



Sent via Email

August 25, 2017

Agricultural Marketing Service
US Department of Agriculture
1400 Independence Ave SW
Washington, DC 20250

RE: Proposed Rule Questions Under Consideration (National Bioengineered Food Disclosure Standard)

Dear Sir or Madam:

The Calorie Control Council (“the Council”), representing manufacturers and end users of low- and reduced-calorie products such as low-calorie sweeteners and dietary fiber, submits these comments to the US Department of Agriculture’s (USDA) Agricultural Marketing Service (AMS) with regard to the proposed questions under consideration for the National Bioengineered Food Disclosure Standard. The Council’s specific comments on some of the questions put forward by AMS are noted below.

1. Which breeding techniques should AMS consider as conventional breeding? (Sec. 291(I)(B))

As noted in the context for this question, AMS would consider conventional breeding modifications to be exempt from mandatory disclosure. The Council believes that a well-known traditional example of conventional breeding would be natural or manual transfer of pollen and breeding of animals by natural or artificial insemination. Moreover, during the past years, a multitude of modern breeding techniques were developed that create plants that are nature-identical, meaning they could have been the result of a conventional breeding method or a coincidental natural mutation. These plants are not different from conventionally bred plants – neither in their genetic structure nor in their properties. They do not contain any foreign genes or genes that were modified outside the plant. The essential difference: what nature only brings about coincidentally, what the traditional breeder needs to work on for years, can be achieved by modern methods specifically and precisely in a very short time. The results adhere to what is possible in nature and are in accordance with the crossbreeding and recombination possibilities described by Mendel. At the same time, they make it possible to plan coincidence and therefore lead to a more efficient and effective breeding. Therefore, we suggest that AMS should consider these as “conventional breeding” which result in an organism in which the genetic material has been changed through biotechnology in a way which also occurs naturally by multiplication and/or natural recombination.

2. Which modification should AMS consider to be found in nature? (Sec. 291(I)(B))

Within the context for this question, AMS notes that they are considering what would be defined as modifications found in nature which would be exempt from mandatory disclosure. The Council believes that polyploids, plants and microorganisms which already contain multiple copies of select genes should be considered as modifications found in nature which would therefore be exempt from mandatory disclosure. Further, rather than creating a list of permitted techniques, we believe that techniques can be considered conventional if they do not introduce exogenous DNA into the existing genome. Some examples would include: UV radiation; long-range X-ray radiation; dihaploid breeding; non-directed chemical,

environmental and radiation induced mutation; or methods which have examples whereby genetic material already present within the species is expressed or silenced (e.g., CRISPR/Cas9). Additional consideration for “modification found in nature” should be given to “self-cloning” and “natural occurrence,” in which host and donor microorganisms belong to the same or phylogenetically closely related species.

8. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))

The amount of a bioengineered substance present in a food to require disclosure should be based on the finished product on a ready-to-consume basis. If the percentage of cumulative ingredients derived from genetically modified crops and animals does not exceed an appropriate threshold, no mandatory disclosure should be required. In order to calculate this percentage, water and salt contributions should not be excluded from the finished product (e.g., beverage) formulation on a ready-to-drink basis. AMS may also want to consider international standards with regard to an appropriate threshold for disclosure.

9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))

As noted by AMS, there is consideration of the necessity to have various disclosure categories based on different characteristics. The Council believes that it would be simpler to have a simple framework relative to disclosure categories since this is a marketing standard, not a health standard. There could be two categories for “contains” bioengineered ingredients and “may contain” bioengineered ingredients, as presence could vary due to factors such as seasonality and production constraints.

26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))

The Council believes that AMS required recordkeeping should be maintained in a central manufacturing clearinghouse and traceability records be sufficient to verify whether a product that does not disclose is in fact not considered bioengineered for the purpose of disclosure. The retention policy for these records should be at least three years.

30. What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))

The Council believes the import requirements should be consistent with those requirements for domestic products.

We appreciate the opportunity to provide feedback to AMS prior to development of a proposed rule to implement the standard and any related materials, such as guidance. Please let us know if there are any questions.

Sincerely,



Robert Rankin
President