Proposed National Bioengineered Food Disclosure Standard (NBFDS):
List of questions and proposals Canada may wish to address in comments

As indicated in our message on May 9, 2018, please find below some key parts of the document which may be of interest to Canadian Stakeholders. This is not an exhaustive list but is intended to facilitate your review of the document.

DEFINITIONS

"*Bioengineering*" and "*Bioengineered Food*"
The USDA Agricultural Marketing Service (AMS) invites comments on how to interpret the statutory definition of "bioengineering," and thus the scope of the regulatory definition of "bioengineered food" as it is unclear if highly refined food and ingredients should fall within the definition and be subject to disclosure.

"*Conventional Breeding*" and "*Found in Nature*"
AMS seeks comments on whether the NBFDS should include a definition for these terms and what they should be.

FOOD SUBJECT TO DISCLOSURE (BIOENGINEERED FOODS)

Legislative scope
The NBFDS limits the disclosure to (1) food that is subject to the labeling requirements of the FDCA; or (2) food that is subject to the labeling requirements of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), with certain exceptions, as set forth in the amended Act.

List of Bioengineered Foods
To determine foods that would be subject to disclosure, AMS proposes the creation of two lists based on the proposed definition of "bioengineered food":

1) a proposed list of BE foods that are commercially available in the U.S. with a high adoption rate (i.e., cultivated in the U.S. at rates above 85%), and

2) a proposed list of BE foods that are commercially available in the U.S. that are not highly adopted.

For products that contain a food (end-product ingredient) on either of the two lists, regulated entities would either make a disclosure consistent with the NBFDS or not disclose if they believe the food is not required to have a BE disclosure.

List Maintenance and Revisions
AMS proposes a process whereby the two lists would be reviewed and revised on an annual basis. Regulated entities would have an 18-month grace period for compliance.

Treatment of new Technologies
The proposed process for establishing and amending the BE food lists would provide a vehicle by which AMS could evaluate whether a particular crop meets the definition of "bioengineering." AMS would consult with U.S. Government Agencies responsible for oversight of the products of biotechnology to understand if foods resulting from the new technologies are consistent with the definition of "bioengineered food" and are commercially available.

AMS solicits comments on several aspects of the proposed lists. Questions are listed under "Request for Comments on the Lists" in the Proposed rule.

FACTORS AND CONDITIONS

The amended act does not specify the process by which the Secretary will determine other factors and conditions under which a food is considered a BE food; rather, it provides the Secretary with discretion in setting up such a process.

Incidental Additives – Intended to clarify disclosure requirements
Incidental additives that are present in food at an insignificant level and do not have any technical or functional effects in the food are exempt from certain labeling requirements under the FDCA. Under this proposed factor or condition, such an item would only trigger disclosure when it is used as an ingredient that is included on the ingredient list, not when used as an incidental additive.

Undetectable Recombinant DNA – Intended to provide a means to potentially exclude products where modified genetic material cannot be detected if " bioengineering" definition includes all GM foods including highly refined products (Position 2)
If regulated entities can demonstrate that the manufacturing process results in a final product where the modified genetic material cannot be detected and their records prove as such, food subjected to that process would no longer be considered a bioengineered food. AMS proposes that regulated entities would need to maintain records showing that food subjected to a specific process has been tested for that purpose by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines.

EXEMPTIONS

The amended Act includes two express exemptions to the disclosure requirement: food served in a restaurant or similar retail food establishment and very small food manufacturers.

AMS proposed to define "very small food manufacturer" as a food manufacturer with annual receipts less than $2.5 million. AMS is seeking comment on alternative revenue cutoffs of $500,000 and $5,000,000.

Other exemptions include animals fed with bioengineered feed and their products as well as food certified organic under the National Organic Program.

EXEMPTION THRESHOLD

AMS is proposing and seeking comment on three different alternative thresholds, compliance (including verification of 'inadvertent' or 'technically avoidable') with each of which would be verified through the regulated entity's customary and reasonable business records.

Alternative 1: Would establish that food, in which an ingredient contains a BE substance that is **inadvertent or technically unavoidable**, and **accounts for no more than 5% of the specific ingredient by weight**, would not be subject to disclosure as a result of that one ingredient.

Alternative 2: Would establish that food, in which an ingredient contains a BE substance that is **inadvertent or technically unavoidable**, and **accounts for no more than 0.9%** of **the specific ingredient by weight**, would not be subject to disclosure as a result of that one ingredient.

Alternative 3: Allow regulated entities to use BE ingredients and not have to disclose under the NBFDS as long as the total amount of **all BE ingredients used in the product were not greater than 5% of the total weight of the product**.

DISCLOSURE

Responsibility for Disclosure

AMS proposed three categories of entities responsible for disclosure:

1) Food manufacturers
2) Importers
3) Certain retailers

AMS believes that this approach would align responsibility for labeling with that currently required under other mandatory food labeling laws and regulations, including those administered by FDA and FSIS.

International impact

Under the proposed rule, importers would be subject to the same disclosure and compliance requirements as domestic entities. AMS seeks comment on any impact this proposal might

have on importers. AMS seeks comment from all stakeholders regarding any unique issues associated with BE disclosure for imports and on any potential impacts on international stakeholders.

The proposed rule allows for the establishment of recognition arrangements. This only applies to countries with mandatory labelling requirements. Imports of products from countries that do not have bioengineered food labeling regulations or with whom AMS had no mutual recognition arrangement would be subject to the disclosure and recordkeeping requirements of the NBFDS.

Placement of the disclosure

AMS proposes that the BE food disclosure be placed one of the following places:

1) The information panel adjacent to the statement identifying the name and location of the manufacturer/distributor or similar information
2) anywhere on the principal display panel; or
3) an alternate panel if there is insufficient space to place the disclosure on the information panel or the principal display panel.

Text Disclosure

AMS proposed using the terms "bioengineered food" of "bioengineered food ingredient". Alternative phrases such as "genetically modified" or "genetically engineered" were considered but AMS believes that the statutory term "bioengineering" adequately describes food products of the technology that Congress intended to be within the scope of the NBFDS.

Voluntary disclosure

AMS is proposing provisions in the NBFDS that would allow for such voluntary labeling for food that meets the definition of "bioengineering" in the statute.

OPTIONS FOR DISCLOSURE

1) **Text Disclosure**

   AMS proposes using the terms "bioengineered food" or "bioengineered food ingredient" to differentiate between BE food and BE food ingredients through the on-package text disclosure alternatives. They believe this approach would recognize that some foods are entirely a product of bioengineering and that some foods are a mix of BE and non-BE food ingredients.

   a) **High adoption bioengineered food**

      For BE food or BE food ingredients that appear on the high-adoption list, entities would be required to use one of two alternative statements. The first statement—"Bioengineered food"—would be for raw agricultural products that meet the proposed definition of "bioengineered food," as well as for processed products that only contain BE food ingredients (e.g. BE cornmeal). The second statement—"Contains a bioengineered food ingredient"—would be for all other foods. AMS believes this

statement would cover all multi-ingredient products that contain both BE food ingredients and non-BE food ingredients (e.g. processed food products such as cereals).

b) Non-high adoption bioengineered food

AMS is proposing that regulated entities would disclose the presence or possible presence of BE food and BE food ingredients that are on the list of BE foods commercially available, but not highly adopted, using the following statements: "Bioengineered food," "May be bioengineered food," "Contains a bioengineered food ingredient," or "May contain a bioengineered food ingredient." The default presumption would be that any foods on the non-high adoption BE food list may be bioengineered, and regulated entities would have discretion to use any of these disclosure options.

AMS seeks comments on several aspects of the proposed text disclosure options under "Non-High Adoption BE food" section under "Text Disclosure".

2) Symbol disclosure

A symbol is another form of BE food disclosure regulated entities can use. AMS proposes three alternative symbols with variations of those symbols, and invites comment on each alternative and its variation (see attachment).

3) Electronic or Digital Link Disclosure

The amended Act requires that the use of an electronic or digital link to disclose BE food must be accompanied by the statement "Scan here for more food information" or equivalent language that reflects technological changes.

4) Text message option

The Secretary conducted a study to identify possible technological challenges that may impact whether consumers would have access to the bioengineering disclosure (i.e. availability of wireless internet or cellular networks). Although the study is under review, and no determination has been made, AMS is proposing a text message as a digital disclosure method.

RECORDKEEPING AND ENFORCEMENT

Recordkeeping requirements

Persons required to keep records for food on the lists maintained by AMS of bioengineered foods commercially available in the United States would include food manufacturers, importers, retailers who label bulk foods or package and label foods for retail sale, and any other entities responsible for labeling for retail sale foods on the BE food lists. AMS anticipates that **each entity subject to the disclosure requirement would decide for itself what records and records management protocol are appropriate**, given the scope and complexity of individual businesses, as well as the food being produced.

1) Entities subject to this subpart must maintain records that are customary or reasonable to demonstrate compliance with the bioengineered food disclosure requirements of this part.

2) The records must contain sufficient detail as to be readily understood and audited.

3) Records **must be maintained for at least two years** beyond the date the food or food product is sold or distributed for retail sale.

Non-disclosure of foods on either list
AMS proposes that regulated entities who offer for retail sale foods on either list of commercially available BE foods, but do not disclose that the products are BE foods or contain bioengineered food ingredients, would be required to maintain documentation that verify the foods are not bioengineered. Such documentation might include supply chain documents, purchase orders, sales confirmations, bills of lading, supplier attestations, purchase receipts, written records, labels, contracts, brokers' statements, analytical testing results, or process certifications.

Disclosure of foods on either list
AMS proposes that entities making affirmative disclosures for BE food on either list of BE foods would only need to maintain records to show that their product contains a food or food ingredient on one of the BE food lists. As described in the Disclosure section above, “may” disclosure statements could be used for any foods that are on the list of commercially available, but not highly adopted, BE foods. Recordkeeping to substantiate a “may” claim would only need to demonstrate that the food is on the list.

Request for comments on recordkeeping provisions
AMS seeks comments on several aspects of the proposed recordkeeping requirements of the NBFDS. Specific questions are listed under “Request for Comments on Recordkeeping Provisions” in the Proposed rule.

COMPLIANCE

AMS intend that any final rule resulting from this rulemaking would become effective 60 days after the date of the final rule's publication in the Federal Register, with a compliance date of January 1, 2020, and with a delayed compliance date of January 1, 2021, for small food manufacturers. The proposed compliance dates are intended to provide a balance between the time industry will need to come into compliance with the new labeling requirements and the need for consumers to have the information in a timely manner.

AMS invites comment on the proposed compliance dates.