



Kraft Foods

1567 '03 AUG 13 P3:35

August 8, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities (Docket No. 03D-0195)

Dear Sir or Madam:

Kraft Foods is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. Our interest in the FDA guidance on food product categories is directly related to our need to register and maintain accurate data for approximately 1000 food facilities. We welcome this opportunity to comment on the most recent guidance on the use of food product categories in registration of food facilities.

Once again, Kraft wishes to express its appreciation for the hard work and long hours FDA personnel have devoted to ensuring that the rulemakings required by the Bioterrorism Act are completed within the mandated timeframe. Kraft has consistently supported the agency's efforts in this regard. Indeed, we have invested considerable time and effort in developing and sharing with FDA suggestions that we believe will improve the agency's proposals. Those suggestions are based on Kraft's years of experience and involvement with virtually all segments of the food industry.

Publication of the guidance document seems to foreshadow a conclusion by FDA in the final rule that food product category information is a necessary part of food facility registration. We sincerely hope that is not the case.

Although FDA proposed to require food product category information as part of the registration process, Kraft and many others submitted detailed comments pointing out that food product categories bear no identifiable relationship to the risks of terrorist attack. Also, because one manufacturer's product is another's ingredient, relying on the categories to communicate with food facilities in an emergency situation might well result in a failure to communicate with affected facilities, rather than the focused and accurate communication FDA desires. As a practical matter, determining the proper categories to include in a registration would be quite difficult because the

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descriptions for some categories overlap others, yet there also products that do not seem to fit clearly into any of the described categories. Inconsistencies among facilities would be inevitable, undermining the usefulness of the data collection effort.

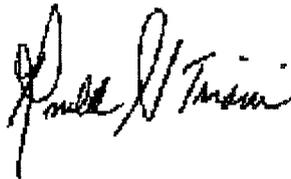
If FDA is not persuaded by the comments asserting that FDA should track establishment types, but not product code categories, industry needs the agency at least to insure that the categories are designated clearly and do not overlap, so the correct category for any product is obvious without significant research. One possibility might be to combine some of the proposed categories into larger, less ambiguous categories. Through this effort targeting food categories may be more effective and efficient given the relationship of ingredient to finished product. An example of a revised approach is described in Attachment I.

Many interested stakeholders spent valuable time and resources preparing their comments. Kraft trusts that those comments will be given full and fair consideration by the agency. Surely by including a provision relating to submission of food product category information in its proposed rule, the agency obligated itself under the notice and comment provisions of the Administrative Procedure Act to reach a final conclusion on that point only after a thorough review of all comments in the record. Any other approach would necessarily be arbitrary.

As FDA works to complete the registration proposal, as well as the other rulemakings required by the Act, we urge the agency to consider the challenges that compliance will present for all companies in the food chain, as well as for the agency. Deploying government and industry resources as effectively and efficiently as possible is essential.

Thank you for your continued consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald J. Triani". The signature is fluid and cursive, with the first name being the most prominent.

Ronald J. Triani
Sr. Director, Scientific Relations

ATTACHED 1 - REVISED GENERAL PRODUCT CATEGORIES

Categories are derived from the proposed food facility registration form, cross-referenced to the categories found in the Product Code Builder and 21CFR170.3.

Omitted optional selection categories.

- 1) Alcohol
(General Category 1)
[21CFR 170.3 (n)(2)]
- 2) Bakery products, cereals, breakfast foods, noodle products, snacks (flour, meal, or vegetable base), whole grains (flour or starch), and gelatin, rennet, pudding mixes, or pie fillings
(General Categories 3, 6, 19, 22, 29, 36)
[21CFR 170.3 (n) (1), (4), (9), (22), (23), (37)]
- 3) Beverage bases, coffees and teas, soft drinks and waters
(General Categories 4, 9, 32)
[21CFR 170.3 (n) (3), (7), (16), (35)]
- 4) Confections w/o chocolate, with chocolate
(General Categories 5, 8)
[21CFR 170.3 (n) (3), (6), (9), (25), (38), (43)]
- 5) Cheese, cheese products, ice cream, imitation milk, milk, butter, or dried milk products
(General Categories 7, 20, 24, 27)
[21CFR 170.3 (n) (5), (10), (12), (20), (21), (30), (31)]
- 6) Color additives, dietary supplements, food sweeteners, food additives
(General Categories 10, 12, 16, 17)
[21CFR 170.3 (o), (1), (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (20), (21), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32);
21CFR 170.3 (n), (9), (41), (42)]
- 7) Multiple food dinners, gravies, sauces and specialties, dietary conventional foods or meal replacements, dressings and condiments, spices, flavors and salts, soups
(General Categories 11, 13, 25, 30, 31)
[21CFR 170.3 (n) (8), (11), (12), (14), (17), (18), (23), (24), (26), (29), (31), (34), (39), (40)]
- 8) Nuts and edible seed products
(General Categories 26)
[21CFR 170.3 (n), (26), (32)]
- 9) Fishery/seafood products
(General Category 14)
[21CFR 170.3 (n), (13), (15), (39), (40)]
- 10) Fruits and Fruit Products
(General Category 18)
[21CFR 170.3 (n) (16), (27), (28), (35), (43)]
- 11) Meat, meat products, and poultry (FDA regulated), shell egg and egg products
(General Categories 23, 28)

[21CFR 170.3 (n) (11), (14), (17), (18), (29), (34), (39), (40)]

12) **Vegetable oils (includes olive oil, vegetable protein products, vegetables and vegetable products)**
(General Categories 33, 34, 35)

[21CFR 170.3 (n), (12), (19), (33), (36)]