

## Memorandum

Date: 8 January 1992

From: Mitchell J. Smith, Ph.D.

Subject: Comments on Draft Federal Register Notice on Food Biotechnology (Dec 12, 1991 duft)

To: Jim Maryanski

Dear Jim,

My specific comments are delineated below, as requested. My general conclusion is that this issue turns the conventional connotation of food additive on its head. It also conveys the impression that the public need not know when it is being exposed to "new food additives," for lack of a better descriptor.

P28, L 10: Add "the extent of expression of the introduced DNA."

P31, L 3-7: Overly optimistic since one could argue just the opposite and be equally valid.

P33: Version # 1 is better.

P46, L 24: To call a "trait" a new substance misconstrues the scientific connotations of both, particularly the latter, which is usually interpreted to mean a physical component or chemical. In any event, just because the agency failed to evaluate 'new substances' introduced by conventional breeding gives it no reason to continue to do so now with new biotechnology. Moreover, on page 51 you go on to state that "Foods derived from genetically modified plants developed by classical plant breeding methods have been regulated by FDA primarily under the adulteration provisions of section 402 (a) (1) of the Act.

P53: The statement "(3) organisms modified by modern molecular and cellular methods are governed by the same physical and biological laws as are organisms produced by classical methods" is somewhat erroneous because in the former, natural biological barriers to breeding have been breached.

P55, L 6-7: The statement "to the extent that it is known" begs the question as to what degree of identification and toxicological evaluation is sought or prudent. In this instance ignorance is not bliss.

P60, L 9: You now use the normal connotation of substance, in contradistinction to a trait being a substance (P46, L 24).

P60, L 9: "Heavy metals" may require qualification since some, e.g., iron, are both essential and toxic.

P63, L 23: Your distinction between "added" and "inherent" is fanciful. The two two are not dichotomous; thus the ambiguity is in your choice of language, not reality.

18960

P67, L 5-8: This contradicts P61, L 8-11!

P68, L 20: This should read that the intended changes . . .

P68, L 24: This should read that the substances intended, per se, . . .

P73, L 3 & P74, L 1: It is immaterial that the FDA doesn't believe methods of genetic modifications are material information important to consumers if regulations do indeed indicate that the former will be a material fact when consumers view such information as important.

P83, L 4: This is a very contestable issue for a variety of reasons, amongst which are that many plants will be engineered to be sterile . . .

P83, L 28-31: What degree of "monitoring," is actually being suggested?

P86: Version #1 is better, although both fail to address the interdependency between chemical analyses and toxicological testing.

P87, L 20-30 & P88, L 1-9: This section seems very arbitrary.

P90: Version #1 is better.

P92: Version #1 is better.

Sincerely,

Mitchell J. Smith, Ph.D. Head, Biological and Organic Chemistry Section NPIB, CDC, CFSAN