Jim -

Here are my comments on the Federal Register document "Statement of Policy: Foods from Genetically Modified Plants".

1. What is the objective of this policy statement? I see the following possibilities, based on what is in the document:

   a. To respond to numerous requests to the agency to clarify our position with respect to the use of the new techniques of biotechnology, and specifically genetic engineering, to produce new cultivars of food crops.
   b. To prepare a comprehensive agency policy with respect to new cultivars of food crops - regardless of whether those food crops are prepared by new or traditional methods.

   The current document (particularly the section on scientific issues and the appendix) is very schizophrenic in regard to the objective. Some of this has been provoked by conflicting comments from multiple sources on previous drafts. Some advice has been "the recommended actions should be the same for cultivars developed by new and traditional methods, because it is the product and not the process that is regulated". Other advice has been "Do you realize that you are proposing regulations for an entire industry that has previously been virtually unregulated and has a history of safety" (i.e., traditional plant breeding).

   Therefore, perhaps the relevant question is not only what the objective of the document as a whole is, but what the objective of the Appendix is. Should this in fact be "Points to Consider" for new methods of biotechnology, since guidance has been requested, and guidance on traditional breeding has already been given (GRAS symposium, CFR)? Can the objective of the Appendix be "A" even if the objective of the policy statement is "B"?

   The June 1986 Coordinated Framework does not seem to be so concerned with traditional methods and makes no apologies for discussing only biotechnology. It is very concerned with making it clear that no new legislation is needed. It notes that the framework seeks to distinguish those organisms that need review and those that do not. So why can't the current appendix deal only with new biotechnology? Why try to make it appear that we are discussing all modified crops?

2. I believe that there are at least two situations relative to this document in which it is trying to fit a square peg into a round hole. The first square peg in a round hole is that the document is trying to force an ultimate conclusion that

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there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices. This is because of the mandate to regulate the product, not the process.

a. The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks. There is no data that addresses the relative magnitude of the risks - for all we know, the risks may be lower for genetically engineered foods than for foods produced by traditional breeding. But the acknowledgement that the risks are different is lost in the attempt to hold to the doctrine that the product and not the process is regulated.

b. I don't see how the acknowledgement of the fact that the risks are different compromises the position that it is the product that is regulated. The "Points to Consider" for products of genetic engineering must be different than the "Points to Consider" for products of traditional breeding - how can you expect a traditional breeder to have the most basic molecular data (e.g. DNA sequence of the inserted material) when he has no idea of the molecular identity of the genetic material being introduced? Are we to insinuate that practitioners of genetic engineering do not need to adhere to the most basic level of good laboratory techniques simply because the traditional breeding community cannot also provide that data?

3. The second square peg in a round hole is that the approach of at least part of the document is to use a scientific analysis of the issues involved to develop the policy statement.

a. In the first place, are we asking the scientific experts to generate the basis for this policy statement in the absence of any data? It's no wonder that there are so many different opinions - it is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts.

b. In the second place, I don't think that the scientific analysis as presented is complete. The scientific issues section of the document talks of the "possibility of unintended, accidental changes in genetically engineered plants" but I believe that in most cases the word "risk" is avoided. This is probably at least partly due to the fact that there is no data that could quantify risk. But if the scientific issues section of the document deals totally in hypotheses about "possibilities", why does it not address the fact that multiple events would have to

occur in order for the "possibility of unintended, accidental changes in genetically engineered plants" to result in a danger to the public health. Surely the following series of events must all occur in order to present a danger to the public health: (1) The accidental change must activate a pathway for production of a toxin that was unanticipated, or for which there is no suitable analytical method. (2) This unanticipated toxin must be expressed at a high enough level to exert an effect. (3) This toxin must have serious adverse consequences to humans and/or animals that consume it. (4) The presence of this dangerous unanticipated toxin in amounts sufficient to cause a public health problem must not manifest itself in any other way, so that the first and only clue will be the "body count", so to speak.

c. I wonder if part of the problems associated with this approach - using scientific issues to set the stage for the policy statement - are due to the fact that the scope of technical experts assigned to the project did not include any whose usual job is risk analysis. This does not eliminate the problem with a lack of data, but if the molecular biology, chemistry, and toxicology experts are being forced to deal with hypotheses rather than data, why not the risk analysis experts?

4. Are there any alternatives to toxicology testing that could tip the scales to a level where the modified food can meet a safety standard of reasonable of no harm? My impression is that the limitation of the number of insertion sites to one is not sufficient - what does that actually tell you about safety? Could a recommendation that any new cultivars that are produced by genetic engineering only be used (at least for the present) after they have been crossed by traditional breeding into an established cultivar take us over the edge to where no tox testing is necessary? Is that what we expect the plant breeding community to be doing anyway? If so, then such a suggestion is not a burden.

5. If we don't get specific and substantial input from CVM on animal feed, should the objective be reduced to human food?

6. This is a minor comment in relation to the overall problems in the document, but there needs to be a decision as to whether we use one phrase exclusively to refer to certain issues/topics/procedures (i.e. to promote clarity), or if we use multiple terms to liven the document up. E.g. the document tends to use the phrase "new methods of biotechnology" in its entirety when applicable; but the document uses "traditional breeding practices", "conventional plant breeding", classical plant breeding",