From: helena [redacted]
Sent: Saturday, August 26, 2017 2:21 AM
To: AMS - GMO Labeling
Subject: Proposed Rule Questions Under Consideration - response

Thank you for the invitation. Here are my responses to some of your questions

USDA:

Proposed Rule Questions Under Consideration

https://www.ams.usda.gov/rules-regulations/gmo-questions

General remarks

Consumers have a right to be fully informed about their food. This is a basic principle that should be applied in answering all the questions below. We do not yet understand fully the impacts on genetic engineering on food. All we do know for certain is that the engineering process itself may cause many unintended mutations in unexpected parts of the genome. This means that the whole genome needs to be sequenced in order to find out where changes may have taken place. Some of these mutations may be neutral or even positive, but some could be harmful. Mutations of no more than one DNA letter (a point mutation) can mean malformed or missing proteins with potentially severe consequences.

1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))

Bioengineering as a word is somewhat misleading because of the 'bio'. What we need are terms that show clearly that genetic engineering has taken place, eg: genetic engineering, new genetic engineering techniques….

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

All genetic engineering techniques including all kinds of genome editing are liable to cause unintended effects, such as mutations in any part of the genome. Thus products from genetic engineering are very **different** from those obtained through conventional breeding. The EU has **process based assessment**, not **product based**. This means that the unintended effects could be found under EU regulation but WOULD ESCAPE DETECTION AND CONSIDERATION under the US product-based assessment. This is potentially dangerous for consumers.

3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))

This could easily be applied wrongly because a modification that occurs in a completely different plant or context must not be used for defining that modification as "otherwise found in nature". It could easily be used as an excuse to exclude products from mandatory disclosure with potentially deleterious effects.

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))

These ingredients should be disclosed in all foods that contain them. The fact that they appear undetectable is irrelevant. Highly processed oils and sugars may well have side effects that we have not properly investigated, eg, interfering with processes within the body that tell a consumer they have eaten enough. Far more research needs to be done in order to understand the impacts of such ingredients.

5. Although the Law states that the definition of bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government, could there be potential areas of confusion between the definition of bioengineering as

used in the Law and other similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))

Again care must be taken **not** to exclude any organism 'created' or produced through recombinant DNA techniques due to 'potential overlap or confusion over terms'. Especially since companies do not want consumers to be uncertain whether to consume their products and will have a considerable incentive to exclude mention of genetically engineered ingredients.

6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act. How will AMS determine the predominance of ingredients? (Sec. 292(c))

All ingredients, not simply the most predominant, should be subject to labelling requirements for reasons noted above.

7. How should AMS craft language in the regulations acknowledging that the Law prohibits animal products from being considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance? (Sec. 293(b)(2)(A))

It is very important to label food from animals nourished with genetically engineered products because they are NOT the same as animals produced without being nourished with genetically engineered products.

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))

ANY amount of a genetically engineered substance present in food should cause it to be disclosed as genetically engineered or containing genetically engineered ingredients.

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

More than one disclosure category is fine and also is essential if clarified as set out in a, b and c above. I would add d) includes animals fed with genetically engineered products. The public has a right to know in order to be able to choose, eg: a product from part of the year when the ingredients are NOT genetically engineered.

10. What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2)(C))

The public should be fully consulted, not just informed about these issues. A process should be developed in order to decide these issues and develop clear information about what has or has not been genetically engineered in a product or its constituents. This is crucial in order for people to have an informed choice about what they eat or do not eat.

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

All foods including so-called medical food (how is this defined???) and dietary supplements should be fully disclosed.

12. If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure? (Sec. 293(b)(2)(D))

To say **may be produced with genetic engineering** is somewhat ambiguous. However, to choose this wording is positive, because at least the consumer can decide for themselves whether they wish to risk it.

There should be basic clear rules for phrases used and where the disclosure is placed because consumers have a right to know where to look and companies may wish to try to hide the information in one way or another.

I have gone no further than this point.

Helena Paul