



RECEIVED
FSIS DOCKET ROOM
05 AUG 19 PM 10:17

August 18, 2005

FSIS Dockets Clerk
Docket No. 95-051P, Rm. 102
Cotton Annex Building
300 12th St. SW
Washington, DC 20250-3700

95-051P
95-051P-2
Cheryl A. Digges

Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Docket No. 1995N-0294

Dear Sir and Madam:

The Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) (collectively The Agencies) stated in their Proposed Rule that the procedure of submitting petitions is the best possible option for the food industry as well as consumers to amend an existing standard of identity. The Sugar Association (Association) contends that inherent lack of knowledge about the petition process, food ingredients and food technology places consumers at such a disadvantage that substantive input is automatically minimized by this process. The Association maintains that the public interest is best served only if The Agencies maintain strict standards for foods, and is pleased to provide the following comments for The Agencies' consideration.

Consumer Understanding and Expectation

The Agencies have stated that, in order to maintain the intent of the Food Drug and Cosmetic Act (Act), it is unrealistic to rely on consumer understanding of nutrition labeling and ingredient declarations to evaluate foods, thereby creating a need to maintain standards of identities for foods. The Association agrees that this is important especially with the plethora of new ingredients entering today's food supply. It is unreasonable to expect the average consumer to have sufficient knowledge of food technology to evaluate whether new ingredients used to reformulate a food item improves or worsens the quality or nutritional profile of a food.

Food standards were established in the Act to assure consumers that their foods contained not only the highest quality ingredients, but also that these ingredients were present at specified minimum and maximum amounts. Anything less would undermine the intent for requiring standard of identities.

Be Sure It's Sugar: The Natural Sweetener... 15 Calories Per Teaspoon!

THE SUGAR ASSOCIATION, INC.

1101 15th Street, NW Suite 600 • Washington D.C. 20005



tel 202.785.1122 fax 202.785.5019 www.sugar.org

Flexibility in Food Technology

The Agencies have announced guiding principles in the proposed rule for evaluating changes to standards of identity to assure consumer interests are maintained. We request The Agencies give careful consideration to potential unintended consequences of relaxing standards to achieve flexibility in food technology as stated in proposed changes to 9 CFR 410.1(a) (6) and 21 CFR 130.5(b)(6).

The Association does not presume to understand the nuances of all technological advancements in food production or how current standards impede these processing advances. We request that The Agencies revise current standards to accommodate these processing advances only as long as such revisions do not mislead consumers about their expectations of quality and ingredients in the food item.

We understand that some ingredient standards are outdated, but the proposal to describe ingredients as generically as possible is so expansive that consumer understanding of, and expectation about, ingredients present in purchased food items would be essentially absent. The Association contends that this degree of flexibility consequently places traditional food ingredients at distinct disadvantages. The Association requests that, whenever existing standards of identity are amended, The Agencies require all reformulated foods to be denominated in such a manner that consumers are totally aware that the reformulated food contains one or more novel ingredients. For example, The Agencies should require a notice on the Principal Display Panel that this food is now sweetened with ingredient X.

Changes in food formulations that incorporate such important constituents as fiber, whole grains and calcium empower consumers to achieve public health goals. Food additives can also play an important role in food safety. However, the Association asks The Agencies to critically analyze past changes made to the U.S. food supply for empirical evidence that reformulating foods by simply replacing “standard food ingredients” has resulted in a food supply that provides improved nutritional profiles or has improved the overall health of the American public.

To the contrary, the Association asserts that too often “standard food ingredients” are replaced with less expensive ingredients and fillers that have not improved the quality of, or provided any nutritional benefit to, the U.S. food supply. In many instances, food reformulation has done little to lower the caloric content of such foods, which is one of the stated goals of FDA’s Calories Count initiative. While this FDA initiative encourages the food industry to reformulate the U.S. food supply, the Association respectfully reminds The Agencies that targeting one or two ingredients for elimination may generate unintended consequences. The best evidence of unintended consequences is the tremendous number of reduced-fat and no-fat food items developed in the early 1990s that did not significantly improve the overall health of the American public, particularly in regards to weight control.¹

¹ Allred, JB, *Too much of a good thing? An overemphasis on eating low-fat foods may be contributing to the alarming increase in overweight among US adults*, 95 J. Am. Dietetic Ass’n 4 (1995);

The Association requests The Agencies consider consumer benefits by citing the following examples of reformulated foods. Many were created under the pretext of lowering constituents associated with negative health impact:

- Hydrogenated oils leading to increased intakes of *trans* fats;
- Non-dairy products are primarily starch solids that lack the calcium and other minerals, such as Vitamin D, of dairy products;
- Less sugar products often contain higher fat contents with little, if any, calorie reduction;
- Most filler and bulking agents are less expensive carbohydrates possessing 4 calories per gram and thus do not provide any nutritional advantage over sugar or other ingredients they replace;
- “Less Sugar” juices are watered-down versions of the original that are artificially sweetened; and
- Many egg replacers are primarily protein and micronutrient deficient oils.

Maintaining a food supply that insures the quality of ingredients is important to consumers. This is evident in the growing trend in natural and organic food purchases as well as the increasing number of thriving businesses catering to this consumer trend. According to the Iowa State University Agricultural Marketing Resource Center, “the combination natural/organic food category has grown significantly since 1990, increasing four-fold in the decade after and averaging 14 percent annual growth (compared to historic growth rate of 4 percent in the overall food industry).”² Assurance of high quality foods and food ingredients is important to all consumers.

FDA CFSAN’s May 30, 2001 *Memo on Standards Focus Groups* details important findings in focus groups held by FDA to get consumer understanding and input regarding the issues surrounding standard of identities. The memo reported this finding, “...the general flavor of the discussion was that it was more important for standards to address characteristics that participants could not readily observe (such as ingredients in products with multiple, unrecognizable ingredients) than characteristics they could observe (such as appearance, size or number).” With FDA identifying over 3000 additives in its report “*Everything Added to Food in the United States (EAFUS)*, it is impossible for consumers to properly evaluate changes in the food supply with so many approved food additives.

Also the relationship between fat and sugar intake known as the fat-sugar seesaw is well established and taken away from the important message of calories count M. Gibney et al., *Consumption of Sugars*, 62 Am. J. Clinical Nutrition 178S (Supp. 1995). This relationship was reflected in a more recent study that examined the impact of low fat interventions in school lunches—it was noted that “[a]s percent of calories from fat or saturated fat in lunches decreased, that from sugars increased.” J.T. Dwyer et al., *Fat-Sugar See-Saw in School Lunches: Impact of a Low Fat Intervention*, 32 J. Adolescent Health 428 (Supp. 6 2003) See also R.P. Farris, *Nutrient Intake and Food Group Consumption of 10-Year-Olds by Sugar Intake Level: The Bogalusa Heart Study*, 17 J. Am. College Nutr. 579 (1998) J.O. Hill and A.M. Prentice, *Sugar and Body Weight Regulation*, 62 Am. J. Clin. Nutr. 262S (Supp. 1995)

² J. Norwood, *Natural Products* Agricultural Marketing Resource Center Iowa State University January 2004

It is important to note, by contrast, that the European Union (EU) has only 311 approved food additives and Australian and New Zealand Food Standards (FSANZ) report 299 approved direct and indirect food additives.³ Current EU regulations require that the petitioner must first provide evidence of a technological need for that additive in the food supply before a food additive is approved.⁴ This threshold prior to evaluating a new food additive could help decrease the burden on Agency resources, help maintain viability for “standard food ingredient” and decrease the potential of unintended negative health effects.

Consumer interests are further compromised by statutes that prohibit FDA from assessing new food additives petitions regarding benefit to the food supply or the diet. Therefore; standards of identity are an important regulatory tool to balance consumer and industry interests.

Lastly, another stated benefit for flexibility in the proposed rule is the potential for the savings to be passed on to consumers from food manufacturers resulting from technological advances in food ingredients and processing technology. The Association is providing an analysis of USDA data showing that food manufacturer savings obtained from less expensive ingredients is very seldom passed through to the consumer.
(Attachment 1)

Conclusion

The Association maintains that consumer unawareness of ingredient changes in food products does not automatically equate to consumer acceptance. The Agencies should put consumer interests first and not encourage food reformulation that puts “standard farm-based ingredients” at a distinct disadvantage in the marketplace.

The Association agrees, “Preserving the basic nature and essential characteristics of a food would promote honesty and fair dealing in the interest of the consumers and protect the public by ensuring that consumer’s expectations of economic and nutritional value of food is [sic] met”

Thank you for careful consideration of these comments.

Sincerely,



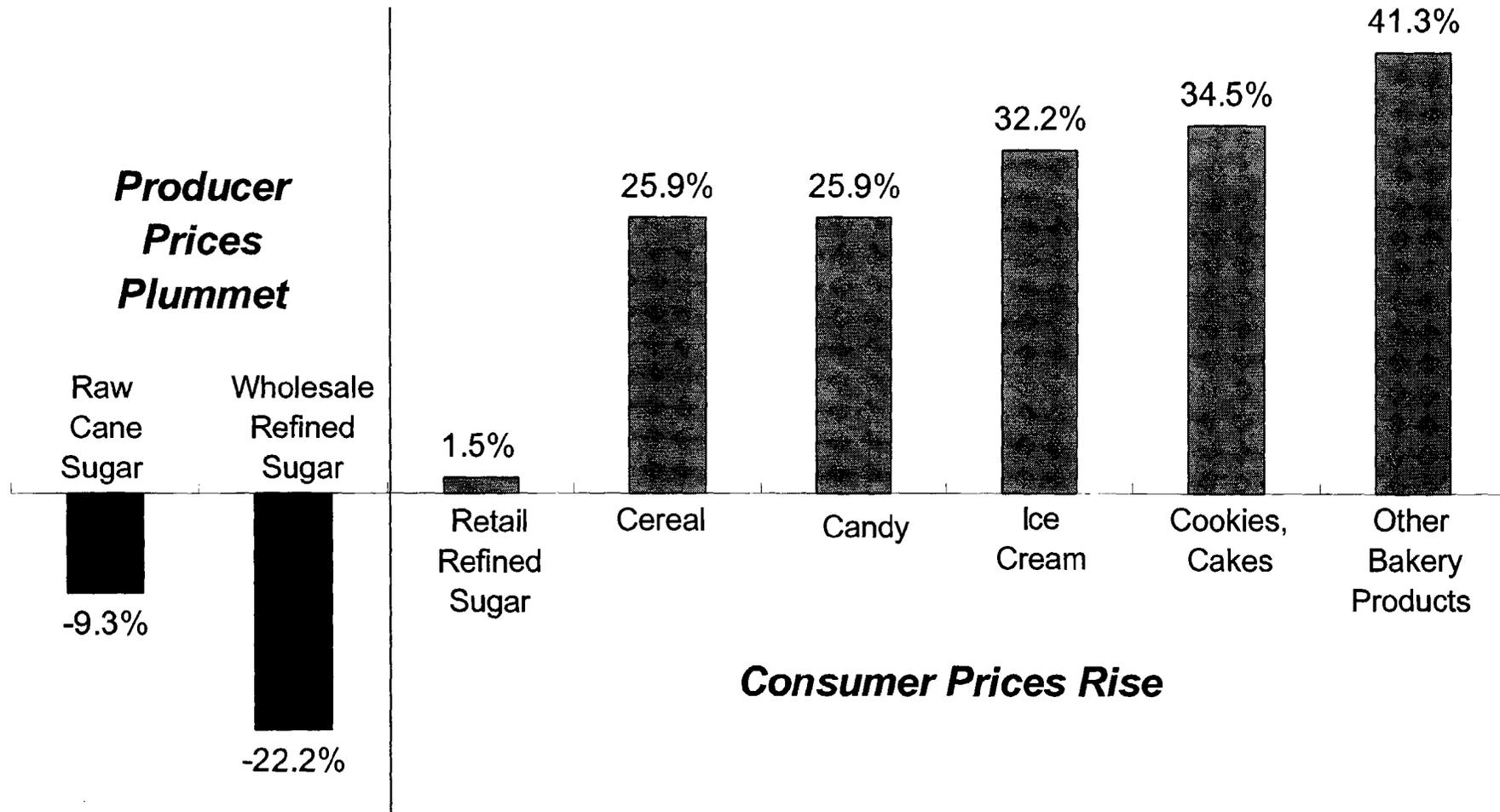
Cheryl A. Digges
Director Public Policy and Education

³ www.foodstandards.gov.au/_srcfiles/new_alpha_list_0902.pdf

⁴ Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption. Official Journal of the European Communities L 40, 11.02.1989 p. 27-33 (Article 1.2 includes definition of a food additive)

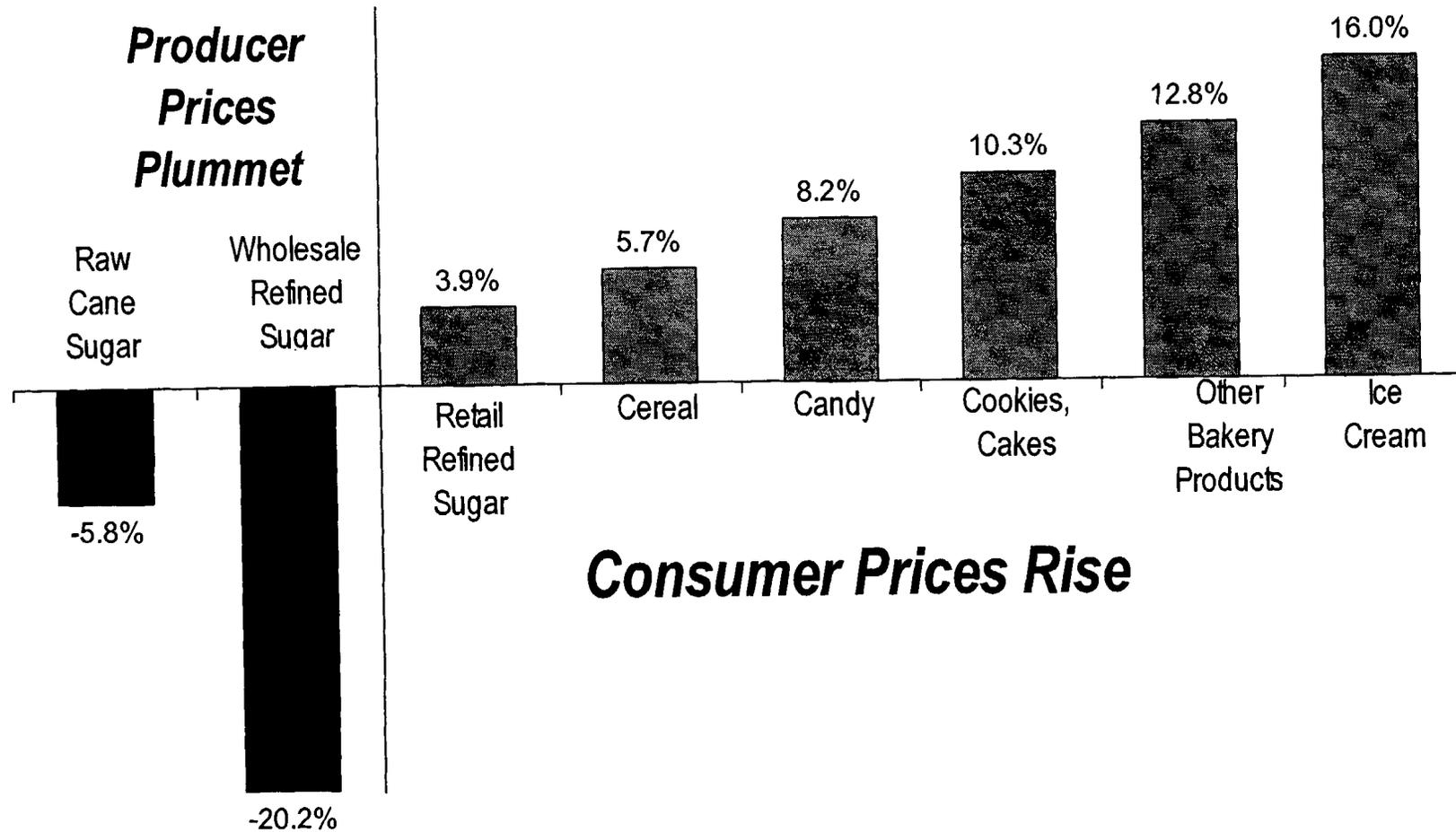
The Sugar Association, Inc. represents the United States sugar cane growers and refiners and sugar beet growers and processors. Association members account for over 90% of this country's US sugar production. As the public information arm of the sugar industry, the Association disseminates scientifically substantiated information concerning sugar through public education and communication programs.

From 1990 to 2001: Producer Prices for Sugar Plummet, Consumer Prices for Sugar & Products Rise*



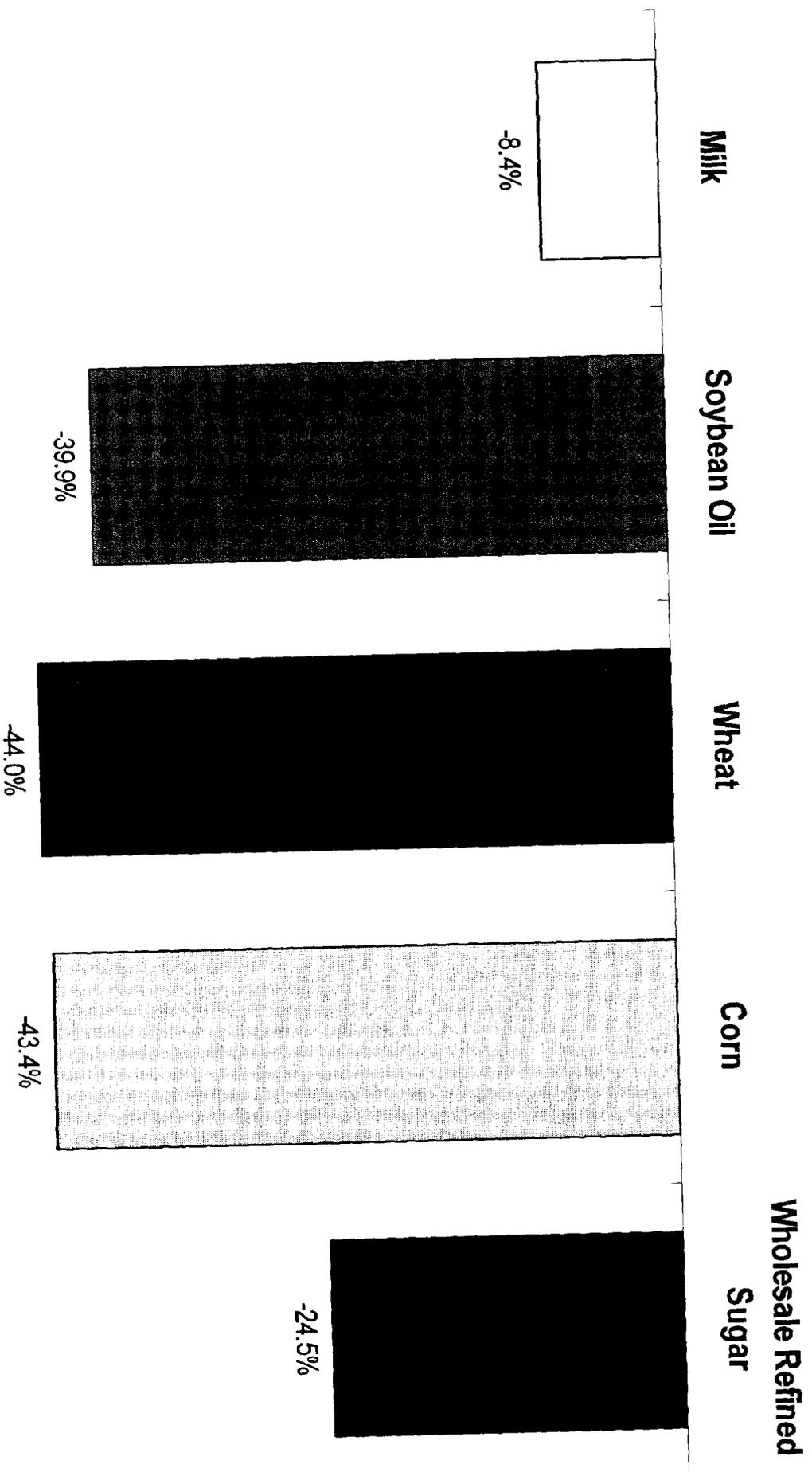
* Change in annual average prices from 1990 to 2001. Raw cane: duty-free paid, New York. Wholesale refined beet sugar: Midwest markets. Retail prices: Bureau of Labor Statistics consumer price indices. Data source: USDA.

From 1996 to 2001: Producer Prices for Sugar Plummet, Consumer Prices for Sugar and Sweetened Products Rise



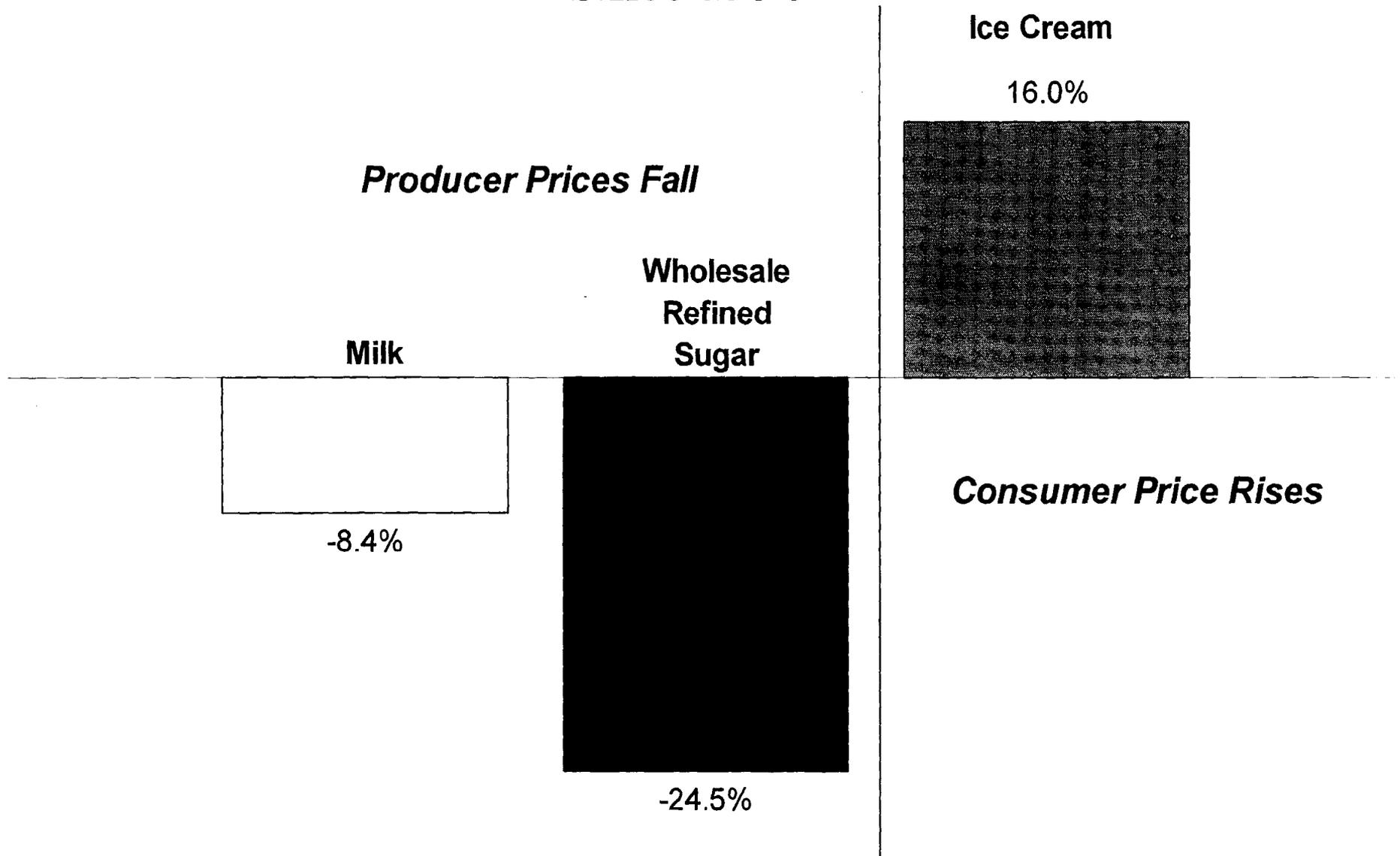
Annual average prices, 1996 compared with 2001. Raw cane: Duty-fee paid, New York. Wholesale refined beet: Midwest markets.
 Retail prices: BLS indices. Data source: USDA.

Sweetened-Product Ingredient Prices Changes Since 1996*



*Data source: USDA; 2000-2001 annual average compared with 1996 annual average.

Ice Cream: Raw Ingredient and Retail Product Price Changes Since 1996*



*Data source: USDA; 2000-2001 average compared with 1996 annual average.

Cookies, Cakes: Raw Ingredient and Retail Product Price Changes Since 1996*

Producer Prices Fall

Wheat

Soybean Oil

**Wholesale
Refined
Sugar**

**Cookies,
Cakes**
10.3%

*Consumer
Price Rises*

-39.9%

-44.0%

-24.5%

10.3%

*Data source: USDA; 2000-2001 average compared with 1996 annual average.