June 27, 2016

FDA/HHS Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW16734)

These comments are intended only to provide technical assistance on the draft bill and are by no means to be interpreted as any kind of approval or endorsement of the proposed legislation by HHS and its agencies or the Administration.

General Comments

The bill would give USDA alone certain regulatory authorities over claims on human food labeling that the food is bioengineered. Those authorities would apply to any food that is subject to labeling requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to certain foods that are subject to labeling requirements of the Federal Meat Inspection Act or the Egg Products Inspection Act. Thus, the bill would give USDA these authorities over food labeling that is otherwise under FDA's sole regulatory jurisdiction (as well as over certain other foods).

FDA has a long-held policy position that the use of genetic engineering (GE) in the production of food has not presented any safety concerns for such foods as a class, and therefore the use of GE techniques in the production of food is not a material fact that must be disclosed on the labeling of food products. Since FDA's key responsibilities and focus with respect to food are for safety, any issuance by FDA of regulations governing labeling of foods as bioengineered could be understood by the public as reflecting on the safety of such foods. In the absence of reliable data indicating any safety concerns with bioengineered foods as a class, FDA has not expressed a desire to be the responsible agency for any such regulatory program.

We note that provisions to allow information regarding the GE content of food to be presented only in an electronically accessible form and not on the package label would be in tension with FDA's statute and regulations, which require disclosures on food labels. For example, under FDA's provisions, information such as Nutrition Facts and the list of ingredients must be displayed directly on the label. To avoid potential conflicts, the drafters could make clear in this bill that it will not affect FDA's labeling requirements in the future.

We are concerned that USDA's regulations implementing the mandatory standard under this bill could conflict with FDA's labeling requirements. For example, depending on what USDA requires for small packages, it is possible that a manufacturer would not be able to fit both FDA's required statements and USDA's required information on the label. Here also, to avoid conflicts, the drafters could amend the bill to state clearly that it shall not be construed to authorize a regulatory requirement that would supersede or conflict with any labeling requirement under the FD&C Act.

Technical Comments

We note several points in the drafting of the bill that raise confusion (references of the form "(5:4-7)" mean page 5, lines 4-7, of the bill.):

1. (2:10-15) The definition of "bioengineering" (new sec. 291) would result in a somewhat narrow scope of coverage. First, in subparagraph (A), the phrase "that contains genetic material" will likely mean that many foods from GE sources will not be subject to this bill. For instance, oil made from GE soy would not have any genetic material in it. Likewise, starches and purified proteins would not be covered.

Second, subparagraph (B) would limit coverage to foods where the genetic modification "could not otherwise be obtained through conventional breeding or found in nature." It may be difficult to demonstrate that a particular modification could not be obtained through conventional breeding (or even that it could not occur in nature). In addition, it is unclear whether this refers to the effect of the rDNA construct or the location in the genome (i.e., the former could arguably be obtained via conventional breeding, whereas the latter cannot).

2. (3:5 - 4:2) This scope provision is problematic. All foods (as defined in the FD&C Act) are "subject to ... the labeling requirements under the [FD&C Act]," so paragraph (1) of the current draft would seem to make all foods subject to the bill, and thus paragraph (2) would be superfluous. It appears that the intent is to have the bill apply to all foods except those that are essentially meat, poultry, or eggs, and that the drafters may have assumed, incorrectly, that products covered by the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act are not covered by the FD&C Act. If this is indeed the intent, we suggest that the following revision of new subsection (c):

"(c) APPLICATION TO FOODS.—This subtitle shall apply to a food, except for a food that satisfies both of the following conditions:
"(1) COVERAGE BY OTHER STATUTES.—The food is subject to the labeling requirements under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 103 et seq.).
"(2) PREDOMINANT INGREDIENT.—The most predominant ingredient of the food —
"(A) would independently be subject to the labeling requirements under one of the Acts identified in paragraph (1); or
"(B) is broth, stock, water, or a similar solution, and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under one of the Acts identified in paragraph (1)."

If this is not the intent, we recommend clarification.

3. (4:8-11) New sec. 293(a)(1) says that USDA is to establish a disclosure standard with respect to any food that is bioengineered and "any food that may be bioengineered". It is not clear whether this means any food that is susceptible to bioengineering or any food about which it is uncertain whether it is in fact bioengineered.

4. (4:23 -- 5:2) New sec. 293(b)(2)(A) would require the USDA regulations to "prohibit a food derived from an animal to be considered a bioengineered food solely because [of a certain fact]". This is unclear -- the language of "prohibit[ion]" and of 'be[ing] considered", if taken literally, would mean that an advocacy group that thought of these foods as being bioengineered would thereby have violated the USDA regulation and could be subject to sanctions. Presumably what was meant was that the regulation "shall provide that a food derived from an animal shall not be deemed, for purposes of this subtitle or for the purposes of the regulation, solely because ...."

5. (6:19 - 7:2) New sec. 293(b)(3) refers to a food that "has successfully completed the pre-market Federal regulatory review process". Because there are a number of different pre-market review paths as well as the voluntary consultation process, we suggest adding “applicable” before “pre-market Federal regulatory review process.”