

OFFICE OF MANAGEMENT AND BUDGET WASHINGTON, D.C. 20803

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MEMORANDUM FOR C. BOYDEN GRAY

FROM:

James B. MacRae, Jr.

SUBJECT:

FDA Food Biotechnology Policy

In response to the May 14, 1992 memorandum from Boyden Gray to members of the Biotechnology Working Group on the FDA Food Biotechnology Policy, I am providing the following comments.

I generally believe FDA's policy is sound and consistent with the recently released Scope Principles. However, the tone of the document could be improved to avoid any ambiguity in its intent, My comments are consistent with ones offered by my staff in earlier discussions with FDA.

First, the title of the Notice should be shortened to "Statement of Policy: Foods Derived from New Plant Varieties." Referencing "plants developed by recombinant DNA techniques" in the title inappropriately suggests that the document focuses on r-DNA techniques. In fact, the policy stresses the importance of focusing on the safety characteristics of the new plants and not on the process by which they are produced.

Second, the policy statement needs to clearly state that method of production is irrelevant unless it directly affects the safety of food. I suggest the following language to replace the last two sentences of the paragraph on page 6:

"The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, not the fact that new methods are used."

This language highlights the first Scope Principle of the Recently published "Exercise of Federal Oversight Within Scope of Statutory Authority."

Third, the policy statement needs to stress the role of lacentralized safety reviews by producers; with informal FDA consultation only if significant safety or nutritional concerns arise. It should avoid emphasizing obligatory FDA review and oversight. In this light, the tone of the first full paragraph on page 9 is inappropriate. I suggest the following replacement:

"Producers of new foods have an obligation under the act to ensure that the foods they offer consumers are safe and in compliance with applicable legal requirements. Because in some cases the regulatory jurisdiction of a new food product including those produced using innovative methods may not be clear, producers can informally consult with FDA prior to marketing new foods to ensure that the safety and regulatory status of a new food is properly resolved."

Fige seven of the Notice already discusses when regulations may be necessary before marketing (e.g. food additives), so it is unnecessary to reiterate the point on page nine.

Finally, the Notice should state that never techniques actually may produce safer foods. I suggest that the following sentence be added to the bottom of page 13:

"Since these techniques are more precise, they increase the potential for safe, better characterized, and more predictable foods."

Again, this stresses a major point from OSTP's Scope policy.

 $\ensuremath{\mathbb{R}}$ would be glad to work with you and FDA in resolving these concerns in a timely manner.

