canolacouncil OF CANADA

United States Department of Agriculture
Agricultural Marketing Services
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Re: Input in Developing a Proposed Bioengineered Food Disclosure Rule

The Canola Council of Canada (CCC) appreciates the opportunity to provide the USDA with comments on the questions for stakeholder input regarding the establishment of a National Bioengineered Food Disclosure Standard as part of the drafting of the proposed rule. The CCC represents the entire canola value chain, including processors, exporters, life science companies, as well as Canada's 43,000 canola growers.

The overwhelming scientific consensus is that food derived from genetically modified organisms is as safe as any other food. The US Food and Drug Administration, Health Canada, European Food Safety and the World Health Organization all have found GMOs are safe for humans and positive for the environment. More than 2,000 studies show a clear consensus among the world's leading scientific organizations that bioengineered ingredients are safe. The Canola Council believes that mandatory labelling of food and ingredients that are not materially different without scientific rationale is misleading consumers by not providing them with straightforward, meaningful and important information. Foods and food ingredients that are derived from bioengineered raw materials or crops, but do not contain any transgenic DNA fragment or transgenic proteins due to refinement or further processing, are indistinguishable from products that do not contain genetically modified ingredients and no type of analytical testing is available to distinguish between the two forms.

Current policies in many countries require labels to provide consumers with information on the composition and nutritional aspects of foods, as well as on any health or safety aspects (allergenicity) pertaining to the food. If a food derived from modern biotechnology affects any of these aspects then policy should require that the food be so labeled.

We thank USDA for providing the opportunity for input into the development of the proposed rule towards the National Bioengineered Food Disclosure Standard. Following are the comments on the questions of importance to our members

Sincerely,

Brian Innes
Vice president, government relations
Canola Council of Canada

Responses to Questions on Proposed Bioengineered Food Disclosure Rule

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

CCC Comment:
Section 291 "Definitions" of the National Bioengineered Food Disclosure Standard of 2016 specifies that transgenic or recombinant DNA plant/animal breeding technologies that cannot be produced through "conventional" breeding techniques are the only technologies that should be considered "bioengineered" and "genetically modified". There is no current scientific rationale for the inclusion of any other breeding technologies within the scope of the proposal.

2. Which breeding techniques should AMS consider conventional breeding? (Sec. 291(1)(B))
Context: AMS is considering what would be defined as modifications that could otherwise be obtained through conventional breeding because these modifications would be exempt from mandatory disclosure.

CCC Comment:
With the exception of in-vitro rDNA breeding techniques, all other methods of breeding should be considered conventional and should be considered to be out of scope of the law and drafting of a proposed rule. As well, jurisdictions in Europe and many other parts of the world which have mandatory bioengineered (GM) labelling laws are all based on the in-vitro rDNA breeding technique, thus to maintain global regulatory coherence and to facilitate efficient trade the technological basis of a US labelling standard should be aligned.

3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))
Context: AMS is considering what would be defined as modifications that could otherwise be found in nature because these modifications would be exempt from mandatory disclosure.

CCC Comment:
Outside of in-vitro rDNA breeding techniques all other modifications could be found in nature and hence should to be exempt from mandatory disclosure, providing global regulatory coherence to facilitate efficient trade.

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))
Context: Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.

CCC Comment:
Highly refined ingredients derived from bioengineered (in-vitro rDNA) organisms that do not contain any novel DNA or novel protein, and do not have an altered characteristic, do not require labelling. These foods are typically highly refined foods, such as sugars and oils, where processing has removed the DNA and protein from the food, including novel DNA and novel protein. Given that the composition of these refined products is indistinguishable from their "conventional" counter-parts and cannot be detected using traditional testing methods, requiring disclosure under the rule may cause consumer confusion. The costs associated with compliance would contribute to unnecessarily higher food costs.

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))
Context: AMS is considering regulatory language similar to the wording in the Law and if the Agency should provide clarity that food derived from any animal, including invertebrates such as crickets or bee products, would not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

CCC Comment:
We agree with the intent to use language similar to the wording in the Law. Animals that are fed with feed that has been produced using rDNA technology (transgenic) are themselves not bioengineered. The food products (e.g. meat, milk, eggs, honey) derived from an animal which has been fed bioengineered feed are not regarded as bioengineered foods and should not require disclosure.

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))
Context: The Law authorizes the Secretary to determine the amount of a bioengineered substance present in food in order for the food to be disclosed as a bioengineered food. The amounts of a bioengineered substance that may be present in food in order for the food to be a bioengineered food might be determined in a variety of ways: if a bioengineered substance is near the top of the list of ingredients, by determining the percentage of bioengineered ingredients in a food product, or by listing any ingredient that was produced through bioengineering, among others. AMS is considering how to determine the amount of bioengineered food or ingredient needed for a product to require a bioengineered disclosure, as well as the advantages and disadvantages of various methods.

CCC Comment:
Food manufacturers source grain and commodities that are transported through a bulk handling system that cannot guarantee zero presence of bioengineered material. The grain industry has consistently recommended at least a 5 percent threshold for low level presence (LLP) in order to avoid significant cost increases to the system. This threshold acknowledges that there is an amount of biotech plant material that can reasonably be expected to be present in non-biotech bulk grain shipments, consistent with current production practices and industry standards. Any labelling regime for bioengineered food should not result in the need for a more stringent standard than this in the bulk handling system.

9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))
Context: AMS is considering if it should develop various categories for disclosure and if it should differentiate between those products that a) are bioengineered, b) contain ingredients that are bioengineered, or c) contain ingredients derived from bioengineered crops or animals. Additionally, AMS is considering the creation of a set of disclosures for a category of bioengineered foods for those products that, due to changes in sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year. AMS is considering the advantages and disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.

CCC Comment:
Yes, AMS could provide flexibility to allow various disclosure categories.

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))
Context: Currently, some food manufacturers use language compliant with the Consumer Protection Rule 121 from the State of Vermont to identify their food products as bioengineered ("Produced with Genetic Engineering," "Partially Produced with Genetic Engineering," or "May be Produced with Genetic Engineering"). AMS is considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard and if their language is appropriate. Further, AMS is considering what phrases could be used as a text disclosure for bioengineered food that consumers would find informative, truthful, and not misleading.
AMS is also considering whether there should be one standard text disclosure language, or whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase and where the bioengineered food disclosure should be placed on food packages.

CCC Comment:
We believe that the industry should be allowed flexibility to choose from more than one acceptable phrase, and where the bioengineered food disclosure should be placed on food packages.

13. If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))
Context: AMS needs to ensure that the symbol designed for the bioengineered disclosure is not disparaging toward bioengineering. As with the text disclosure, AMS must develop criteria for placement of the symbol to ensure consumers can readily locate the symbol, the symbol is scalable for different sized packages, and the symbol is a meaningful representation of bioengineered foods. AMS is considering what the symbol should look like and guidance on its use.

CCC Comment:
We agree that AMS needs to ensure that any symbol designed for the bioengineered disclosure is not disparaging toward bioengineering.

17. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))

Context: AMS is considering if it should mirror FDA's treatment of very small and small packages for nutrition labeling.

a. In 21 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.

b. FDA also has allowances for packages that have less than 40 square inches of total surface are available to bear labeling.

CCC Comment:
To prevent confusion and inconsistencies, AMS should mirror FDA's treatment.

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

Context: Each person or entity subject to the mandatory disclosure requirement would be required to maintain and make available to the Secretary records that establish compliance with the Law. Typically, record keeping requirements include those for the records required to be kept, the place of maintenance of such records, the record retention period, and what it means for AMS to have adequate access to and inspection of such records.

Under current FSIS regulations, records must be maintained at a place where business is conducted, except that if business is conducted at multiple places of business, then records may be maintained at a headquarters office. When the business is not in operation, records should be kept in accordance with good commercial practices. For FSIS, records are required to be maintained for a 2-year period. The maintenance time for FDA records vary from 6 months through up to 2 years.

AMS is considering what recordkeeping requirements for persons subject to the Law would be most appropriate.

CCC Comment:
The FSMA rules "Hazard Analysis and Risk-Based Preventive Controls" provision of FSMA section 103/Food Drug and Cosmetic Act (the FD&C Act) sets out the requirements for what types of records and the required maintenance of these records. These should be incorporated where possible in the Law/regulation to ensure no unnecessary duplication of effort for food manufacturers.

27. How should AMS obtain information related to potential non-compliance with these regulations? Is there information USDA should request prior to conducting an examination of non-compliance? (Sec. 293(g))

Context: AMS is considering what tools could be used to identify potential non-compliance and enforce compliance with the regulations. AMS is considering the types of information needed to verify compliance with the Law and the most optimal way to obtain such information.

CCC Comment:
Compliance to the Law/regulation could be done upon inspection of manufacturing records.
Since this is not a food safety issue, the burden of providing proof of compliance should not be placed on manufacturers.

29. How should AMS make public the summary of any examination, audit, or similar activity? (Sec. 293(g)(3)(C))

Context: AMS is considering if the results and findings of any examination, audit, or similar activity should be posted after the notice and opportunity for a hearing described under Sec. 293(g)(3)(B). AMS is also considering how it should make summaries of the examination, audit, or similar activity public.

CCC Comment:
The overwhelming scientific consensus is that bioengineered ingredients are as safe as any other food. The US Food and Drug Administration, Health Canada, European Food Safety and the World Health Organization all have found GMOs are safe for humans and positive for the environment. Having said this, the requirements for public disclosure should be minimal as to protect business or trade confidentiality.

30. What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))
Context: AMS considering how the disclosure requirements should be applied to imported products.

CCC Comment:
The National Bioengineered Food Disclosure Standard Law applies to food which is "subject to the labelling requirements under the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)." Consequently, our understanding is that bulk grain and oil imports into the US will be out of scope of the Law and the proposed rule. This is appropriate, and allows US food manufacturers the flexibility to enter into agreements with Canadian exporters that will best meet their needs. Whatever method is chosen for disclosure requirements must not add any undue burden or technical barrier to trade over domestic requirements.

Similarly, imported or domestically manufactured packaged products composed of highly refined foods or ingredients – which may be derived from bioengineered crops but themselves contain no protein or DNA and are indistinguishable from their conventional counterparts – should be exempt from the requirement of the Law/regulation. Given that these refined products are indistinguishable, requiring disclosure under the rule may be misleading and cause confusion for the consumer. Furthermore the costs associated with compliance with the rule could in turn contribute to unnecessarily higher food costs.