



KYOWA HAKKO U.S.A., INC.

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To Whom It May Concern:

We are Kyowa Hakko USA and we manufacture amino acids by fermentation. These amino acids are used as raw materials for both the food and the dietary supplement industry. For this reason, we would like to provide feedback on the proposed rule questions relevant to our business:

**4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))**

Disclosure should not be required for products that use or contain such highly refined materials. Such highly refined materials are not foods that have been directly bioengineered. Furthermore, in most cases of such highly refined products (oils or sugars etc.) derived from bioengineering crops, genetically modified materials are virtually undetectable in the final product. Moreover, in some instances like fermentation, the highly refined products are used and/or consumed during manufacturing and the highly refined product is not detectable in the finished product. Setting a quantitative limit and method may be one of solution as it relates to No. 8.

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

This could be confusing to the general public and industry. Thus, it seems best to only require disclosure if there is GM in the finished food product being consumed by the public.

**11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))**

Although regulated under the FD&C act, dietary supplements and medical foods do not



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meet the exact definition of a food and thus should be either excluded or addressed separately. It seems reasonable to exclude medical foods and dietary supplements since medications/pharmaceuticals may also contain excipients/API's that are derived from bioengineered sources.

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