

September 29, 2009

Ron Buckhalt
USDA
Office of the Assistant Secretary for Administration
Room 342, Reporters Building
300 Seventh Street SW
Washington DC 20024

Dear Mr. Buckhalt:

I am writing on behalf of the Industrial and Environmental Section of the Biotechnology Industry Organization (BIO) with respect to the proposed rule for the Voluntary Labeling Program for Biobased Products (74 FR 38296). BIO is the world's largest biotechnology trade association with more than 1200 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

Below is a summary of primary recommendations from BIO's Industrial & Environmental Section, which comprises more than 80 companies that produce a wide array of biobased products, from fuels to fine chemicals and plastics. This is followed by detailed BIO comments responding to specific areas as solicited in the proposed rule.

Who can Apply for the Label

BIO strongly continues to support USDA's inclusion of intermediate ingredients and feedstocks in the voluntary labeling program.

Applicable Minimum Biobased Content

- BIO supports a minimum biobased content of anywhere between 20%-51% for non-designated intermediate ingredients and products
- In order to qualify for the label, there should also be some flexibility in minimum required biobased content to account for small variations in manufacturing and testing.

Label Content

In order to keep the label simple and clear for consumers, BIO supports the following:

- Percentage biobased content should be included in the label.
- The proposed "FP" designator to indicate that a product is eligible for preferred procurement should NOT be included on the label in order to avoid consumer confusion.

Definition of Intermediate Ingredients or Feedstocks

BIO requests clarification of the definition of "intermediate ingredients or feedstocks".

The Labeling of "Complex" Products

We strongly agree with the USDA that complex products are finished products, are separate and distinct from biobased products, and should be included in the labeling program.

The Labeling of Mature Market Products

We strongly agree with the USDA's proposal that products which are considered to be "mature market products" should not be eligible for participation in the labeling program.

Other Possible Label Content

USDA is considering the possible inclusion of information on product performance, life-cycle costs and environmental and human health effects on the label. We strongly recommend against the inclusion of any of this material on the label, as it would likely make the label confusing to purchasers.

Detailed Comments

BIO was one of the very first organizations to endorse and strongly support the Farm Bill's first ever energy title back in 2001 and 2002. The organization continues to support the title and greatly appreciates the expansion of the BioPreferred program in the 2008 Farm Bill. We also appreciate the hard work of the U.S. Department of Agriculture in implementing the BioPreferred and related programs that will bolster the rural economy, expand jobs in the agriculture and biotechnology sectors, and improve sustainability and energy security.

The proposed voluntary labeling program offers tremendous potential to expand biobased markets due to the credibility and visibility that the "USDA Certified Biobased Product" label can offer, both domestically and internationally. To achieve this potential, it is essential to recognize the role of the entire value chain from agricultural feedstocks (e.g. corn, soy, wood, fiber) to intermediate ingredients (biomonomers and polymers) to final products (carpet, apparel, lubricants, packaging, cosmetics, etc). ***We strongly support the inclusion of biobased intermediates as eligible to receive the label under the current rulemaking, and look forward to continued engagement with USDA on this as the program moves forward.***

Although the program has progressed rather slowly over the past seven years, we applaud the recent efforts by the experienced and dedicated team at the USDA Office of Departmental Administration to move the BioPreferred initiatives forward as expeditiously as possible. In order to keep the momentum, we urge a continued, concerted effort by the Department, along with significant cooperation from other federal entities such as the Office of Management and Budget, Office of the Federal Environmental Executive, and others to make the great potential of this program a reality.

We feel that the labeling program has the potential to be an important tool in stimulating biobased market development, and appreciate the opportunity to provide comments in response to the proposed rule. Included below are our specific comments on the program that will enhance its function and improve our ability to stimulate the biobased products industry.

1) Who can apply for the label?

a) For biobased intermediates, the voluntary labeling program presents the opportunity for USDA to reach down the value chain and create additional market pull for these materials upon which final products are based. ***Both intermediate ingredients in addition to final products made from intermediate ingredients should be eligible to receive the label.*** Additionally, to reduce administrative burden and streamline the application process, a finished product made from a qualifying biobased intermediate ingredient should be able to build upon the information already obtained through the USDA for the intermediate ingredient, and, as long as the product meets all other requirements, should qualify to receive the label.

2) Applicable Minimum Biobased Contents

a) ***BIO supports a required biobased content level of anywhere within 20-50% for undesignated intermediate ingredients or final products.*** As the program moves forward, we acknowledge and support USDA's intent to hold stakeholder sessions to finalize details surrounding minimum biobased content levels, intermediate feedstocks, complex products, and other issues. BIO will continue to participate in discussions with USDA and provide feedback on these issues.

b) ***In order to qualify for the label, there should also be flexibility in minimum required biobased content to account for small variations in manufacturing and testing.***

The USDA's proposed approach to establishing and enforcing biobased content levels does not take into account (1) the imprecision in the analytical testing method used to determine biobased content, or (2) manufacturing variations in the production of different batches of products or small formulation changes.

On the first point, the ASTM D6866 test method has precision of +/- 3% on the mean biobased content reported. Because of this, USDA has previously recognized the need for flexibility in establishing biobased content levels. For the BioPreferred procurement program item designations, rather than establishing the minimum biobased content of an item at the tested biobased content level, USDA sets the level at three (3) percentage points less than the tested value. USDA has stated that it "believes that this adjustment is appropriate to account for the expected variations in analytical results."

We urge the USDA to take the same approach in the labeling rule. Products should: (a) be eligible for certification if their biobased content falls within 3 percentage points of the minimum content level, (b) should be considered in compliance if their content falls within 3 percentage points of their label statement, and (c) should not have to reapply for certification if their content falls within 3 percentage points of their label statement.

On the second point, in any manufacturing process there will be some production variation. Also, small changes can be made to formulas over time. Therefore, we urge the USDA to allow a manufacturer applying for a label certification to establish a biobased content for the purpose of the label that may be below the actual D6866 test results in order to account for manufacturing variations. As currently written, the applicant does not appear to have that flexibility. The proposed rule appears to require that the percentage biobased content used for the label be exactly what is reported in the lab test results submitted with the application

c) We recommend that the USDA clarify and explicitly state whether domestic biobased carbon content is required. On "Criteria for Obtaining Certification" (page 38298), biobased product is defined with the language "including renewable domestic agricultural materials". This is a little ambiguous, but it appears that domestic versus foreign source new carbon content is irrelevant in the label application. USDA should state unambiguously and explicitly what the intent is here.

d) We urge that if minimum biobased content is established in the final rule, then the USDA should clearly specify the procedure and steps by which an applicant can request an exception to this minimum biobased content.

e) The proposed labeling contains a definition of "Intermediate Ingredients or Feedstocks" that varies from the statutory definition. In the proposed rule, USDA adds the following language to the definition:

"For the purposes of this subpart, intermediate ingredients or feedstocks do not include raw agricultural or forestry materials, but represent those materials that can be put into a new cycle of production and finishing processes to create finished materials, ready for distribution and consumption"

USDA provides no justification for this additional language. The language is ambiguous, as well as inconsistent with the statute and should not be included in the labeling program rule.

3) The Labeling of “Complex” Products

- a) *We strongly agree with the USDA that complex products are finished products and are separate and distinct from biobased products.*
- b) To avoid ambiguity, the USDA should include a definition of what is considered a “complex product” in its Definitions section, 2904.2.
- c) USDA should continue to work closely with ASTM or equivalent consensus based standards setting authorities to clarify the labeling of complex products.
- d) We recommend that for some complex products, such as a car, it is not practical, or even meaningful, to test and or calculate the overall biobased content of the car. Rather, there should be an option to label the components of that complex product with the biobased content. If a complex product, such as a car, includes components that contain biobased products (e.g., seats, headliners, dashboards), then one approach for doing this would allow a component (e.g., seat) that contained a “USDA Certified Biobased Product” to be eligible to use the label. For example, if the foam used to make the seat had a certification to use the label then that certification could be carried through to the seat. The label could read: “Seat: Contains Foam with XX% USDA Certified Biobased Content.”
- e) Finally, we recommend strongly that a potential lack of final complex product definition and how they are handled should NOT be used as a reason to delay issuing a final rule for voluntary labeling of biobased products. The rule can be readily amended as soon as procedures for complex products are established.

4) The Labeling of “Mature Market Products”

- a) *We strongly agree with the USDA’s proposal that products which are considered to be “mature market products” (i.e., products that had significant market penetration in 1972) should not be eligible for participation in the BioPreferred Labeling program as they could affect the entry of new (i.e., post-1972) biobased products into market segments in which mature market segments already have significant market shares.* Inclusion of “mature market products” would be counter to USDA’s objective to promote development and adoption of new technologies and biobased products.
- b) We recommend that the USDA not allow manufacturers of biobased products to appeal on a case-by-case basis the exclusion of their products. In enacting Section 9002, Congress made it clear that the purpose of the program, including the labeling program, was to grow the market for new biobased products. The value of the label for manufacturers and vendors of these products is to inform consumers that these new and innovative products are available and that USDA has certified the biobased content. If traditional products made of cotton, wood, linen, etc. are also labeled, the message to the consumer becomes confusing.
- c) The prior arguments notwithstanding, we understand that the USDA may still decide ultimately to allow manufacturers of mature market products to appeal. Should this occur in the final rule, then we recommend strongly that the USDA make very clear (a) the information regarding the criteria by which a manufacturer of mature market products can appeal, (b) the details of the appeal process, (c) and how the USDA will determine if an appeal is approved or not. We also recommend that if manufacturers of “mature market products” are allowed to appeal, then the appeal process should include a public comment period to allow the public to review the appeal and to submit comments.

5) The Appropriate Lengths for the Certification Periods

a) We believe that any change that would have significant impact on biobased content would necessitate the product being retested and recertified using ASTM D6866 – Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis.

b) USDA will be implementing an audit and enforcement program, and we believe this should be adequate to make sure applicants remain in compliance.

6) Preliminary Notice of Violations

a) We recommend a 60 day time period to ensure adequate timing (rather than the USDA’s proposed 30 day period) to correct any identified issues. In addition, we agree with USDA’s recommendation for a 60 day period (from the date the notice of violation is received) for the offending party to correct all other violations before a notice of suspension or other remedy is sought.

7) Biobased Content Testing Facilities

BIO has no additional comment on this section.

8) Clarification of Biobased Content of Product Versus Packaging on a Label

a) USDA is recommending that the label clearly identify for the consumer the item for which the label applies. We agree that the material (e.g., product, packaging or both product and packaging) to which the label applies should be clearly identified, and we believe that the USDA’s suggested wording for “product” and “packaging” are clear.

9) Identifying Products That Are Also Eligible for a Federal Procurement Preference Under the Preferred Procurement Program

a) USDA is proposing that biobased products that fall within designated items would be eligible for Federal preferred procurement and would use a label that includes the letters “FP”. *Since Federal procurement officials already have access to a list of products eligible for Federal procurement preference, the “FP” designator is unnecessary in order to inform Federal procurement officials about these items and should not be included in the label.* Since the label is intended to be a consumer communication tool, consumers will not recognize the significance of the “FP” lettering on products so labeled. Incorporation of the “FP” lettering may result in additional consumer confusion regarding the purpose of the label, create unnecessary clutter, and interfere with what is otherwise a clean, powerful, visual graphic.

10) Other Possible Label Content

a) The USDA is considering the possible inclusion of information on product performance, life-cycle costs and environmental and human health effects on the label. *We strongly recommend against the inclusion of any of this material on the label, as it would likely make the label confusing to purchasers.* Furthermore, such information is beyond the scope of the labeling program and is not authorized by the statute.

11) Legibility of the Label

a) We recommend that the USDA develop and make available a simple set of label usage guidelines specifying the proper use of the label and any accompanying text to ensure a legible and consistent presentation of this information.

12) Timeframe for Correcting Violations

- a) We support a 60 day time period, rather than the USDA's proposed 30 days, to ensure adequate timing to correct any identified issues with an offending party. In addition, we agree with USDA's recommendation for a 60 day period from the date the notice of violation is received for the offending party to correct all other violations before a notice of suspension or other remedy is sought.
- b) In addition, to provide more flexibility, USDA could consider adding a provision for "case-by-case" extensions of these periods to deal with special or extenuating circumstances, such as late reporting by a laboratory.

13) Recordkeeping

- a) We support the USDA's proposal that appropriate records be kept in order to allow USDA to verify all information associated with the labeling program and that these records be kept for at least 3 years beyond the end of the label certification period.

14) Benefits and Costs

- a) We strongly agree that the program benefits far outweigh the costs.

15) Application Fees

- a) The proposed application fee of \$500 is reasonable as long as the fee is allocated towards an auditing program.

Other Comments

BIO urges USDA to continue to seek input from all stakeholders, particularly the NGO community, as the labeling program develops. In the coming months, BIO will also be doing the same to gather feedback on this important program from NGOs.

We thank USDA for the opportunity to comment on the proposed rule, and look forward to continued engagement with USDA in the upcoming months to further discuss our comments. Please contact Jocelyne Modine at 202-962-6641, or jmodine@bio.org if you have any questions. Thank you again for your efforts and for giving us the opportunity to comment.

Sincerely,



Brent Erickson
Executive Vice President
Biotechnology Industry Organization