Finley, J. W., S. F. Robinson, and D. J. Armstrong, American Chemical Society Symposium Series 484, pp. 132–139, 1992.

2. Rulis, A. M., D. G. Hattan, and V. M. Morgenroth III, ''FDA's Priority Based Assessment of Food Additives,'' *Regulatory Toxicology and Pharmacology*, vol. 4, pp. 37–56, 1984.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

21 CFR Part 174

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5, 25, 170, 171, and 174 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.61 is amended by adding new paragraph (h) to read as follows:

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

* * * * *

(h) The following officials are authorized to issue letters concerning substances determined to be below the ''threshold of regulation'' under § 170.39 of this chapter:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

3. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 351, 354–361 of the Public Health Service Act (42 U.S.C. 262, 263b–264); 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514 as amended by E.O. 11991; E.O. 12114.

4. Section 25.22 is amended by revising paragraph (a)(10) to read as follows:

§ 25.22 Actions requiring preparation of an environmental assessment.

(a) * * *

(10) Approval of food and color additive petitions, approval of requests for exemptions for investigational use of food additives, and granting of requests for exemption from regulation as a food additive.

* * * * *

5. Section 25.31a is amended by revising the introductory text of paragraphs (a), (b)(1), and (b)(2) to read as follows:

§ 25.31a Environmental assessment for proposed approvals of FDA-regulated products—Format 1

(a) For proposed actions to approve food or color additives, drugs, biological products, animal drugs, and class III medical devices, for proposed actions to affirm food substances as generally recognized as safe (GRAS), and for proposed actions to grant requests for exemption from regulation as a food additive, the applicant or petitioner shall prepare an environmental assessment in the following format:

* * * * *

(b)(1) For actions (either to approve food additive petitions or to grant requests for exemption from regulation as a food additive) concerning components of food-contact articles present in the finished food-packaging material at a level not greater than 5-percent-by-weight, the following information is required for the format items specified:

* * * * *

(b)(2) For actions (either to approve food additive petitions or to grant requests for exemption from regulation as a food additive) concerning components of food-contact articles to be used in surfaces of permanent or semipermanent equipment or of other food-contact articles intended for repeated use, the following information is required for the items specified:

* * * * *

PART 170—FOOD ADDITIVES

6. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

7. Section 170.3 is amended by redesignating paragraph (e) as (e)(1) and