Council for Responsible Nutrition
The Science Behind the Supplements

CRN ANALYSIS OF BE FINAL RULE

CRN Comment	AMS Response
AMS should develop a single official list of commercially available BE foods.	The Agricultural Marketing Service (AMS) developed the List of Bioengineered Foods to identify the crops or foods that are available in a bioengineered form throughout the world and for which regulated entities must maintain records.
However, instead of two lists—one identifying highly adopted BE plants and the other identifying BE plants that are not highly adopted—AMS should create only one list identifying the ten BE plants that are currently available commercially.	For simplicity, AMS consolidated the two lists into one and expanded the consolidated list to include bioengineered crops and foods that may be produced in other countries.
CRN supports the goal of the National Bioengineered Food Disclosure Standard (NBFDS) to provide reliable information about the presence of bioengineered (BE) material in food products, including dietary supplements.	AMS has adopted the statutory definition of "bioengineering," which makes clear that food must "contain genetic material that has been modified through in vitro rDNA techniques. . . " to be labeled as a "bioengineered food." Highly refined products have undergone processes that removed genetic material such that it cannot be detected using common testing methods. As such, the NBFDS will not require disclosure for refined products that do not contain modified genetic material. NBFDS applies to all foods subject to its labeling requirements, including but not limited to raw produce, seafood, dietary supplements. …
AMS should incorporate factors into the definition of "bioengineered food" that would permit exclusion of certain food products from the disclosure requirement.	There will be a process for additional adopting factors or conditions under which a food is considered a BE food, and AMS is adopting the proposed process described in the NPRM.
A food that is not subject to FDCA labeling requirements should not be within the definition of "bioengineered food."	Incidental additives that are present in food at an insignificant level and do not have any technical or functional effect in the food are exempt from BE labeling requirements.

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CRN recommends AMS to clarify that processing aids and substances migrating to food from equipment or packaging which are exempt from labeling requirements pursuant to 21 CFR 101.100(a)(3) would not be subject to BE disclosure under the NBFDS.	FDA regulation describes the circumstances in which incidental additives are not labeled as an ingredient – Title 21 CFR 101.100(a)(3) provides an exemption for incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of §101.100(a)(3), incidental additives are: • Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect. • Processing aids, which are as follows: ➢ Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form. ➢ Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food. ➢ Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food. • Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

CRN Comment	AMS Response
Foods derived from organisms (rather than only "animals") that consumed BE feed should be exempt from disclosure under the NBFDS.	Food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance. Exempting yeast, microbial rennet, and enzymes that are not derived from animals as an extension of the exemption for animal fed with bioengineered feed is beyond AMS's statutory authority. As discussed above, those substances may not be subject to BE disclosure if they qualify as an incidental additive that is not required to be labeled or if the modified genetic material in those products is undetectable Similarly, ingredients produced through the chemical transformation of a bioengineered food or ingredient and substantially transformed into a new ingredient, such as caramel flavoring and color, polydextrose, vitamin C, and sugar alcohols are subject to the NBFDS. They are not automatically exempt from disclosure. Based on AMS's understanding, these products would not qualify as products derived from animals that consumed bioengineered feed. However, they may not be subject to disclosure if they qualify as an incidental additive that is not required to be labeled or if the modified genetic material in those products is undetectable.
A food in which an ingredient contains a BE substance that is unintentional or technically unavoidable and accounts for no more than 5% by weight of the specific ingredient should be exempt from disclosure under the NBFDS.	Section 66.5(c) establishes a threshold for the inadvertent or technically unavoidable presence of bioengineered substances of up to five percent (5%) for each ingredient, with no such allowance for any BE presence that is intentional.