

Response from Society for In Vitro Biology (<https://sivb.org>)

Agricultural Marketing Service

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Proposed Rule Questions Under Consideration [1]

The Society for In Vitro Biology (SIVB), formerly the Tissue Culture Association, is a professional society devoted to fostering the exchange of knowledge of in vitro biology of cells, tissues and organs from both plant and animals (including humans). The focus is on biological research, development, and applications of significance to science and society. The SIVB membership is composed of academics, ranging from professors to students, industry members and other interested expert members that work in the area of tissue culture. SIVB members have played leading roles in the development, safety evaluation, and deployment of GE crops; therefore, the SIVB membership counts with unparalleled expertise on the topic. Even so, AMS is requesting answers to questions that not biological in nature, and which consequently, SIVB lacks the proper expertise to answer, so we did not provide answers to all the questions.

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

genetic engineering

gene splicing

GMO

Context: The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use of other **terms to provide for disclosure**.

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

inbred line development

haploid induction

diploidization

micropropagation

embryo rescue

sport selection

plant breeding

animal breeding

plant hybridization

animal hybridization

plant inbreeding

animal inbreeding
mutation breeding (animal & plant)
irradiation breeding
plant selection
animal selection
plant varietal selection
animal varietal selection
pedigree breeding
bulk population breeding
asexual breeding
alien cytoplasm
allopoloid
amphidiploid breeding
apomixis
apospory
autopolyploid
backcross breeding
backcross-pedigree breeding
isogenic line development
restoration backcrossing
cytoplasmic male sterility
plant and animal domestication
haploid breeding
specific combining ability
general combining ability
dialle crossing
diploidization
double-cross hybrids
single-cross hybrids
chromosome doubling
genetic male sterility
hybrid vigor
inbreeding depression
introgression
anther culture
mass selection
ear-to-row breeding method
open pollinated
recurrent mass selection
somaclonal variation
parthenogenesis
early generation selection
natural selection
phenotypic selection

polyploidy breeding
progeny testing
pure line breeding
random mating
reciprocal crosses
reciprocal recurrent selection
recurrent parent
non-recurrent parent
phenotypic recurrent breeding
genotypic recurrent breeding
roguing
seed certification
seed production
somatic hybridization
specific combining ability
synthetic cultivar
synthetic cultivar development
tester parent
transgressive segregation
disease resistance
insect resistance
heterosis
virus resistance
interspecific hybridization

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

SIVB Response: Examples can be found in nature that has resulted from all of the breeding methods mentioned in 2. Many of these occurred during the process of domestication of plants and animals for agricultural use by humans. Horizontal gene transfer has been found to be ubiquitous in nature and thus can be considered as a naturally occurring event.

Sample references:

- Bergthorsson U, KL Adams, B Thomason, & JD Palmer 2003. Widespread horizontal transfer of mitochondrial genes in flowering plants. *Nature*, 424:197-201.
- El Baidouri M, M-C Carpentier, R Cooke, D Gao, E Lasserre, C Llauro, M Mirouze, N Picault, SA Jackson and O Panaud. 2014. Widespread and frequent horizontal transposable elements in plants. *Genome Research* 24: 831-838
- Geering ADW, F Maumus, D Copetti, N Choisne, DJ Zwicky, M Zytynicki, AR McTaggart, S Scalabrin, S Vezzulli, RA Wing, H Quesneville and P-Y Teycheyney. 2014. Endogenous florendoviruses are a major components of plant genomes and hallmarks of virus evolution. *Nature Communications* 5(5269) doi:10.1038/ncomms6269.
- Kyndt T, D Quispe, H Zhai, R Jarrett, M Ghislain, Q Liu, G Gheysen, and JF Kreuze. 2015. The genome of cultivated sweet potato contains *Agrobacterium* T-DNAs with expressed genes: an example of a naturally transgenic food crop. *Proc. Natl. Acad. Sci. USA* 112:5844-5849

- Liu et al 2012. Evolutionary force of AT-rich repeats to trap genomic and episomal DNAs into the rice genome: lessons from endogenous pararetrovirus. *Plant Journal* 72:817-82
- Staginnus et al. 2007 Endogenous pararetroviral sequences in tomato (*Solanum lycopersicum*) and related species *BMC Plant Biology* 7:24

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))

SIVB Response: If it cannot be reliably and easily tested in a lab, it should not be disclosed. At the end of the day, a sugar or oil molecule from a bioengineered plant is indistinguishable from that of a non-bioengineered plant.

7. How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed? (Sec. 293(b)(2)(A))

SIVB response: “Animals or animal products fed any amount of bioengineered feeds do not become bioengineered and are thus exempt from the disclosure requirements as bioengineered.”

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))

SIVB response: AMS already has standards that can be used for the purpose, namely the organic labeling standards. It is incumbent upon AMS to ensure both technologies are treated equally in it’s rule making.

Each of the existing organic labeling categories (100% organic, organic, and made with organic ingredients) should have a counterpart in bioengineered, and with the same thresholds.

When setting thresholds, it is important to remember that the smaller the threshold, the larger the amount of sampling that must be done to get statistically valid measurements.

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

Yes, to be consistent with the organic standards. AMS already has standards that can be used for the purpose, namely the organic labeling standards, and it has multiple

categories in it. It is incumbent upon AMS to ensure both technologies are treated equally in its rule making.

For ingredients that may be seasonably present, a 'May have' bioengineered ingredients label to any one ingredient that qualifies as a bioengineered ingredient under #8 above. AMS should be cognizant that repeated testing of each batch of food is unnecessarily expensive.

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

SIVB response: If the final rDNA or its protein is in the final product, and is present over the threshold from #8, it should be considered covered, otherwise it is not.

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

SIVB response: If the final rDNA or its protein is in the final product, and is present over the threshold from #8, it should be considered covered, otherwise it is not

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))

SIVB response: Should be parallel to organic disclosure.

However, the GMO-free label should be explicitly prohibited whenever the ingredient has no bioengineered counterpart, as such labels are very misleading.

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))

SIVB response: *Either nothing should be on the label, or "May be produced with Genetic Engineering" should be included on all labels.