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7 CFR Part 2904

Voluntary Labeling Program for Biobased Products; Proposed Rule

DEPARTMENT OF AGRICULTURE

7 CFR Part 2904

RIN 0503–AA35

Voluntary Labeling Program for Biobased Products

AGENCY: Departmental Administration, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Agriculture (USDA) is proposing to establish a voluntary labeling program for biobased products under section 9002 of the Farm Security and Rural Investment Act of 2002, as amended by the Food, Conservation, and Energy Act of 2008. Under the proposed labeling program, a biobased product, after being certified by USDA, could be marketed using the ''USDA Certified Biobased Product'' label. The presence of the label will mean that the product meets USDA standards for the amount of biobased content and that the manufacturer or vendor has provided relevant information on the product for the USDA BioPreferred Web site. The proposed rule applies to manufacturers and vendors who wish to participate in the voluntary labeling program. The proposed rule also applies to other entities (*e.g.,* trade associations) that wish to use the label to promote biobased products.

DATES: USDA will accept public comments on this proposed rule until September 29, 2009.

ADDRESSES: You may submit comments by any of the following methods. All submissions received must include the agency name and Regulatory Information Number (RIN). The RIN for this rulemaking is 0503–AA35. Also, please identify submittals as pertaining to the ''Proposed Voluntary Labeling Program.''

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail/commercial/hand delivery:* Mail or deliver your comments to: Ron Buckhalt, USDA, Office of the Assistant Secretary for Administration, Room 342, Reporters Building, 300 Seventh Street, SW., Washington, DC 20024.
- Persons with disabilities who require alternative means for communication for regulatory information (Braille, large print, audiotape, *etc.*) should contact the USDA TARGET Center at (202) 720–2600 (voice) and (202) 690–0942 (TTY).

You may also send comments on the information collection aspects of this rule directly to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for Agriculture, Margaret Malanoski, 725 17th Street, NW., Room 10202, Washington, DC 20503. Comments should reference OMB control number 0503–NEW.

FOR FURTHER INFORMATION CONTACT: Ron Buckhalt, USDA, Office of the Assistant Secretary for Administration, Room 342, Reporters Building, 300 Seventh Street, SW., Washington, DC 20024; e-mail: *biopreferred@usda.gov*; phone (202) 205–4008. Information regarding the Federal Procurement Program of Biobased Products (one part of the BioPreferred Program) is available on the Internet at *http://www.biopreferred.gov.*

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Background

A. Authority

The voluntary labeling program for biobased products is proposed under the authority of section 9002 of the Farm Security and Rural Investment Act of 2002 (FSRIA)(referred to in this preamble as ''section 9002''), as amended by the Food, Conservation, and Energy Act of 2008 (FCEA), 7 U.S.C. 8102.

B. Overview of Section 9002

Section 9002 establishes a program for the Federal procurement of biobased products by Federal agencies and a voluntary program for the labeling of biobased products. These two programs, which are referred to collectively by USDA as the BioPreferred℠ Program, are briefly discussed below.

Federal Procurement of Biobased Products. Section 9002 requires Federal agencies to develop procurement programs that give preference to the purchase of biobased products (hereafter referred to in this **Federal Register** notice as the ''preferred procurement program''). Federal agencies and their contractors are required to purchase biobased products, as defined in regulations implementing the statute, that are within designated items [1] when the cumulative purchase price of the procurement item(s) procured is more than $10,000 or when the quantities of functionally equivalent items purchased over the preceding fiscal year equaled $10,000 or more. Each Federal agency and contractor must procure biobased products at the highest content levels within each designated item unless the agency determines that the items are not reasonably available, fail to meet applicable performance standards, or are available only at an unreasonable price.

The final guidelines for the preferred procurement program were published in the **Federal Register** on January 11, 2005 (70 FR 1792). The guidelines are contained in 7 CFR part 2902, ''Guidelines for Designating Biobased Products for Federal Procurement.''

Part 2902 is divided into two subparts, ''Subpart A—General,'' and ''Subpart B—Designated Items.'' Subpart A addresses the purpose and scope of the guidelines and their applicability, provides guidance on product availability and procurement, defines terms used in part 2902, and addresses affirmative procurement programs and USDA funding for testing. Subpart B identifies designated items and specifies their minimum biobased contents, the effective date of the procurement preference for biobased products within each designated item, and other information (*e.g.,* biodegradability). USDA is responsible for designating biobased items at the highest practicable biobased content levels for the Federal agencies' preferred procurement programs.

[1] The term ''designated item'' refers to items (generic groupings of specific products that perform the same function) that have been afforded preferred procurement by Federal agencies under the BioPreferred Program.

As part of the preferred procurement program, section 9002 also requires USDA to provide information to Federal agencies on the availability, relative price, performance, and environmental and public health benefits of products within such items and, as applicable under section 9002(e)(1)(C), to recommend the minimum level of biobased content to be contained in the products within a designated item.

To date, USDA has designated 33 items used in a variety of applications, including cafeteria ware, personal and institutional cleaning products, construction products, and lubricants and greases.

Voluntary Labeling Program. Section 9002 also requires USDA to establish a voluntary labeling program under which USDA authorizes manufacturers and vendors of biobased products to use a ''USDA Certified Biobased Product'' label (hereafter referred to in this preamble as ''the label''). The voluntary labeling program is intended to encourage the purchase and use of biobased products by reaching beyond the Federal purchasing community and promoting the purchase of biobased products by the general public. In establishing this program, USDA must identify the criteria to determine those products on which the label may be used and must develop specific requirements for how the label can be used. It is USDA's intent that the presence of the label on a product will mean that the labeled product is one for which credible factual information is available as to the biobased content, consistently measured across labeled products by use of the ASTM radioisotope test D6866.

In developing the proposed voluntary labeling program, USDA held discussions with other agencies that have implemented labeling programs, such as the ''ENERGY STAR®'' program implemented by the U.S. Department of Energy and the U.S. Environmental Protection Agency (EPA). USDA has also consulted with representatives of the Department of Agriculture's National Organic program and others of the Agricultural Marketing Service. Further, USDA consulted the Federal Trade Commission, which issues the ''Guides for the Use of Environmental Marketing Claims'' to ensure that the provisions of the proposed voluntary labeling program were consistent with the Guides. USDA also held a public meeting on July 22, 2008, to seek input on the content and use of the label from the public and industry stakeholders.

The following section of the preamble presents the goal of the voluntary labeling program and the objectives toward achieving that goal. That section is followed by a summary of the voluntary labeling program that USDA is proposing to implement under section 9002(h).

II. Goal of the Voluntary Labeling Program

USDA's goal in proposing this voluntary labeling program is to encourage the increased use of biobased products in all market sectors. To achieve this goal, USDA has identified the following objectives:

Promotion of biobased products. The voluntary labeling program is intended to promote and increase the use of biobased products. In general, the labeling program supports this goal by recognizing manufacturers and vendors that produce and market products that utilize biobased materials and by encouraging consumers to purchase such products.

Whereas the preferred procurement program is specific to Federal agencies, the voluntary labeling program is intended to encompass all individuals and organizations making purchasing decisions. We are proposing that there be two slightly different versions of the label, one for those biobased products that have been designated for Federal preferred procurement because they are within a designated item, and another for those products that are not within a designated item. The label artwork for products within designated items would include the letters ''FP'' to indicate that they are Federally preferred. USDA believes that informing consumers that these products have been designated for Federal preferred procurement will be beneficial. As part of the process of designating items for preferred procurement, USDA gathers and evaluates information regarding the biobased product's life cycle costs and environmental performance as well as functional performance. Thus, the ''FP'' on the label will inform consumers that USDA has evaluated representative products within the designated item and found them to be qualified for the Federal preferred procurement program. USDA also notes that the identification of products that have been designated for preferred procurement would also be accomplished by listing those products on the USDA Web site and in Federal procurement catalogues.

Furthermore, the voluntary labeling program will increase the amount of information available to manufacturers whose products may utilize biobased materials or products as a component of their finished products or as part of their manufacturing process. USDA expects that this increased information will encourage these manufacturers to consider using and/or increasing the amount of biobased materials when designing or manufacturing their products, thereby further increasing the purchase of biobased materials. For example, manufacturers of equipment that uses hydraulic fluids are encouraged to consider the use of biobased hydraulic fluids if available information indicates that the performance of these fluids meets or exceeds their requirements.

Increase public awareness of biobased products. The voluntary labeling program will raise the visibility of biobased products within the Federal government and within the commercial marketplace. The labeling program will also provide a unique and identifiable designator recognized in the U.S. and foreign markets.

To the extent that the voluntary labeling program achieves these objectives, there may be an increased purchase of biobased products, which is then expected to reduce petroleum consumption, increase the use of renewable resources, better manage the carbon cycle, and, may contribute to reducing adverse environmental and health impacts. The program is also expected to promote economic development for biobased product manufacturers and vendors by creating new jobs and providing new markets for farm commodities.

III. Voluntary Labeling Program

In developing the voluntary labeling program, USDA has one primary goal—to encourage the purchase of biobased products. In implementing this goal, USDA aims to ensure that only biobased products that meet the criteria set forth in the voluntary labeling program are labeled with the ''USDA Certified Biobased Product'' label and that the label is used properly. USDA believes that products carrying the label will become readily recognizable as biobased products, distinct from those that do not carry the label. Further, as the label will have the percent of biobased material printed on it, consumers will recognize that products carrying the label meet certain criteria that set them apart from other products.

A. Applicability

The proposed rule would apply to manufacturers and vendors of biobased products, as well as to other entities (*e.g.,* trade associations, public interest groups) that promote, sell, or use the products. USDA believes that each of these groups must comply with the labeling requirements in order to ensure that only certified biobased products

(*i.e.,* biobased products that have been approved for use of the label under this program) carry the label and that the label is used correctly. USDA believes that the goals of the voluntary labeling program can be achieved, and the beneficial impacts of the BioPreferred program can be increased, if manufacturers, vendors, and other entities are allowed to market and promote the manufacturers' biobased products with a credible biobased products labeling program.

Once USDA has approved a biobased product for labeling by its manufacturer or vendor, an equally important aspect in ensuring the integrity of the labeling program is the proper use of the label. Label misuse can occur at the manufacturer level (*e.g.,* affixing the label to a non-certified biobased product) and at the retail level (*e.g.,* using the label to imply that a non-certified biobased product has been certified), or by other entities wishing to use the label in promoting the sales or public awareness of non-certified biobased products (*e.g.,* on a Web site or in promotional materials).

While the labeling of biobased products is voluntary, manufacturers, vendors, and other entities wishing to use the label in their marketing, promotional, or educational efforts would be required to comply with regulatory requirements as proposed herein. USDA believes these requirements for use of the label are necessary to avoid misleading consumers regarding whether a product has been certified by USDA under the voluntary labeling program.

B. Criteria for Obtaining Certification

To be eligible for USDA certification to use the label, USDA proposes that a product meet two criteria, as discussed below.

Criterion 1: Biobased Product. The product must be a biobased product. Biobased product is defined in section 2904.2 of today's proposed rule as follows: ''The term 'biobased product' means a product determined by the Secretary to be a commercial or industrial product (other than food or feed) that is—(A) composed, in whole or in significant part, of biological products, including renewable domestic agricultural materials and forestry materials; or (B) an intermediate ingredient or feedstock. For the purposes of this subpart, the term 'biobased product' does not include motor vehicle fuels, heating oil, electricity produced from biomass, or any mature market products. Products from a mature market will be determined on a case-by-case basis.''

Rationale for Criterion 1: As discussed earlier, section 9002 requires USDA to establish a voluntary labeling program under which USDA authorizes manufacturers and vendors of biobased products to use a ''USDA Certified Biobased Product'' label. USDA is proposing that mature market products not be eligible to use the label except on a case-by-case basis. Mature market products are those biobased products that had significant national market penetration in 1972. Examples of mature market products include cotton shirts or towels, paper plates, and wood furniture. USDA has excluded mature market products from the Federal preferred procurement program. In USDA's explanation for excluding mature market products from the preferred procurement program, USDA stated in the preamble to the final Guidelines (70 FR 1802), ''The intent of section 9002, as described in the conference report accompanying FSRIA, 'is to stimulate the production of new biobased products and to energize emerging markets for those products.' ''

Based on conference report, it is clear that Congress did not intend for mature market products to be given Federal procurement preference. It is not clear, however, whether this exclusion of mature market products was intended to apply to the voluntary labeling program. The procurement preference program and the labeling program are contained in different paragraphs of the statute, and the conference report does not specifically state whether the language quoted above refers to just one or to both paragraphs.

USDA believes, however, that the widespread labeling of mature market products could negatively impact the entry of new biobased products into market segments in which mature products already have significant market shares. Thus, USDA believes that it is reasonable to exclude many mature market products from the labeling program, as it has done for the preferred procurement program. USDA is, however, proposing to allow manufacturers of mature market products to appeal (on a case-by-case basis) the exclusion of their products from the program.

Criterion 2: Minimum Biobased Content. For a biobased product to receive certification under this proposed rule, the biobased content of that product must be at or above its applicable minimum biobased content, as described below. USDA believes this requirement is necessary so that the label is not used to promote products with de minimis biobased content. As discussed below, the applicable minimum biobased content depends under which of the three proposed categories the product falls.

1. *Biobased products within one or more designated items.* If a biobased product (including an intermediate ingredient or feedstock) is within a designated item at the time of submitting an application for certification, the applicable minimum biobased content for use of the label would be the minimum biobased content specified for that item in 7 CFR 2902. As discussed in more detail below, once an item has been designated, its minimum biobased content, as specified in 7 CFR part 2902, becomes the applicable minimum biobased content for all products within that designated item, regardless of any previous minimum biobased content used to qualify a product for using the label.

If a biobased product is marketed within more than one designated item, and uses the same packaging, its biobased content must meet or exceed the specified minimum biobased content for each of the designated items in order to use the label for each item. For example, Product A is currently marketed as a ''glass cleaner'' and a ''bath and tile cleaner'' and uses the same packaging in both markets. USDA has designated both these categories of products as items under its BioPreferred procurement program. Product A has a biobased content of 60 percent. The minimum biobased content of designated item ''glass cleaners'' is 49 percent and the minimum biobased content of designated item ''bath and tile cleaners'' is 74 percent. The manufacturer would not be eligible to apply for use of the label for Product A under either designated item. If the biobased content of Product A were instead 80 percent, the manufacturer would be eligible to use the label under both designated items.

If, on the other hand, the manufacturer packaged the product in different packaging for marketing within the two designated items (*e.g.,* a blue bottle for the glass cleaner and a green bottle for the bath and tile cleaner), the product marketed as a glass cleaner would be eligible to apply to use the label while the product marketed as bath and tile cleaner would not be eligible.

2. *Finished biobased products that are not within designated items.* If a biobased product is not within a designated item at the time the application for certification is submitted, the applicable minimum biobased content for the product for using the label would be 51 percent,

unless USDA approves an alternative applicable minimum biobased content. The proposed rule would allow manufacturers, vendors, and trade associations (individually or collectively) who believe that the 51 percent minimum biobased content is not appropriate for the biobased product to conduct an analysis, as discussed under ''Alternative Minimum Biobased Content Analysis'' later in this preamble, to support an alternative applicable minimum biobased content. If USDA approves the alternative applicable minimum biobased content, then that content becomes the applicable minimum biobased content for that product.

USDA recognizes that there will be groups of biobased products that will be certified to use the label that will never be designated for preferred procurement, primarily because these products are produced by only one manufacturer and, thus, there is not sufficient market competition to justify preferred procurement or they are not used prevalently in the Federal marketplace. However, USDA expects that the majority of the biobased products certified to use the label will be within a group of products that USDA designates for preferred procurement. In those cases where USDA subsequently designates an item under which the certified biobased product falls for inclusion in the preferred procurement program, the applicable minimum biobased content for the product will then become the minimum biobased content established for the designated item under which the product falls. As of the effective date of the designation, only those products that meet the new minimum biobased content may continue to use the label.

3. *Products that are intermediate ingredients or feedstocks that are not within designated items.* If a biobased product is an intermediate ingredient or feedstock and is not within a designated item at the time the application for certification is submitted, the applicable minimum biobased content for the product for using the label would be 51 percent, unless USDA approves an alternative applicable minimum biobased content. As with the previous product category, the proposed rule would allow manufacturers, vendors, and trade associations (individually or collectively) who believe that the 51 percent minimum biobased content is not appropriate to conduct an analysis, as discussed under ''Alternative Minimum Biobased Content Analysis'' later in this preamble, to support an alternative applicable minimum biobased content. If USDA approves the alternative applicable minimum biobased content, then that content becomes the applicable minimum biobased content for that product.

Rationale for Criterion 2: USDA believes setting the applicable minimum biobased content of products within designated items at the minimum biobased content specified under the preferred procurement program is appropriate, as USDA has had an opportunity to perform an analysis on these products, including identifying similar biobased products and their manufacturers, and obtaining biobased contents for similar biobased products. USDA intends to proceed with the designation of numerous items for which it has, or is currently gathering, information. Once the designation process has been completed for those items that have been identified for designation, USDA intends to revisit, on a periodic basis, the minimum biobased content that was established for designated items at the time of their designation. As scientific advances and economic conditions warrant, USDA would expect that the applicable minimum biobased content for designated items will rise as competitors apply advances and increase the biobased content of designated products. Thus, it is USDA's expectation that the applicable minimum biobased content of designated items will increase as advancements are made in biobased product technology. USDA also notes that proposed revisions to the applicable minimum biobased content for designated items will be announced in the **Federal Register** and the public will have an opportunity to provide comments on the proposal.

For the second and third categories of products (finished biobased products and intermediate ingredients and feedstocks that are not within designated items) USDA considered several options for setting the minimum biobased content, including the use of the lowest minimum biobased content for any item designated to date. USDA decided, however, that in the absence of the level of detailed product information for setting a minimum biobased content based on product-specific data (as is used under the preferred procurement program), and in an effort to discourage minimal use of biobased feedstocks in what are otherwise not biobased products, it is reasonable to consider such finished products as ''biobased'' if they contain a significant amount of biobased materials; that is, at least 51 percent of the product is biobased. Thus, USDA is proposing that all finished products that are not within designated items and all intermediate ingredients and feedstocks that are not within designated items must contain at least 51 percent biobased content to be qualified for the label.

USDA recognizes, however, that for some finished products (and intermediate ingredients) a 51 percent minimum biobased content may result in a product that is not viable. USDA also recognizes that the 51 percent minimum biobased content could discourage the development of new biobased products or the continued development of existing biobased products. With this in mind, USDA will continue to gather product-specific data under the preferred procurement program to determine applicable minimum biobased contents. Additionally, USDA believes that it is reasonable to provide a procedure to allow manufacturers, vendors, and trade associations to propose an alternative applicable minimum biobased content for such products.

Alternative Minimum Biobased Content Analysis

As noted above, manufacturers, vendors, and trade associations would be allowed to propose an alternative minimum biobased content for products not within a designated item if they believe that the proposed minimum biobased content is not appropriate for their product(s). For USDA to consider an alternative minimum biobased content for these types of products, manufacturers, vendors, and trade associations would be required to develop an analysis, in consultation with USDA, that demonstrates the need for an alternative applicable minimum biobased content. USDA believes that manufacturers, vendors, and trade associations should consult with the Department in developing the analysis to help ensure that an appropriate analysis is conducted.

While the analysis of the data supporting a specific request for an alternative minimum biobased content will be performed on a case-by-case basis, USDA anticipates that the evaluation process will be standardized and will be similar to the process used to set minimum biobased contents under the preferred procurement program. Such a process would include identifying similar biobased products and their manufacturers and determining biobased contents for similar biobased products. USDA recognizes the difficulties involved in collecting biobased contents, due in large part to the unpredictability of manufacturer and vendor participation

in providing products for testing. Similar to the process used in the preferred procurement program, the establishment of alternative minimum contents for the labeling program will require a measure of flexibility to address the variability in product type and level of industry development. In general, the number of samples that should be obtained for the biobased content analysis would depend on the number of manufacturers of a product and similar products available. USDA would expect applicants to coordinate with program officials to identify and agree upon a reasonable number of samples for the analysis. Emphasis would be focused on obtaining the maximum number of samples possible without restricting the analysis process.

C. Initial Approval Process

Application

Manufacturers and vendors seeking use of the label on a qualified biobased product must submit to USDA a separate USDA-approved application for certification for each product for which the manufacturer or vendor wishes to receive USDA approval to use the label. Both the application and instructions for submittal of the application will be available on the USDA BioPreferred Web site.

Each application must contain both contact and product information. Contact information would include the applicant's name, mailing address, e-mail address, and telephone number, and the name, mailing address, telephone number, and e-mail address (if available) of the person who prepared the application.

Product information would include the brand names or other product identifying information (such as model name or number, or UPC number) for the product, the biobased content of the product for which certification is sought, contact information on the third-party testing entity that tested the biobased content and documentation that the testing entity is ISO 9001 conformant, the product category under which the product falls, and the intended uses of the product. If the product falls within a designated item(s), the applicant would also identify the name of the designated item(s).

Lastly, the applicant would be required to sign a statement that certifies that the product identified in the application is a biobased product as defined in the labeling program and commits the applicant to provide to USDA, and to keep up-to-date, the product's brand name(s), or other identifying information; contact information, including the name, mailing address, e-mail address, and telephone number of the applicant; the biobased content of the product; and a hot link directly to the applicant's Web site (if available). USDA is also requiring that if manufacturers make claims on the product packaging about the environmental and human health effects, life-cycle costs, sustainability benefits, and performance of their products that documentation supporting such claims be maintained.

Justification for Required Information

USDA considers the information required for the initial approval process to be the minimum that will be needed by USDA to confirm that products meet the criteria for certification. The following paragraphs summarize the rationale for requiring the information specified.

Contact Information. This information is necessary for communicating with the applicant concerning any issues with the application, whether the application is deficient, and whether the application has been approved.

Brand Names. Because a manufacturer or vendor may market the same product under different brand names (or other product identifiers such as model names or numbers), the application requires that all brand names or other applicable product identifiers for that product be provided. This will prevent the necessity of multiple applications from the same manufacturer or vendor for the same product.

Biobased Content Information. For products in the three categories discussed earlier, the biobased content of the product for which certification is sought would be determined by ISO 9001 certified or conformant,[2] third-party testing firms using ASTM Method D6866, ''Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis.''

In the case of a product that is marketed under different brand names, the proposed rule would allow the manufacturer or vendor to test the product once rather than requiring brand-name specific data, thereby minimizing unnecessary testing of the same product that is simply marketed under different brand names.

The applicant is required to provide the product's biobased content, as determined using ASTM Method D6866, and contact information on the entity that performed the testing. The applicant is also required to provide documentation that the third-party testing entity that determined the biobased content reported for the product is ISO 9001 conformant. This information is necessary to demonstrate that the product's biobased content meets or exceeds the applicable minimum biobased content and that a qualified, independent, third-party testing entity conducted the testing.

Product Category. The applicant is required to identify whether the product (1) falls within one or more designated items under the preferred procurement program (and if so, the applicant is required to identify the item(s)), (2) is a finished biobased product that is not within a designated item, or (3) is an intermediate ingredient or feedstock that is not within a designated item. This information is necessary to identify the applicable minimum biobased content and then to ensure that the biobased content of the product meets or exceeds the applicable minimum biobased content.

Intended use(s). The applicant is required to provide a description of the intended uses of the product (*e.g.,* as a glass cleaner or as a penetrating lubricant). USDA will use this description to confirm that the product is assigned to the appropriate designated item(s), if applicable. This will also allow USDA to determine if a product should have been assigned to a designated item, if the application incorrectly indicates that the product falls outside the designated item category.

Certifications and statements. The applicant must certify that the product for which certification is sought is a biobased product, as defined by the labeling program. USDA is proposing that applicants certify to this criterion and keep appropriate records to demonstrate that the product complies with this certifying statement, which USDA can then review during an audit. This condition must be met in order to ensure compliance with statutory requirements under which the voluntary labeling program is being established.

As noted earlier in this preamble, the applicant is also required to commit to providing to USDA information, and keeping it up-to-date, for posting by USDA on the BioPreferred Web site. This information includes the product's brand name(s) or other product identifiers; contact information, including the name, mailing address, e-mail address, and telephone number of the applicant; biobased content; and a

[2] ISO 9001 conformant means that the entity meets the requirements of ISO 9001, but is not required to be ISO 9001 certified.

hot link directly to the applicant's Web site (if available).

While USDA is not requiring manufacturers to analyze the environmental and human health effects, life-cycle costs, sustainability benefits, and performance of their products, manufacturers making claims regarding these attributes of their products must maintain documentation to substantiate those claims pursuant to the Federal Trade Commission (FTC) Act. Section 5 of the FTC Act (15 U.S.C. 45) makes unlawful deceptive acts and practices in or affecting commerce. The FTC ''Guides for the Use of Environmental Marketing Claims'' (16 CFR part 260) state that ''any party making an express or implied claim that presents an objective assertion about the environmental attribute of a product, package or service must, at the time the claim is made, possess and rely upon a reasonable basis substantiating the claim.''

Evaluation

USDA will evaluate each application to determine if it is a ''complete'' application (*i.e.,* that it contains all of the required information). If USDA determines that the application is not complete, it will return the application to the applicant and provide an explanation of the deficiencies in the application. Once the deficiencies have been addressed, the applicant may resubmit the application for review by USDA.

USDA will evaluate each complete application to determine if the product meets the criteria for certification discussed above (and specified in § 2904.4). There will be no specified deadline for application submissions; applications will be worked on in a first come first serve basis. Based on this evaluation, USDA either will conditionally approve the application or will disapprove the application. USDA will provide to each applicant a written response within 60 days after the receipt of a complete application, informing the applicant whether or not its application has been conditionally approved or has been disapproved. An applicant who receives notice from USDA that its application has been conditionally approved may not begin using the label on its product until the applicant receives a notice of certification from USDA (see next paragraph). For those applications that are not approved, USDA will notify the applicant and identify each criterion not met. Applicants whose applications are not approved have the right to appeal under the proposed program first to USDA's BioPreferred program office and then to USDA policy officials.

Notice of Product Certification

After an applicant receives notice from USDA that its application (for the product to bear the label) has been conditionally approved, the applicant must provide certain information, as discussed in Section E in this preamble, to USDA. Once USDA has confirmed that the information supplied by the applicant is complete, USDA will approve the product label application and will issue a notice of product certification to the applicant. USDA will include in the notice of certification information necessary for the applicant to access the applicable label artwork from the USDA BioPreferred Web site. Upon receipt of the notice of certification, the applicant may begin using the label on the certified biobased product.

Term of Product Certification

The effective (beginning) date of the product certification is the date that the applicant receives the notice of certification from USDA. The certification will remain valid for as long as the biobased product is manufactured in accordance with the information supplied in the approved application and presented on the USDA Web site, with one exception. As discussed earlier, it is USDA's intent that the applicable minimum biobased content of designated items will increase over time as advancements are made in biobased product technology. If the applicable required minimum biobased content for a product to be eligible to display the label is revised by USDA, manufacturers and vendors may continue to label their previously certified product only if it meets the new minimum biobased content level. In those cases where the biobased content of a certified product fails to meet the new minimum biobased content level, USDA will notify the manufacturer or vendor that their certification is no longer valid. Such manufacturers and vendors must increase the biobased content of their product to a level at or above the new minimum biobased content level and must re-apply for certification within 60 days of receiving USDA's notice if they wish to continue to use the label. Manufacturers and vendors who have re-applied for certification may continue using the existing label until they receive notification from USDA on the results of their re-application for certification.

USDA considered proposing a certification period of either three or five years, but decided that a fixed certification period was unnecessary and that the process of reapplying every three or five years would impose an undue burden on manufacturers who did not reformulate their products. In the case of items that become designated, it is likely that the required minimum biobased content for the item could be different from the 51 percent level used to qualify the item before it was designated. USDA believes that, in those cases, only those products that meet the new minimum biobased content should be eligible to display the label. Thus, USDA is proposing that if a certified product's biobased content is below the newly established minimum biobased content, the manufacturer must discontinue applying the label as of the effective date of the item designation. The same would be true in any other case where USDA, through established notice and comment rulemaking procedures, revises the minimum biobased content applicable to a previously certified product.

USDA points out that affixing the label to a certified biobased product does not imply that the useful life or the shelf life of the product has been affected in any way. Purchasers of labeled certified biobased products, therefore, should continue to look to information from the manufacturer or vendor to ascertain whether a product will perform as advertised at the time the purchase is made.

D. Appeals

Today's proposed rule includes provisions for appeal by an applicant whose application for certification is denied by USDA. In addition, entities that have been cited for a violation or that have received a notice of suspension or a notice of revocation may also file an appeal. All appeals must be filed within 30 days of receipt of the applicable notice. Appeals must be made in writing to the Program Manager of the Voluntary Labeling Program for Biobased Products and must contain, in part, a statement, including appropriate substantiating documentation, of the appellant's reasons for believing that USDA wrongfully denied the application or issued a notice of violation, suspension, or revocation. If the appellant is dissatisfied with the results of this appeal, he/she may raise the appeal to the Assistant Secretary for Administration by letter request. Appeals to the Assistant Secretary for Administration must be filed within 30 days of receipt of the notice of decision from the appeal to the Program Manager.

The proposed rule also includes provisions for manufacturers or vendors of mature market products to appeal the exclusion of their products from the voluntary labeling program if they believe that conditions justify the use of the label on their products.

E. Information Posted on Web Site

Before USDA issues the notice of certification to a manufacturer or vendor to use the label on a biobased product, the manufacturer or vendor must submit contact and product information to USDA, which USDA will then post on the USDA BioPreferred Web site (which can be accessed at *http://www.biopreferred.gov*). This information must be complete and must be provided to USDA before USDA will provide to the manufacturer or vendor, the notice of certification and the information for accessing the label artwork. The information that must be provided to USDA is:

- Product brand name(s) or other identifying information;
- Contact information for the applicant;
- Biobased content level; and
- A hot link directly to the applicant's Web site (if available).

In addition to the information listed above, USDA encourages manufacturers to provide other information related to product features and applicability for posting to the Web site.

USDA believes that making the information identified above available on the USDA BioPreferred Web site will be an extremely valuable step in establishing a database of certified biobased products. Ideally, both Federal agencies and public consumers will be able to readily access information that will help them in their decision-making regarding the purchase of biobased products. USDA believes that making this information available not only to Federal agencies, but also to public consumers will result in increased consumer awareness of and use of biobased products. USDA is also proposing that manufacturers of certified biobased products must include the USDA Web site address on or in close proximity to the label.

Manufacturers must provide to USDA updated information for posting by USDA to the USDA BioPreferred Web site whenever any of the information on the Web site becomes outdated or if additional relevant information becomes applicable. As discussed in Section I of this preamble, failure to provide USDA with updated information will be considered a violation of the requirements of the labeling program.

F. Applications for Reformulated Products

A manufacturer may decide to change the formulation of a certified biobased product for various reasons including performance issues, raw material availability, or changes in production processes. As discussed earlier, manufacturers may also be required to reformulate products that are within designated items in response to USDA re-evaluating and increasing the applicable minimum biobased content for products within the designated item. For such reformulated products to be eligible for USDA certification to use the label, USDA proposes that a new application be submitted to USDA, as discussed below.

If a certified product's biobased content is decreased by any amount, a new application would be required. In any case where the biobased content of a product is decreased from the original formulation, the biobased content of the reformulated product must still be at or above the applicable minimum biobased content for the product in order for the product to qualify for the label.

In the case of a product whose biobased content is reduced, the manufacturer or vendor cannot affix the label to the reformulated product until they have submitted a new application, provided USDA with the required information on the reformulated product for posting to the USDA BioPreferred Web site, and received the notice of certification for the reformulated product from USDA. If the manufacturer or vendor also continues to sell the product in its original formulation, the manufacturer or vendor may continue to affix the label to the original product.

If a certified product's biobased content is increased, and the manufacturer wishes to change the label to report the higher value, a new application would be required. The manufacturer or vendor may continue to affix the label to the reformulated product. However, the manufacturer or vendor may not revise the biobased content displayed on the label until they have submitted a new application, provided USDA with the required information on the reformulated product for posting to the USDA BioPreferred Web site, and received the notice of certification for the reformulated product from USDA.

G. Requirements Associated With the Label

Today's proposed rule establishes specific requirements for the use of the label. The requirements in today's proposed rule specify who may use the label, correct and incorrect uses of the label, the physical appearance of the label, and restrictions on the use of the label. These requirements are summarized in the remainder of this section.

USDA is also developing a Marketing Guide that will be made available to manufacturers and vendors of labeled products. The purpose of this Marketing Guide is to provide expanded discussions of, and guidance on resolving, implementation issues that may arise related to the use of the label. For example, USDA anticipates that there will be questions related to the best way to apply the label on very small products, such as those within the designated item ''lip care products.'' USDA believes that a Marketing Guide, that can be updated frequently, is the most efficient way to keep label users informed of guidance provided by USDA in response to implementation issues that arise.

Who May Use the Label?

Any manufacturer or vendor who has received notice of certification from USDA, and any designated representative of such manufacturers and vendors, may use the label on the product and its associated packaging and in the advertising of the certified biobased product. As proposed, only the manufacturer or vendor (and their designated representatives) of a certified biobased product would be granted the authority to affix the label to the product. The process of applying for and receiving certification requires specific knowledge of the product and its characteristics and formulation. Obtaining certification also imposes the requirement on the manufacturer and vendor to provide certain information to USDA, which USDA will then post on the USDA BioPreferred Web site.

Other entities may use the label to advertise or promote certified biobased products (*e.g.,* in catalogs or procurement databases), as long as the manufacturer or vendor of the product (or one of their designated representatives) has affixed the label to the product or its packaging. USDA believes that allowing other entities to use the label in informational, promotional, and educational materials for certified biobased products will promote the goal of encouraging the use of biobased products.

Use of the Label

The label may be affixed only to products (or associated packaging) for which a manufacturer or vendor has received a notice of certification under

this part. USDA's intent is for the label to be used by manufacturers, vendors, and other entities to distinguish biobased products that meet or exceed the criteria established by USDA from those that do not meet the criteria. It is also important that the label be used in a consistent manner such that the label and its meaning will become recognizable in the marketplace. Use of the label on non-certified products or alterations in the appearance of the label may confuse consumers and diminish the value of not only the label, but also the entire biobased product program. Therefore, USDA has identified correct and incorrect uses of the label, which are discussed in the following paragraphs.

Correct Uses. Proposed section 2904.7 identifies correct usages of the label. These include, but are not limited to the following:

- The label may be used in advertisements, catalogs, procurement databases, Web sites, and promotional and educational materials;
- The label may appear next to a picture of the product(s) or text describing the product(s); and
- The label may be used without reference to a specific certified biobased product only when informing the public about the purpose of the label. For example, the following or similar claim is acceptable: ''Look for the 'USDA Certified Biobased Product' label. It means the product meets USDA standards for the amount of biobased content and the manufacturer or vendor has provided relevant information on the product for the USDA BioPreferred Web site.'' This exception allows manufacturers, vendors, and other entities to use the label in documents such as corporate reports, but only in an informative manner, not as a statement of product certification.

Incorrect Uses. Proposed § 2904.7 also identifies incorrect usages of the label. These include, but are not limited to the following:

- The label may not be used on non-certified products or in advertisements or informational materials for non-certified products;
- The label may not be used to imply endorsement by USDA or the BioPreferred Program of any particular product, service, or company; and
- The label may not be used in any form that could be misleading to the consumer, or on business cards, company letterhead, or company stationery.

Imported Products

Because other countries may have different definitions of ''biobased'' and/or use other terms, it is necessary to address the use of the label on products for import. The ''USDA Certified Biobased Product'' label signifies that a product meets specific USDA criteria for biobased products. Therefore, in order for products imported for sale in the U.S. to carry the label, they must meet the same criteria as U.S.-sourced biobased products, and their manufacturers and vendors must apply for certification to use the label, even if the products are considered biobased products in the country in which they are manufactured.

Contents of the Label

The label must consist of the following:

- The logo with the phrase ''USDA Certified Biobased Product'' and, where applicable, the letters ''FP'' to indicate that the product is within a Federally preferred designated item (this label content is collectively referred to as the ''label artwork''); and
- A statement that identifies the biobased content of the product, as reported in the approved application for the product at the time the label is affixed to the product or its packaging, and whether the label applies to the product or packaging.

USDA is proposing that the statement that identifies the biobased content also indicate whether the label applies to the product or the packaging (*e.g.,* Product: 57% biobased; Packaging: 90% biobased). The USDA is proposing that this statement be included in the label in order to make it clear as to what the certified biobased product is. USDA believes that there will be instances where the placement of the label on a product or its packaging will not clearly identify the certified biobased product. For example, it is possible that a label placed on a container will refer to the container itself (in which case the statement ''Packaging: XX% biobased'' would be used) or to the contents within the container (Product: YY% biobased). It may also be possible that both the container and its contents are certified biobased products, in which case two statements would appear (Product: YY% biobased. Packaging: XX% biobased). Without tying the label to the product or the packaging, the consumer may be unable to determine which product is the certified biobased product. Therefore, USDA is proposing that the appropriate statement(s) be included in the label in order to identify clearly the product or products to which the label applies.

Furthermore, the proposed rule requires that, at the time the label is affixed to the product or its packaging, the biobased content shown on the label is the same as the biobased content found in the approved application for the product. It is possible, however, that the biobased content of a certified product could be changed by the manufacturer. If a certified product's biobased content is changed to a level below that shown on the label, the product is considered a reformulated product and a new application is required. If a certified product's biobased content is increased and the manufacturer wishes to change the label to the higher value, a new application is also required.

USDA also requires manufacturers and vendors to include the USDA BioPreferred Web site address on or in close proximity to the label. USDA is not proposing to require that the Web site address be on the label itself because the label on many products will not be large enough to accommodate this extra information. USDA believes that, where practicable, the presence of the USDA BioPreferred Web site address on the label will assist consumers in obtaining information about biobased products.

Physical Aspects of the Label

The rule addresses the physical aspects of the label artwork and the presentation of the biobased product statement. In addition to the requirements of the rule, USDA anticipates that guidance on specific issues related to the physical aspects of the label will be provided in the Marketing Guide.

Label Artwork

To maintain the distinctiveness of the label artwork (which consists of the logo, the phrase ''USDA Certified Biobased Product'' and, where applicable, the letters ''FP'') and to make sure that it is readily recognizable, USDA has established requirements related to the physical appearance of the label artwork. The applicable label artwork provided by the BioPreferred Program must be used.

USDA is also proposing color requirements to ensure that the label artwork remains distinctive and recognizable. USDA is proposing to require that one of three label versions be used, depending on the need of the product. (1) A three-color version of the label artwork (white plus two shades of green); (2) a one-color version of the label artwork as long as the color used is one of the two greens specified in section 2904.7(f) of today's proposed rule; and (3) a black and white version of the label artwork is also acceptable. The contrast between the light and dark

sections of the label artwork should be great enough to maintain the distinctiveness of the design.

Finally, the label artwork may not be altered, cut, separated into components, or distorted in appearance or perspective.

Biobased product statement. The applicable biobased product statement(s), which identifies the product(s) to which the label applies and the biobased content(s), would be placed below the label artwork. The biobased content must be expressed as ''XX%,'' where XX% represents the actual biobased content of the product. The biobased content must be easily readable. Figure 1 illustrates the placement of the biobased product statement.

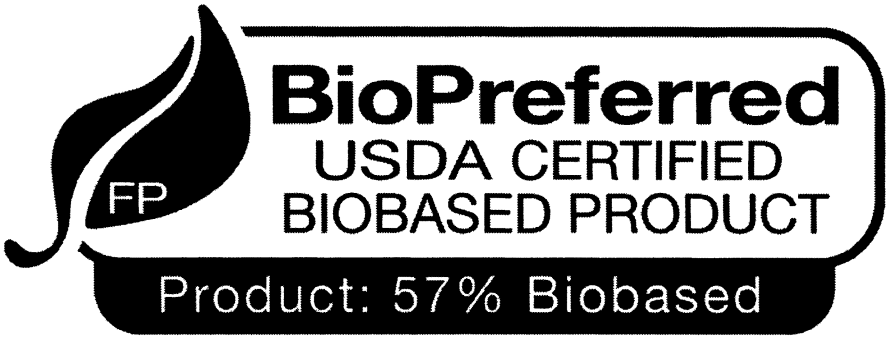

Figure 1. Label, with Biobased Product Statement, for a Product that is Within a Designated Item

Placement of the Label

Whether the label is placed directly on a product, on associated packaging, in user manuals, or in other material, it should always be placed in a manner that ensures that the label (label artwork and biobased product statement(s)) can be readily associated with the applicable certified biobased product. The label should not be placed in a manner that is ambiguous about which product is a certified biobased product or that could indicate certification of a non-certified product. If all products on a printed page are certified biobased products, the label may be placed anywhere on the page. However, if a printed page contains a mix of certified biobased products and non-certified products, the label must be placed in close proximity to the certified biobased products. An individual label located near each certified biobased product may be necessary to avoid confusion.

Minimum Size and Clear Space Recommendations for the Label

USDA recognizes that a specific size requirement for the label would not be appropriate because of the variety of sizes and shapes of products that may be certified. Therefore, the label may be sized to be appropriate for the particular application as long as the correct proportions are maintained and the label remains legible.

A border of clear space must surround the label and must be of sufficient width to offset it from surrounding images and text and to avoid confusion. If the label's color is similar to the background color, an outlining color may be used to enhance contrast.

Where To Obtain Copies of the Label Artwork

The two versions of the label artwork (with and without the letters ''FP'', as applicable) will be available at the USDA BioPreferred Web site. Only manufacturers and vendors approved for use of the label for certified biobased products will be able to obtain the label from the Web site. USDA will provide the necessary access (through the notice of certification) once a manufacturer or vendor has provided USDA with the required information, which USDA will post to the USDA BioPreferred Web site, for a product whose application for certification has been approved by USDA.

H. Violations

Although the decision to participate in the certified biobased products labeling program is voluntary, compliance with the program requirements and specifications will be essential to the success of the program. Proposed section 2904.8 identifies examples of the types of actions that would be violations of the labeling program.

To enforce the provisions of the voluntary labeling program, USDA will implement an audit program. This audit program will include, but not necessarily be limited to, conducting inspections of manufacturer and vendor facilities, visiting retail facilities, and testing the biobased content of certified biobased products. Visiting manufacturer and vendor facilities and inspecting their records, for example, will help USDA identify potential label and application violations. Testing certified biobased products for their biobased contents will help USDA determine any violations associated with biobased contents. Manufacturers, vendors, and their designated representatives are required to cooperate fully with all USDA audit efforts for the enforcement of the voluntary labeling program. USDA envisions selecting five to ten percent of labeled products at random for audit each year.

Both the violations being proposed and any penalties associated with a violation would be applied on a per product basis. For example, a manufacturer has two certified biobased products, Product A and Product B. The manufacturer has been cited for a labeling violation for Product A and the certification for Product A has been revoked. As proposed, the manufacturer would be required to discontinue labeling Product A, and USDA would remove the information for Product A from the USDA BioPreferred Web site. If no actions were taken against the manufacturer with regard to Product B, the manufacturer's certification for Product B would not be affected by the violation associated with Product A. Thus, the manufacturer would still be allowed to affix the label to Product B, and Product B's information would

remain on the USDA BioPreferred Web site.

Finally, the appeals process described previously is also applicable when a notice of violation, suspension, or revocation is issued.

Biobased Content Violations. As noted earlier, as part of its audit program, USDA will conduct random tests of certified biobased products taken from market shelves to determine their biobased contents and compare the results to a product's applicable minimum biobased content and the biobased content reported by the manufacturer or vendor in the approved application. USDA will conduct such testing using ASTM D6866, Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis.

If the USDA testing shows that the biobased content of a certified biobased product is less than the applicable minimum biobased content identified in the approved application for the product, then a violation of the labeling regulations has occurred.

If USDA testing shows that the biobased content of a certified biobased product is less than that reported in the approved application, but is still equal to or greater than the applicable minimum biobased content, USDA will notify the manufacturer or vendor of its results. USDA may forward the test results to the Federal Trade Commission for possible enforcement. The manufacturer or vendor would then have 30 days to submit a new application, showing a revised biobased content for the product. The revised biobased content could be either the biobased content from the USDA test or a biobased content reported by the manufacturer or vendor based on a new test conducted by the manufacturer or vendor. If the manufacturer or vendor elects to conduct a new biobased content test, the manufacturer or vendor must test a current sample of the product. Failure to provide a new application (including new test results) with a revised biobased content within 30 days of receipt of USDA's written notification would be considered a violation.

USDA notes that if its testing shows that the biobased content of a certified biobased product is greater than the biobased content reported in the approved application, no violation would have occurred. USDA will, however, notify the manufacturer or vendor of the results of the testing, ask if they would like to submit a second product test, and potentially be allowed to increase the biobased content shown on their label.

Label Violations. Any usage or display of the label that does not conform to the requirements proposed in section 2904.7 would be considered a violation of the proposed labeling regulations. For example, applying a label to a product that does not have a valid certification would be a label violation.

Application Violations. Knowingly providing false or misleading information in any application for certification of a biobased product would be a violation of the proposed labeling regulations. For example, certifying in the application that the product meets the definition of a biobased product when it does not would be an application violation.

USDA BioPreferred Web site Violations. As proposed, failure to provide to USDA updated information on a certified biobased product when the information for the certified biobased product becomes outdated (*e.g.,* a change in a product's biobased content), would be a violation.

Notice of Violations and Associated Actions. When a violation has been identified, USDA will provide written notification of the violation to the applicable entity, which may be the manufacturer, vendor, or its designated representative or other entity. In all instances, the manufacturer of the product for which USDA has identified the violation will also be notified. The notice of violation will identify the violation. In the case of biobased content violations, the offending party will then have 30 days from the date the notice of violation is received to correct the violation. For other types of violations, the offending party will have 60 days from the date the notice of violation is received to correct the violation. The 30-day period for resolving violations of biobased content violations is more stringent than the 60-day period allowed for resolving other types of violations because biobased content violations, whether intentional or not, are viewed as misleading consumers and could result in inappropriately influencing their purchasing decisions.

If the party receiving the notice of violation is an ''other entity,'' USDA will pursue remedies as provided for under proposed section 2904.8(c). If the party is a manufacturer, vendor, or one of its designated representatives, USDA will first pursue notices of suspension and revocation, as discussed below. USDA also reserves the right to pursue other remedies as provided in § 2904.8(c).

Suspension of Certification. After receiving a notice of violation, if the manufacturer, vendor, or designated representative, as applicable, fails to make the required corrections within 60 days (or 30 days, in the case of biobased content violations), USDA will notify the manufacturer or vendor of the continuing violation and will suspend USDA certification for that product. As of the date the manufacturer or vendor receives a notice suspending product certification, the manufacturer or vendor and any designated representatives must not affix the label to any of that product, or associated packaging, not already labeled. Also, the manufacturer or vendor must not distribute any additional products bearing the label after receiving a notice of suspension of product certification. When USDA suspends a product's certification, USDA will issue a press release informing the public of the suspension and will also remove the information on that product from the USDA BioPreferred Web site. If USDA learns that entities whose certification has been suspended continue to use the label, USDA will refer that information to the Federal Trade Commission for enforcement.

In order to resume use of the label for a product whose certification has been suspended, the manufacturer, vendor, or designated representative must correct the violation and notify USDA that the violation has been corrected within 30 days from receipt of the notice of suspension and must receive approval from USDA before use of the label can be resumed. Once USDA has approved the corrections to the violation, USDA will restore the product information to the USDA BioPreferred Web site.

Revocation of Certification. If a manufacturer or vendor whose USDA product certification has been suspended fails to make the required corrections within 30 days of the date of the suspension, USDA will notify the manufacturer or vendor that the certification for that product is revoked. As of the date that the manufacturer or vendor receives the notice revoking USDA certification, the manufacturer or vendor and any designated representatives must not affix the label to any of that product, or associated packaging, not already labeled. In addition, the manufacturer or vendor and its designated representatives are prohibited from further sales of the product to which the label has already been affixed to any entity. However, if, prior to receipt of a notification of revocation, a manufacturer or vendor has stored a supply of product with the label that has already been sold to

another entity, the manufacturer or vendor must notify the entity of the label revocation and allow the entity to cancel the transaction. If a manufacturer or vendor whose product certification has been revoked wishes to use the label, the manufacturer or vendor must follow the procedures required for original certification.

Other Remedies. In addition to the suspension or revocation of the certification to use the label, depending on the nature of the violation, USDA may pursue suspension or debarment of the entities involved in accordance with part 3017 of this title. USDA further reserves the right to pursue any other remedies available by law, including any civil or criminal remedies, against any entity that violates the provisions of this part.

I. Recordkeeping Requirements

Manufacturers and vendors who choose to participate in the voluntary labeling program will be required to keep certain records related to their labeled biobased products. USDA believes these records are necessary to ensure compliance with the labeling regulations. Manufacturers and vendors may keep these records in either electronic or hard copy format. The records that must be kept include:

- The results of all tests, and any associated calculations, performed to determine the biobased content of the product;
- The results, and the supporting documentation, of industry standard functional performance tests to support product performance claims made by the manufacturer or vendor;
- The results, and the supporting documentation, of analyses the manufacturer or vendor has performed to support claims of environmental or human health effects, life cycle costs, and sustainability benefits of the product;
- Documentation that the product for which certification is sought meets the definition of biobased product, as defined in § 2904.2 of this part; and
- The date of the certification by USDA and the dates when the biobased content of certified biobased products was tested.

Records created under the requirements of today's proposed rule must be maintained for at least three years beyond the end of the label certification period (*i.e.,* three years beyond the period of time when manufacturers and vendors cease using the label). If electronic records are maintained, they must be readily accessible during an audit by USDA. USDA believes that a three-year record retention period is the minimum necessary to allow verification of the information supporting active certifications. Manufacturers, vendors, and their designated representatives must allow Federal representatives access to these records for inspection and copying during normal Federal business hours to determine compliance with the applicable regulations.

J. Reporting

USDA encourages manufacturers certified to use the label to provide data in order to enable USDA to estimate and publicly report the benefits and general effectiveness of the Voluntary Labeling Program. The quantity, frequency, and format of the data will be as the parties mutually agree. Such data may include, if and as available: (1) The total number of units of each product shipped by manufacturer for sale in the U.S., and (2) the type of customer (*e.g.,* government, other public institution, private/corporate institution, private individual) to whom such products were sold.

USDA recognizes that manufacturers and vendors may consider some of the requested information to be confidential. USDA stresses that information claimed as confidential by the manufacturer or vendor will not be released and that individual manufacturer or vendor data will not be reported. Only summary information regarding the benefits and impacts of the entire program will be released.

IV. Suggested Comment Topics

USDA invites comment on any aspect of today's proposed requirements for the voluntary labeling program for biobased products. USDA invites specific comments in the areas identified below.

1. *Who can apply for the label*? Under the proposed rule, both manufacturers and vendors of biobased products can apply for use of the label for their products. USDA is interested in comments on whether it is appropriate to include vendors as an entity eligible to apply for use of the label. Some of the requirements associated with approval for use of the label will require information generally only available to the manufacturer. In addition, it is the manufacturer, not the vendor, who determines a product's formulation and production process. What issues would a vendor face in complying with the proposed rule in light of this?

2. *Applicable minimum biobased contents.* For products (including intermediate ingredients and feedstocks) not within a designated item, USDA is interested in comments associated with; (a) the 51 percent applicable minimum biobased contents that products within this category must meet in order to be eligible for use of the label, and (b) the procedure under which an applicant can request an alternative applicable minimum biobased content (*i.e.,* an applicable minimum biobased content other than 51 percent).

3. *The labeling of ''complex products.''* In addition to the three categories of products (products within designated items, those that are not within designated items, and those that are intermediate ingredients and feedstocks that are not within designated items) that would be eligible to use the label under today's proposed rule, USDA also intends to develop provisions for the labeling of ''complex products'' once several implementation issues have been resolved. A complex product is considered to be a finished, consumer product that is composed of many different types of components. Examples of complex products would be products such as computers, vacuum cleaners, lawn mowers, and automobiles. Each of these products contains many component parts made of different materials. For products such as these, it may be feasible to produce one or more of the component parts with biobased materials.

Today's proposed rule does not contain provisions to allow for the labeling of complex products because there is currently no approved method to determine the biobased content of a complex product. USDA has consulted with ASTM representatives regarding the lack of an approved test method. ASTM is gathering information on complex products and they intend to proceed with the development of a method that can be used to determine the biobased content of complex products. USDA will continue to work closely with ASTM and the manufacturers of complex products and, once an acceptable test method is available, expects to amend the voluntary labeling rule to allow for the labeling of complex products.

USDA requests that commenters provide information on the types of complex products containing biobased components that are in the marketplace today, as well as those which may be in the developmental stage. Information on the types of components that contain biobased materials, the typical biobased content of these components, and the market share of the biobased components is requested by USDA. Information on current research efforts to develop new biobased components for complex products is also requested. USDA is also interested in commenters' opinions regarding how complex

products and their biobased components should be addressed in the designation process as well as the voluntary labeling program.

4. *The labeling of ''mature market products.''* The proposed rule does not allow the label to be applied to products that are considered to be ''mature market products'' (*i.e.,* products that had significant market penetration in 1972), except on a case-by-case basis. Section 2902.5(c)(2) of the final Guidelines also excludes mature market products from the designation process. However, USDA is proposing to allow manufacturers of mature market products to appeal (on a case-by-case basis) the exclusion of their products from the voluntary labeling program if they believe that conditions justify special consideration for their products. A possible example would be the manufacturer of a traditional biobased product that had a significant market share in 1972, lost that market share to petroleum-based alternative products during the years between 1980 and 2000, is now attempting to re-enter the market, and believes the label will be helpful in this attempt. Other instances where USDA might consider granting appeals of the exclusion of mature market products include those where labeling a product could be shown to: reduce dependence on foreign petroleum sources; create new ''green'' jobs; or reduce greenhouse gas emissions.

USDA welcomes comment on whether mature market products should be eligible for labeling and whether the labeling of mature market products could negatively affect the entry of new (*i.e.,* post-1972) biobased products into market segments in which mature products already have significant market shares. USDA also requests comments regarding what criteria should be used to evaluate *appeals* to include mature market products in the labeling program and what types of information manufacturers and vendors should be required to submit as justification for their appeal. Commenters should provide specific reasons why the use of the label on mature market products should be considered, including information on the expected benefits of the label. USDA is also seeking comments on why this label might be preferred over, or how it could be used in conjunction with, other available labels such as the ''cotton,'' ''renewable,'' or ''organic'' labels that can be used on many mature market products.

5. *The appropriate lengths for the certification periods.* USDA is proposing that certifications remain valid for as long as the certified product is manufactured in accordance with the approved application. USDA considered a certification of either three or five years, but chose not to propose a specified time period, primarily to reduce the burden that would be associated with reapplying for certification. USDA welcomes comments on the appropriate length of time that a certification should be valid. Be sure to include rationale for any recommendations of alternative certification periods.

6. *Preliminary notice of violations.* USDA welcomes comments on whether a preliminary notice of violation for any of the proposed violations should be issued before action is taken by USDA against the violators and, if so, how long a violator should be given to correct the violation before action is taken.

7. *Biobased content testing facilities.* USDA solicits comments on the appropriateness of requiring that labs be ISO 9001 conformant. Specifically, are there benefits in such a requirement in terms of the quality of the resulting data and, if so, is ISO 9001 the appropriate standard? Commenters are encouraged to provide their opinions on whether there are other standards (such as ISO 17025) that would be more appropriate.

8. *Clarification of biobased content of product vs. packaging on label.* As discussed earlier in this preamble, USDA believes that it is important to identify for the consumer the item to which the label applies. Therefore, USDA is proposing that the label include the appropriate biobased product statement(s) to make this clear.

USDA seeks comments to determine if the use of the word ''product'' in the statement ''Product: YY% biobased'' is clear enough. For example, if the label applies to a biobased hydraulic fluid, but not to its container, does the statement ''Product: YY% biobased'' found on the container clearly convey that the label applies to the hydraulic fluid and not the container? If this statement does not clearly convey this, please suggest alternatives that would more clearly accomplish this.

When the label applies to both the product and its packaging, is it necessary to provide the biobased content of both the product and its packaging? As proposed, two statements would be included on the label (Product: YY% biobased. Packaging: XX% biobased). USDA welcomes suggestions on how to address providing biobased content information when the label applies to both the product and its packaging.

9. *Identifying products that are also eligible for a Federal procurement preference under the preferred procurement program.* As proposed, biobased products that fall within designated items and are, therefore, eligible for Federal preferred procurement, would use a label with the letters ''FP'' included in the label artwork. USDA considered simply allowing manufacturers to indicate in the product's literature that the product is eligible for preferred procurement rather than requiring such information on the label itself. USDA decided that there may be a benefit to either Federal agencies or to the public consumers to have this information on the label. USDA is seeking comments on whether the ''FP'' lettering on the label will be sufficient to distinguish products that are eligible for Federal preferred procurement. USDA is also requesting comments on whether consumers will recognize that the lettering on products means that these products, or similar products, have undergone life cycle costs and environmental performance analyses. USDA also welcomes comments on how the labeling program and the preferred Federal procurement program should work together.

10. *Other possible label content.* As discussed above, USDA is proposing that the label include the biobased content (expressed as a percentage), a statement indicating whether the biobased content refers to the product or the packaging or both, and the BioPreferred Web site address (either on or in close proximity to the label). USDA also considered the possible advantages and disadvantages of requiring additional information on the label. For example, USDA is proposing that information on product performance and on the life-cycle costs and environmental and human health effects of the labeled products be maintained if manufactures make claims regarding these attributes for their products. USDA considered whether providing this type of additional information on the label would be beneficial to purchasers.

The primary advantage of providing additional information on the label is to further educate purchasers about the attributes of the biobased products they choose to purchase. However, because the results of these analyses would typically be available only for labeled biobased products, a comparison to non-labeled biobased, or non-biobased, competing products may often be impossible. Also, the amount of space that would be needed for a legible presentation of this information could be a serious drawback for many small products (*e.g.,* household cleaners, hair care products, lip care products).

USDA is proposing to require manufacturers to include the BioPreferred Web site address either on or in close proximity to the label. USDA is requesting comments on the possible benefits of this proposed requirement and also on any expected drawbacks or negative impacts.

USDA requests comments and recommendations regarding the value of providing the types of additional information discussed above on the label and specifically requests input on what types of information should be included and how it should be presented.

11. *Legibility of the label.* As proposed, the label would consist of two items, the label artwork and the biobased product statement(s) with the accompanying biobased content(s). This is a significant amount of information and, for some small products, could result in a label that is difficult to read. Therefore, USDA is seeking comment on ways to help ensure that the information proposed to be included will be legible. Depending on the comments it receives and the rationale behind those comments, USDA may require a different presentation of this information.

12. *Timeframe for correcting violations.* Under the proposed rule, USDA would allow up to 60 days for entities to correct violations (30 days for biobased content violations) before a notice of suspension or other remedy is sought. USDA is seeking comment on whether it is preferable for the timeframe to correct a violation to be fixed, including the appropriate length to allow (*e.g.,* are the 30- and 60-day periods in the proposed rule reasonable?) or to be determined on a case-by-case basis to be specified in the notice of violation.

13. *Recordkeeping.* The proposed rule requires certain records be kept in order to allow USDA to verify information associated with the labeling program and that these records be kept for at least three years beyond the end of the label certification period (*i.e.,* three years beyond the period of time when manufacturers and vendors cease using the label). USDA welcomes comments on the specific records to be kept and the length of time they must be kept, including comments related to recordkeeping costs.

14. *Benefits and Costs.* USDA requests comments on the potential benefits (social and private) and costs (*e.g.,* testing, submitting applications and associated information, and recordkeeping) of the proposed rule.

15. *Application Fee.* USDA is considering the option of charging an application fee for each application to use the label. While Departmental Administration does not currently have the statutory authority to collect such a fee, available options are being explored. As discussed elsewhere in this preamble, USDA plans to implement an audit program to ensure compliance with the requirements for the use of the label. Based on experience with other programs, USDA believes it may be necessary to assess user fees in order to maintain a viable audit program. The proceeds from the application fee would, therefore, be used to help offset the cost of the audit program. USDA believes that it is in the best interest of not only USDA but also the manufacturers of labeled products that an audit program be implemented so that the integrity of the label can be assured. Were authority provided to do so, USDA would consider charging a fee of $500 for each submitted application and requests comments on the appropriateness of that amount as well as on the charging of a fee at all.

Please be sure to include your rationale for all suggested changes to the proposed rule. Comments must be submitted as directed in the **ADDRESSES** section of this notice.

V. Regulatory Information

A. Executive Order 12866: Regulatory Planning and Review

Executive Order 12866 requires agencies to determine whether a regulatory action is ''significant.'' This proposed rule has been reviewed under Executive Order (EO) 12866 and has been determined to be significant. Today's proposed rule establishes a voluntary labeling program that allows manufacturers and vendors of certified biobased products to use the ''USDA Certified Biobased Product'' label. Although the labeling program is voluntary, there will be costs associated with meeting the criteria for, and applying for, certification to use the label.

1. Costs of the Proposed Rule

The primary costs associated with participating in this program are those for developing applications, testing to document the biobased content of products, providing information to USDA for posting by USDA on the USDA BioPreferred Web site, maintaining applicable records, and redesigning the product packaging to incorporate the label. USDA estimates that the combined annualized cost of the voluntary program, as proposed, to manufacturers and vendors would average approximately $2,813,811 per year for the first three years of the program. USDA estimates an average of 352 manufacturers and vendors per year will submit applications to participate in the labeling program for the first three years of the program. This yields an average annualized cost per manufacturer/vendor of approximately $7,994.

The level of presumed impact is not expected to exceed $100 million because of the offsetting nature of the labeling program (*i.e.,* an increase in demand for biobased products is likely to be offset by a decrease in demand for non-biobased products). While the program is anticipated to have a widespread effect on the marketplace (including shifting purchases away from non-biobased products toward the purchase of biobased products), it is not expected to have a widespread adverse effect on the economy.

2. Benefits of the Proposed Rule

As an integral part of USDA's BioPreferred℠ Program, the voluntary labeling program is expected to raise public awareness of, and increase the demand for, biobased products. While the benefits of the labeling program are not quantifiable at this time, an increased demand for biobased products will, in turn, achieve the benefits as outlined in the objectives of section 9002: To increase domestic demand for many agricultural commodities that can serve as feedstocks for production of biobased products; to spur development of the industrial base through value-added agricultural processing and manufacturing in rural communities; to enhance the Nation's energy security by substituting biobased products for products derived from imported oil and natural gas; and to substitute products with a possibly more benign or beneficial environmental impact, as compared to the use of fossil energy-based products. On a national and regional level, today's proposed rule can result in expanding and strengthening markets for biobased materials used in these items. The program is also expected to promote economic development for biobased product manufacturers and vendors by creating new jobs and providing new markets for farm commodities.

B. Regulatory Flexibility Act (RFA)

Under the RFA, an agency is not required to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute if the agency can certify that the rule will not have a significant economic impact on

a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

Of these three types of entities, the labeling requirements in today's rulemaking would be applicable to small businesses only. For purposes of assessing the impacts on small entities, a small business is defined by the RFA using the definitions for small business based on Small Business Administration size standards, which vary depending on the type of business (*e.g.,* less than 500 employees, less than 1,000 employees). Most of the manufacturing companies and vendors associated with products within items that USDA has designated or proposed for designation would qualify as small businesses under SBA guidelines.

While we do not have enough information to evaluate fully the potential effect of this proposed rule on small entities, we have some information to make some initial conclusions. We identified six North American Industrial Classification System (NAICS) categories under which many biobased products are manufactured: Petroleum lubricating oil and grease manufacturing, plastics material and resin manufacturing, soap and other detergent manufacturing, urethane and other foam product (except polystyrene) manufacturing, carpet and rug mills manufacturing, and fertilizer manufacturing. We then used economic census data to determine the average value of shipments, a reasonable surrogate for annual sales, for companies in these categories. The analysis indicates that the average value of shipments in 2002, the most recent year for which there are complete census data, for the six NAICS categories examined is over $10 million per year per establishment. USDA requests comments on the quality of this analysis and ways to improve it.

More recent manufacturing census data on firm size, from 2006, indicates that, collectively, over 94 percent of the firms in the six categories meet the Small Business Administration definition of small business for the six categories.

The benefit-cost analysis USDA conducted for the proposed rule, discussed in Section I. below, indicates that the annualized cost associated with participating in the voluntary labeling program is about $7,994 on average and, relative to total sales by small businesses in the NAICS categories where many biobased products are manufactured, appears not to represent an undue burden in most cases.

Moreover, participation in the voluntary labeling program would provide manufacturers and vendors a marketing advantage over those who choose not to participate. This marketing advantage could lead to greater sales, thus offsetting some of the costs associated with participating in the labeling program.

Finally, the program requirements for the voluntary labeling program are applicable to all manufacturers and vendors of biobased products seeking to use the label under this program, regardless of the size of their business. For instance, all manufacturers and vendors are required to submit an application, conduct certain testing, and provide to USDA certain information that USDA will post to the BioPreferred Web site. These requirements are necessary to certify biobased products and are independent of the size of the manufacturer or vendor. The integrity of the labeling program would be compromised if biobased products manufactured by small businesses were allowed to be subject to different criteria in order to reduce costs to small businesses.

Based on this initial analysis, USDA has not prepared a Regulatory Flexibility Analysis because USDA has determined that this rule does not have a significant impact on a substantial number of small entities.

C. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

This proposed rule has been reviewed in accordance with Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and does not contain policies that would have implications for these rights.

D. Executive Order 13132: Federalism

This proposed rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. Provisions of this proposed rule will not have a substantial direct effect on States or their political subdivisions or on the distribution of power and responsibilities among the various government levels.

E. Unfunded Mandates Reform Act of 1995

This proposed rule contains no Federal mandates as defined under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, for State, local, and tribal governments, or the private sector. Therefore, a statement under section 202 of UMRA is not required.

F. Executive Order 12372: Intergovernmental Review of Federal Programs

For the reasons set forth in the Final Rule Related Notice for 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), this program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials. This program does not directly affect State and local governments.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The proposed rule does not impose any mandate on tribal governments or impose any duties on these entities. Thus, no further action is required under Executive Order 13175.

H. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), USDA is seeking OMB approval of the reporting and recordkeeping requirements contained in this proposed rule. USDA conducted a burden analysis of the costs associated with this proposed rule, as well as a benefit-cost analysis. The primary costs of participating in the voluntary labeling program are the costs of testing the biobased content of products and the costs of labor associated with reading the rule, applying for certification, gathering and submitting the information for posting to the BioPreferred Web site, and keeping applicable records for the products for which certification is sought. See the contact information at the end of this section for details on how to request a copy of materials related to the Information Collection Request.

Methodology

To estimate the average annual burden over the first three years of the rule, USDA estimated the number of hours that each activity (*e.g.,* read the rule, complete the application, submit information to USDA, appeal denied applications, keep records) would take, summed the estimates for each activity to get an average total number of hours per manufacturer/vendor, and multiplied that total by the estimated number of manufacturers/vendors. The total cost of biobased content testing was then projected by multiplying the estimated total number of biobased

products for which certification is expected to be sought by the cost of the test. The labor component of the cost and the testing component were then summed to give a total estimated burden.

Assumptions

In estimating the costs for the burden analysis, USDA made the following assumptions.

1. In the first year of the voluntary labeling program, USDA estimates that 100 items will have been designated as eligible to receive the procurement preference, another 36 items will have been designated in the second year of the labeling program, and another 30 items will have been designated in the third year of the labeling program.

2. Based on information gathered during the item designation rulemakings, USDA estimates that approximately 830 manufacturers of products within these 166 designated items and an additional 830 manufacturers of biobased products (including intermediate ingredients or feedstocks) within items that are not designated for preferred procurement are expected to have an interest in using the label, yielding 1,660 manufacturers with eligible biobased products over the first three years. USDA estimates that an additional 200 vendors over the first three years would be interested in the voluntary labeling program. This yields a total of 1,860 manufacturers and vendors. Finally, USDA estimates that 166 other entities over the first three years would be interested in the voluntary labeling program.

3. Because the voluntary labeling program is new and the benefits to manufacturers of labeling their biobased products are not yet demonstrated, USDA anticipates that many manufacturers may be reluctant to participate during the first few years of the program. USDA expects that during the first three years of the program, participation by one half to two thirds of eligible manufacturers/vendors would be a reasonable estimate. Therefore, USDA assumed that sixty percent of the manufacturers of products within designated items, sixty percent of the manufacturers of products that are not within designated items, and thirty percent of the vendors with eligible biobased products would apply for certification to use the label. Thus, 1,056 manufacturers and vendors $((830 \times 0.6) + (830 \times 0.6) + (200 \times 0.3) = 1{,}056)$ would apply to use the label over the first three years (an average of 352 per year).

4. Based on information gathered to support the designation of items for preferred procurement, the average number of biobased products per manufacturer is between six and seven. For this analysis, USDA estimates that each applicant would submit applications for six products. This results in the submittal of 2,112 applications (352 applicants times 6 products per applicant) for products, on average, for each of the first three years. Of these, USDA estimates that 95 percent will be approved for use of the label.

5. In estimating the cost of the labor for reading the rule, completing applications, gathering and submitting information for posting on the BioPreferred Web site, and maintaining the applicable records, USDA used an average labor cost of $49.98 per hour. This hourly rate is based on the Federal salary schedule, step 6, GS 14 ''rest of the United States'' salary of $103,957 per annum (with 2080 hours worked per annum). The salary level is deemed reasonable under the expectation that at least half the burden hours would likely be provided by private sector employees earning less than this hourly rate and up to half the private sector employees would be earning more.

6. Based on the biobased content testing performed to support the item designation rulemakings, USDA estimated an average cost of $500 to perform biobased content testing.

Estimated Burden

During the first three years the labeling program is in effect, the total annual burden on all respondents is estimated to be $2,813,811. For the estimated 352 manufacturers/vendors (see item 3 above) certified to use the label, the average burden is, therefore, estimated to be $7,994 ($2,813,811 ÷ 352 = $7,994).

Abstract

The Farm Security and Rural Investment Act of 2002 (2002 Act), as amended by the Food, Conservation, and Energy Act of 2008, established the Biobased Markets Program under Title IX, Section 9002. The 2002 Act requires the Secretary of Agriculture to create a voluntary labeling program for biobased products.

The information requirements contained in this proposed rule require information from manufacturers and vendors of biobased products that seek to use the label on qualified biobased products. The information is vital for USDA to evaluate the qualifications of biobased products to carry the USDA label and to ensure that the label is used properly. This collection of information is necessary in order to implement the voluntary labeling program for biobased products established under the 2002 Act.

Copies of this information collection can be obtained from Ron Buckhalt at the following address: Ron Buckhalt, USDA, Office of the Assistant Secretary for Administration, Room 300, Reporters Building, 300 Seventh Street SW., Washington, DC 20024; e-mail: *biopreferred@usda.gov;* phone (202) 205–4008.

As part of our continuing effort to reduce paperwork and respondent burdens, USDA invites the public and other Federal agencies to comment on any aspect of the reporting burden in the proposed rule. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of USDA in the operation and management of this labeling program; (2) the accuracy of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for Agriculture, Margaret Malanoski, 725 17th Street, NW., Room 10202, Washington, DC 20503. Comments should reference OMB control number 0503–NEW. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

I. Government Paperwork Elimination Act Compliance

USDA is committed to compliance with the Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504 note), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. USDA is implementing an electronic information system for posting information submitted by manufacturers and vendors on the products they intend to label under the voluntary labeling program for biobased products. For information pertinent to GPEA compliance related to this rule, please contact Ron Buckhalt at (202) 205–4008.

J. Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 804(2). This rule will not have an annual effect on the economy of $100 million or more; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

List of Subjects in 7 CFR Part 2904

Biobased products, Labeling.

For the reasons stated in the preamble, the U.S. Department of Agriculture (USDA) proposes to amend 7 CFR chapter XXIX as follows:

CHAPTER XXIX—DEPARTMENTAL ADMINISTRATION, DEPARTMENT OF AGRICULTURE

1. A new part 2904 is added to chapter XXIX to read as follows:

PART 2904—VOLUNTARY LABELING PROGRAM FOR BIOBASED PRODUCTS

Sec.

Authority: 7 U.S.C. 8102.

§ 2904.1 Purpose and scope.

The purpose of this part is to set forth the terms and conditions for voluntary use of the ''USDA Certified Biobased Product'' label. This part establishes the criteria that biobased products must meet in order to be eligible to become certified biobased products to which the ''USDA Certified Biobased Product'' label can be affixed, the process manufacturers and vendors must use to obtain and maintain USDA certification, and the recordkeeping requirements for manufacturers and vendors who obtain certification. In addition, this part establishes specifications for the correct and incorrect uses of the label, which apply to manufacturers, vendors, and other entities. Finally, this part establishes actions that constitute voluntary labeling program violations.

§ 2904.2 Definitions.

Applicable minimum biobased content. The biobased content at or above the level set by USDA to qualify for use of the label.

ASTM International (ASTM). A nonprofit organization that provides an international forum for the development and publication of voluntary consensus standards for materials, products, systems, and services.

Biobased content. The amount of biobased carbon in the material or product expressed as a percent of weight (mass) of the total organic carbon in the material or product. For products within designated items, the biobased content shall be defined and determined as specified in the applicable section of subpart B of part 2902. For all other products, the biobased content is to be determined using ASTM Method D6866, Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis.

Biobased product. A product determined by the Secretary to be a commercial or industrial product (other than food or feed) that is:

(1) Composed, in whole or in significant part, of biological products, including renewable domestic agricultural materials and forestry materials; or

(2) An intermediate ingredient or feedstock. For the purposes of this subpart, the term 'biobased product' does not include motor vehicle fuels, heating oil, electricity produced from biomass, or any mature market products. Products from a mature market will be determined on a case-by-case basis.

Certified biobased product. A biobased product for which the manufacturer or vendor of the product has received approval from USDA to affix to the product the ''USDA Certified Biobased Product'' label.

Days. As used in this part means calendar days.

Designated item. For the purposes of this part means a generic grouping of biobased products designated for preferred procurement under subpart B of part 2902 of this title.

Designated representative. An entity authorized by a manufacturer or vendor to affix the USDA label to the manufacturer's or vendor's certified biobased product or its packaging.

Intermediate ingredients or feedstocks. A material or compound made in whole or in significant part from biological products, including renewable agricultural materials (including plant, animal, and marine materials) or forestry materials, that are subsequently used to make a more complex compound or product. 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.

ISO. The International Organization for Standardization, a network of national standards institutes working in partnership with international organizations, governments, industries, business, and consumer representatives.

ISO 9001 conformant. An entity that meets all of the requirements of the ISO 9001 standard, but that is not required to be ISO 9001 certified. ISO 9001 refers to the International Organization for Standardization's standards and guidelines relating to ''quality management'' systems. ''Quality management'' is defined as what the manufacturer does to ensure that its products or services satisfy the customer's quality requirements and comply with any regulations applicable to those products or services.

Label. Collectively, the label artwork (as defined in this section) and the biobased product statement(s), including the applicable biobased content(s).

Label artwork. The certification marks, ''USDA Certified Biobased Product'' and the ''USDA Certified Biobased Product'' logo, and, where applicable, the letters ''FP'' to indicate that the product is within a designated item and eligible for Federal preferred procurement, as shown in Figure 1. Application of either certification mark by a manufacturer or vendor signifies that USDA has certified that the product meets the qualifications in this part.

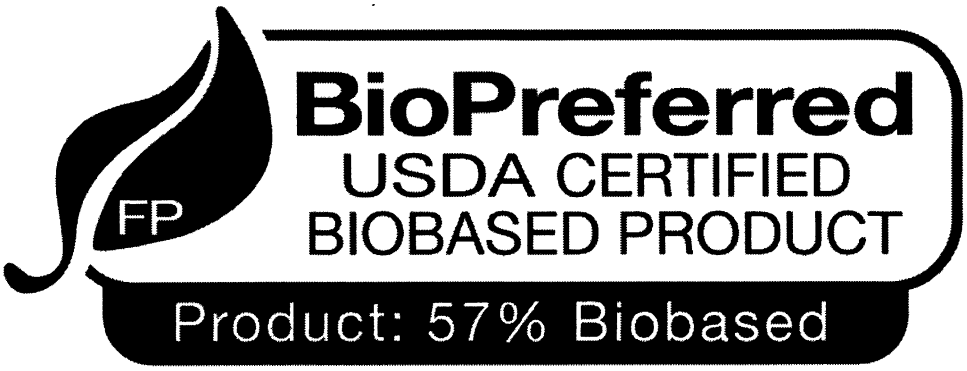

Figure 1. USDA Certified Biobased Product Label Artwork (Including Product Statement) for a Product that is Within a Designated Item

Manufacturer. An entity that performs the necessary chemical and/or mechanical processes to make a final marketable product.

Mature market products. Biobased products that are not eligible for designation for BioPreferred preferred procurement or labeling as defined under subpart B of part 2902 of this title because they had significant national market penetration in 1972. The eligibility of mature market products for the voluntary labeling program will be considered on a case-by-case basis, based on manufacturer's or vendor's appeal of the exclusion.

Other entity. Any person, group, public or private organization, or business other than USDA, or manufacturers or vendors of biobased products that may wish to use the ''USDA Certified Biobased Product'' label in informational or promotional material related to a certified biobased product.

Program Manager. The manager of the BioPreferred Program.

USDA. The United States Department of Agriculture.

Vendor. An entity that offers for sale final marketable biobased products that are produced by manufacturers.

§ 2904.3 Applicability.

(a) *Manufacturers, vendors, and designated representatives.* The requirements in this part apply to all manufacturers and vendors, and their designated representatives, who wish to participate in the USDA voluntary labeling program for biobased products. Manufacturers and vendors wishing to participate in the voluntary labeling program are required to obtain and maintain product certification.

(b) *Other entities.* The requirements in this part apply to other entities who wish to use the label in promoting the sales or the public awareness of certified biobased products.

§ 2904.4 Criteria for product eligibility to use the label.

A product must meet each of the criteria specified in paragraphs (a) and (b) of this section in order to be eligible to receive biobased product certification.

(a) *Biobased product.*

(1) Except as specified in paragraph (a)(2) of this section, the product for which certification is sought must be a biobased product as defined in § 2904.2 of this part.

(2) Products that meet the definition of mature market products, as defined in § 2904.2 of this part, will be considered for certification only in those cases where the Program Manager sustains an appeal by the manufacturer or vendor of the product for inclusion in the voluntary labeling program, as specified in § 2904.6(c) of this part.

(b) *Minimum biobased content.* The biobased content of the product must be equal to or greater than the applicable minimum biobased content, as described in paragraphs (b)(1) through (b)(4) of this section.

(1) *Biobased products within designated items.*

(i) *Product is within a single designated item.* If the product is within a single item that, at the time the application for certification is submitted, has been designated by USDA for preferred procurement, the applicable minimum biobased content is the minimum biobased content specified for the item as found in subpart B of 7 CFR part 2902.

(ii) *Product is within multiple designated items.* If a biobased product is marketed within more than one designated item, uses the same packaging for each designated item, and the applicant seeks certification of the product, the product's biobased content must meet or exceed the specified minimum biobased content for each of the applicable designated items in order to use the label on the product. However, if the manufacturer packages the product differently for each designated item then the applicable minimum biobased contents are those established under paragraph (b)(1)(i) of this section for each designated item for which the applicant seeks to use the label.

(2) *Finished biobased products that are not within designated items.*

(i) If the product is not an intermediate ingredient or feedstock and is not within a designated item at the time the application for certification is submitted, the applicable minimum biobased content is 51 percent. Manufacturers, vendors, groups of manufacturers and/or vendors, and trade associations may propose an alternative applicable minimum biobased content for the product by developing, in consultation with USDA, and conducting an analysis to support the proposed alternative applicable minimum biobased content. If approved by USDA, the proposed alternative applicable minimum biobased content would become the applicable minimum biobased content for the product.

(ii) If a product certified under paragraph (2)(i) of this section is within an item that USDA subsequently designates for preferred procurement, the applicable minimum biobased content shall become, as of the effective

date of the final designation rule, the minimum biobased content specified for the item as found in subpart B of 7 CFR part 2902.

(3) *Products that are intermediate ingredients or feedstocks and are not within designated items.*

(i) If the product is an intermediate ingredient or feedstock that is not within a designated item at the time the application for certification is submitted, the applicable minimum biobased content is 51 percent.

(ii) If a product certified under paragraph (3)(i) of this section is within an item that USDA subsequently designates for preferred procurement, the applicable minimum biobased content shall become, as of the effective date of the final designation rule, the minimum biobased content specified for the item as found in subpart B of 7 CFR part 2902.

(4) [reserved]

§ 2904.5 Initial approval process.

(a) *Application.* Manufacturers and vendors seeking USDA certification to use the label for an eligible biobased product must submit a USDA-approved application for certification for each biobased product. A standardized application form and instructions are available on the USDA BioPreferred Web site (*http://www.biopreferred.gov*). The contents of an acceptable application are as specified in paragraphs (a)(1) through (3) of this section.

(1) *General content.* The applicant must provide contact information and product information including all brand names or other identifying information, biobased content and testing information, product category, intended uses, and, if applicable, the corresponding designated item type. The applicant must attach to the application documentation demonstrating that the reported biobased content was tested by a third-party testing entity that is ISO 9001 conformant.

(2) *Certifications.* The applicant must certify in the application that the product for which use of the label is sought is a biobased product as defined in § 2904.2 of this part.

(3) *Commitments.* The applicant must sign a statement in the application that commits the applicant to submitting to USDA the information specified in paragraph (c)(1) through (4) of this section, which USDA will post to the USDA BioPreferred Web site, and to providing USDA with up-to-date information for posting on this Web site.

(b) *Evaluation of applications.*

(1) USDA will evaluate each application to determine if it contains the information specified in paragraph (a) of this section. If USDA determines that the application is not complete, USDA will return the application to the applicant with an explanation of its deficiencies. Once the deficiencies have been addressed, the applicant may resubmit the application, along with a cover letter explaining the changes made, for re-evaluation by USDA. USDA will evaluate resubmitted applications separately from first-time applications, and those with the earliest original application submittal date will be given first priority.

(2)(i) USDA will evaluate each complete application to determine compliance with the criteria specified in § 2904.4. USDA will provide a written response to each applicant within 60 days after the receipt of a complete application, informing the applicant of whether the application has been conditionally approved or has been disapproved.

(ii) For those applications that are conditionally approved, a notice of certification, as specified in paragraph (c) of this section, must be issued before the use of the label can begin.

(iii) For those applications that are disapproved, USDA will issue a notice of denial of certification and will inform the applicant in writing of each criterion not met. Applicants who receive a notice of denial of certification may appeal using the procedures specified in § 2904.6.

(c) *Notice of certification.* After notification that its application has been conditionally approved, the applicant must provide to USDA (for posting by USDA on the USDA BioPreferred Web site) the information specified in paragraphs (c)(1) through (4) of this section. Once USDA confirms that the information is received and complete, USDA will issue a notice of certification to the applicant. Upon receipt of a notice of certification, the applicant may begin using the label on the certified biobased product.

(1) The product's brand name(s), or other identifying information.

(2) Contact information, including the name, mailing address, e-mail address, and telephone number of the applicant.

(3) The biobased content of the product.

(4) A hot link directly to the applicant's Web site (if available).

(d) *Term of certification.*

(1) The effective date of certification is the date that the applicant receives a notice of certification from USDA. Except as specified in paragraphs (2)(i) through (2)(iv) of this section, certifications will remain in effect as long as the product is manufactured and marketed in accordance with the approved application and the requirements of this subpart.

(2)(i) If the product formulation of a certified product is changed such that the biobased content of the product is reduced to a level below that reported in the approved application, the existing certification will not be valid for the product under the revised conditions and the manufacturer or vendor, as applicable, and its designated representatives must discontinue affixing the label to the product and must not initiate any further advertising of the product using the label. USDA will consider a product under such revised conditions to be a reformulated product, and the manufacturer or vendor, as applicable, must submit a new application for certification using the procedures specified in paragraph (a) of this section.

(ii) If the product formulation of a certified product is changed such that the biobased content of the product is increased from the level reported in the approved application, and the manufacturer wishes to report the higher value on the label, a new application must be submitted using the procedures specified in paragraph (a) of this section.

(iii) If the product formulation of a certified product is changed such that the biobased content of the product is increased, but the label is not revised, the existing certification will continue to be valid for the product.

(iv) If the applicable required minimum biobased content for a product to be eligible to display the label is revised by USDA, manufacturers and vendors may continue to label their previously certified product only if it meets the new minimum biobased content level. In those cases where the biobased content of a certified product fails to meet the new minimum biobased content level, USDA will notify the manufacturer or vendor that their certification is no longer valid. Such manufacturers and vendors must increase the biobased content of their product to a level at or above the new minimum biobased content level and must re-apply for certification within 60 days if they wish to continue to use the label. Manufacturers and vendors who have re-applied for certification may continue using the existing label until they receive notification from USDA on the results of their re-application for certification.

§ 2904.6 Appeal processes.

An applicant for certification may appeal a notice of denial of certification to the Program Manager. Entities that have received a notice of violation, and manufacturers and vendors of certified biobased products who have received a notice of suspension or revocation, may appeal to the Program Manager. Manufacturers and vendors of mature market products may appeal the exclusion of their products from the voluntary labeling program to the Program Manager.

(a)(1) Appeals to the Program Manager must be filed within 30 days of receipt by the appellant of a notice of denial of certification, a notice of violation, a notice of suspension, or a notice of revocation. Appeals must be filed in writing and addressed to: Program Manager, USDA Voluntary Labeling Program for Biobased Products, Room 300, Reporters Building, 300 Seventh Street SW., Washington, DC 20024.

(2) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not made in accordance with applicable program regulations, policies, or procedures, or otherwise was not proper.

(b)(1) If the Program Manager sustains an applicant's appeal of a notice of denial of certification, USDA will issue a notice of certification to the applicant for its biobased product.

(2) If the Program Manager sustains a manufacturer's or vendor's appeal of a notice of violation, USDA will rescind the notice and no further action will be taken by USDA.

(3) If the Program Manager sustains a manufacturer's or vendor's appeal of a notice of suspension, the manufacturer, vendors, and their designated representative(s) may immediately resume affixing the label to the certified biobased product and USDA will reinstate the product's information to the USDA BioPreferred Web site.

(4) If the Program Manager sustains a manufacturer's or vendor's appeal of a notice of revocation, the manufacturer or vendor, and its designated representatives may immediately resume affixing the label to the certified biobased product and sell and distribute the certified biobased product with the label. In addition, USDA will reinstate the product's information to the USDA BioPreferred Web site.

(c)(1) Manufacturers or vendors of mature market products may appeal the exclusion of their products from the voluntary labeling program if they believe that special conditions or circumstances warrant the inclusion of their products in the program. Appeals to the Program Manager from manufacturers or vendors of mature market products must be filed in writing and addressed to: Program Manager, USDA Voluntary Labeling Program for Biobased Products, Room 300, Reporters Building, 300 Seventh Street, SW., Washington, DC 20024.

(2) Appeals for the inclusion of mature market products must include detailed justification showing why the product should be allowed to use the label.

(3) If the Program Manager sustains a manufacturer's or vendor's appeal of its product's exclusion from the program, the manufacturers or vendors may then apply for certification to use the label on that product, as specified in § 2904.5(a) of this part.

(4) Mature market products that are certified by USDA to use the label will be considered to be ''finished biobased products that are not within designated items'' and subject to all provisions of this part that are applicable to that category of certified biobased products.

(d) Appeals of any of the Program Manager's decisions may be made to the USDA Assistant Secretary for Administration. Appeals must be made, in writing, within 30 days of receipt of the Program Manager's decision and addressed to: Assistant Secretary for Administration, Room 209A, Whitten Building, 1400 Independence Avenue, SW., Washington, DC 20250–0103. If the Assistant Secretary for Administration sustains an appeal, the provisions of paragraph (b) of this section will apply.

§ 2904.7 Requirements associated with the label.

(a) *Who may use the label?*

(1) *Manufacturers and vendors.* Only manufacturers and vendors who have received a notice of certification, or designated representatives of the manufacturer or vendor, may affix the label to the product or its packaging. A manufacturer or vendor who has received a notice of certification for a product under this part:

(i) May use the label on the product, its packaging, and other related materials including, but not limited to, advertisements, catalogs, procurement databases, promotional material, Web sites, or user manuals for that product, according to the requirements set forth in this section; and

(ii) is responsible for the manner in which the label is used by its companies, as well as its designated representatives, including advertising agencies and subcontractors.

(2) *Other entities.*

(i) Other entities may use the label to advertise or promote certified biobased products in materials including, but not limited to, advertisements, catalogs, procurement databases, Web sites, and promotional and educational materials, as long as the manufacturer or vendor of the product, or one of their designated representatives, has affixed the label to the product or its packaging.

(ii) Other entities may use the label and the BioPreferred Program name in general statements as described in paragraph (b) of this section, as long as the statements do not imply that a non-certified biobased product is certified.

(b) *Correct usage of the label.*

(1) The label can be affixed only to certified biobased products and their associated packaging.

(2) The label may be used in material including, but not limited to, advertisements, catalogs, procurement databases, Web sites, and promotional and educational materials to distinguish products that are certified for use of the label from those that are not certified. The label may be used in advertisements for both certified biobased products and non-certified products if the advertisement clearly indicates which products are certified. Care must be taken to avoid implying that any non-certified products are certified.

(3) The label may be used without reference to a specific certified biobased product only when informing the public about the purpose of the label. For example, the following or similar claim is acceptable: ''Look for the 'USDA Certified Biobased Product' label. It means that the product meets USDA standards for the amount of biobased content and the manufacturer or vendor has provided relevant information on the product for the USDA BioPreferred Web site.'' This exception allows manufacturers, vendors, and other entities to use the label in documents such as corporate reports, but only in an informative manner, not as a statement of product certification.

(4) The label may appear next to a picture of the product(s) or text describing it.

(5) The label must stand alone and not be incorporated into any other label or logo designs.

(6) The label may be used as a watermark provided the use does not violate any usage restrictions specified in this part.

(7) The text portion of the label must be written in English and may not be translated, even when the label is used outside of the United States.

(c) *Incorrect usage of the label.*

(1) The label shall not be used on any product that has not been certified by

USDA as a ''USDA Certified Biobased Product.''

(2) The label shall not be used on any advertisements or informational materials where both certified biobased products and non-certified products are shown unless it is clear that the label applies to only the certified biobased product(s).

(3) The label shall not be used to imply endorsement by USDA or the BioPreferred Program of any particular product, service, or company.

(4) The label shall not be used in any form that could be misleading to the consumer.

(5) The label shall not be used by manufacturers or vendors of certified products in a manner disparaging to USDA or any other government body.

(6) The label shall not be used with an altered label or incorporated into other label designs.

(7) The label shall not be used on business cards, company letterhead, or company stationery.

(8) The label shall not be used in, or as part of, any company name, logo, product name, service, or Web site, except as may be provided for in this part.

(9) The label shall not be used in a manner that violates any of the applicable requirements contained in this part.

(d) *Imported products.* The label can be used only with a product that is certified by USDA under this part. The label cannot be used to imply that a product meets or exceeds the requirements of biobased programs in other countries. Products imported for sale in the U.S. must adhere to the same guidelines as U.S.-sourced biobased products. Any product sold in the U.S. as a ''USDA Certified Biobased Product'' must have received certification from USDA.

(e) *Contents of the label.* The label shall consist of the items specified in paragraphs (e)(1) through (3) of this section, as applicable.

(1) The label artwork provided by the BioPreferred Program.

(2) The biobased content and applicable biobased product statement(s), as specified in paragraph (f)(2) of this section.

(3) The USDA BioPreferred Web site address must also be included on, or in close proximity to, the label.

(f) *Physical aspects of the label.*

(1) *Label artwork.* The label artwork may not be altered, cut, separated into components, or distorted in appearance or perspective. Labels that are applied to biobased products that have been designated for preferred procurement will include the letters ''FP'' as part of the label artwork. The label must appear only in the colors specified in paragraphs (f)(1)(i) through (iii) of this section, unless approval is given by USDA for an exception.

(i) The three-color version of the label is preferred. The colors used must be Pantone-White, Pantone 356C, and Pantone 362C.

(ii) A one-color version of the label may be substituted for the three-color version as long as one of the following colors is used: Pantone 356C or Pantone 362C.

(iii) A black and white version of the label is acceptable.

(2) *Biobased content and applicable biobased product statement(s).* The biobased content and applicable biobased product statement(s) must be placed directly below the label artwork and must be displayed in a manner that makes it easily readable.

(i) One or both of the following two statements, as applicable, must be used to identify the product to which the label applies:

(A) Product: XX% biobased.

(B) Packaging: XX% biobased.

(ii) The biobased content reported in the biobased product statement(s) specified in paragraphs (f)(2)(i)(A) and (B) of this section shall be expressed as ''XX%,'' where XX% represents the actual biobased content of the product or packaging. The biobased content displayed at the time the label is affixed to the product or its packaging must be the same as the biobased content specified in the most recent approved application for the certified biobased product.

(3) The USDA BioPreferred Web site address must be included either on the label, below the product statement, if space allows or in close proximity to the label on the product or packaging.

(g) *Placement of the label.*

(1) The label can appear directly on a product, its associated packaging, in user manuals, and in other materials including, but not limited to, advertisements, catalogs, procurement databases, and promotional and educational materials.

(2) The label shall not be placed in a manner that is ambiguous about which product is a certified biobased product or that could indicate certification of a non-certified product.

(3) When used to distinguish a certified biobased product in material including, but not limited to, advertisements, catalogs, procurement databases, Web sites, and promotional and educational materials, the label must appear near a picture of the product or the text describing it.

(i) If all products on a page are certified biobased products, the label may be placed anywhere on the page.

(ii) If a page contains a mix of certified biobased products and non-certified products, the label shall be placed in close proximity to the certified biobased products. An individual label near each certified biobased product may be necessary to avoid confusion.

(h) *Minimum size and clear space recommendations for the label.*

(1) The label may be sized to fit the individual application as long as the correct proportions are maintained and the label remains legible.

(2) A border of clear space must surround the label and must be of sufficient width to offset it from surrounding images and text and to avoid confusion. If the label's color is similar to the background color, an outlining color may be used to enhance contrast.

(i) *Where to obtain copies of the label artwork.* The label artwork is available at the USDA BioPreferred Web site.

§ 2904.8 Violations.

This section identifies the types of actions that USDA considers violations under this part and the penalties (*e.g.,* the suspension or revocation of certification) associated with such violations.

(a) *General.* Violations under this section occur on a per product basis and the penalties are to be applied on a per product basis. Entities cited for a violation under this section may appeal using the provisions in § 2904.6. If certification for a product is revoked, the manufacturer or vendor whose certification has been revoked may seek re-certification for the product using the procedures specified under the provisions in § 2904.5.

(b) *Types of violations.* Actions that will be considered violations of this part include, but are not limited to, the following specific examples:

(1) *Biobased content violations.* The Program Manager will utilize occasional random testing of certified biobased products to compare the biobased content of the tested product with the product's applicable minimum biobased content and the biobased content reported by the manufacturer or vendor in its approved application. Such testing will be conducted using ASTM Method D6866. USDA will provide a copy of the results of its testing to the applicable manufacturer or vendor.

(i) If USDA testing shows that the biobased content of a certified biobased product is less than its applicable

minimum biobased content, then a violation of this part will have occurred.

(ii) If USDA testing shows that the biobased content is less than that reported by the manufacturer or vendor in its approved application, but is still equal to or greater than its applicable minimum biobased content(s), USDA will provide written notification to the manufacturer or vendor. The manufacturer or vendor must submit, within 30 days from receipt of USDA written notification, a new application for the lower biobased content. Failure to submit a new application within 30 days will be considered a violation of this part.

(A) The manufacturer or vendor can submit in the new application the biobased content reported to it by USDA in the written notification.

(B) Alternatively, the manufacturer or vendor may elect to retest the product in question and submit the results of the retest in the new application. If the manufacturer or vendor elects to retest the product, it must test a sample of the current product.

(2) *Label violations.*

(i) Any usage or display of the label that does not conform to the requirements specified in § 2904.7.

(ii) Affixing the label to any product prior to issuance of a notice of certification from USDA.

(iii) Affixing the label to a certified biobased product during periods when certification has been suspended or revoked.

(3) *Application violations.* Knowingly providing false or misleading information in any application for certification of a biobased product constitutes a violation of this part.

(4) *USDA BioPreferred Web site violations.* Failure to provide to USDA updated information when the information for a certified biobased product becomes outdated or when new information for a certified biobased product becomes available constitutes a violation of this part.

(c) *Notice of violations and associated actions.* USDA will provide the applicable manufacturer or vendor or their designated representatives and any involved other entity known to USDA written notification of any violations identified by USDA. Entities who receive a notice of violation for a biobased content violation must correct the violation(s) within 30 days from receipt of the notice of violation. Entities who receive a notice of violation for other types of violations must correct the violation(s) within 60 days from receipt of the notice of violation. If the entity receiving a notice of violation is a manufacturer, a vendor, or a designated representative of a manufacturer or vendor, USDA will pursue notices of suspensions and revocation, as discussed in paragraphs (c)(1) and (c)(2) of this section. USDA reserves the right to further pursue action against these entities as provided for in paragraph (c)(3) of this section. If the entity receiving a notice of violation is an ''other entity'' (*i.e.,* not a manufacturer, vendor, or designated representative), then USDA will pursue action according to paragraph (c)(3) of this section. Entities that receive notices of suspension or revocation may appeal such notices using the procedures specified in § 2904.6.

(1) *Suspension.*

(i) If a violation is applicable to a manufacturer, vendor, or designated representative and the applicable entity fails to make the required corrections within 30 days (for biobased content violations) or 60 days (for other types of violations) of receipt of a notice of violation, USDA will notify the manufacturer or vendor, as appropriate, of the continuing violation, and the USDA certification for that product will be suspended. As of the date that the manufacturer or vendor receives a notice of suspension, the manufacturer or vendor and their designated representatives must not affix the label to any of that product, or associated packaging, not already labeled and must not distribute any additional products bearing the label. USDA will issue a press release informing the public of the suspension and will also remove the product information from the USDA BioPreferred Web site.

(ii) If, within 30 days from receipt of the notice of suspension, the manufacturer or vendor whose USDA product certification has been suspended makes the required corrections and notifies USDA that the corrections have been made, the manufacturer or vendor and their designated representatives may, upon receipt of USDA approval of the corrections, resume use of the label. USDA will also restore the product information to the USDA BioPreferred Web site.

(2) *Revocation.*

(i) If a manufacturer or vendor whose USDA product certification has been suspended fails to make the required corrections and notify USDA of the corrections within 30 days of the date of the suspension, USDA will notify the manufacturer or vendor that the certification for that product is revoked.

(ii) As of the date that the manufacturer or vendor receives the notice revoking USDA certification, the manufacturer or vendor and their designated representatives must not affix the label to any of that product not already labeled. In addition, the manufacturer or vendor and their designated representatives are prohibited from further sales of product to which the label is affixed.

(iii) If a manufacturer or vendor whose product certification has been revoked wishes to use the label, the manufacturer or vendor must follow the procedures required for original certification.

(3) *Other remedies.* In addition to the suspension or revocation of the certification to use the label, depending on the nature of the violation, USDA may pursue suspension or debarment of the entities involved in accordance with part 3017 of this title. USDA further reserves the right to pursue any other remedies available by law, including any civil or criminal remedies, against any entity that violates the provisions of this part.

§ 2904.9 Recordkeeping requirements.

(a) *Records.* Manufacturers and vendors shall maintain records documenting compliance with this part for each product that has received certification to use the label, as specified in paragraphs (a)(1) through (3) of this section.

(1) The results of all tests, and any associated calculations, performed to determine the biobased content of the product.

(2) The date the applicant receives certification from USDA, the dates of changes in formulation of certified biobased products, and the dates when the biobased content of certified biobased products was tested.

(3) Documentation of analyses performed by manufacturers to support claims of environmental or human health benefits, life cycle cost, sustainability benefits, and product performance made by the manufacturer.

(b) *Record retention.* For each certified biobased product, records kept under paragraph (a) of this section must be maintained for at least three years beyond the end of the label certification period (*i.e.,* three years beyond the period of time when manufacturers and vendors cease using the label). Records may be kept in either electronic format or hard copy format. All records kept in electronic format must be readily accessible during a USDA audit.

§ 2904.10 Oversight and monitoring.

(a) *General.* USDA will conduct oversight and monitoring of manufacturers, vendors, designated representatives, and other entities involved with the voluntary labeling

program to ensure compliance with this part. This oversight will include, but not be limited to, conducting facility visits of manufacturers and vendors who have certified biobased products, and of their designated representatives. Manufacturers, vendors, and their designated representatives are required to cooperate fully with all USDA audit efforts for the enforcement of the voluntary labeling program.

(b) *Biobased content testing.* USDA will conduct biobased content testing of certified biobased products, as described in § 2904.8(b)(1) to ensure compliance with this Part.

(c) *Inspection of records.* Manufacturers, vendors, and their designated representatives must allow Federal representatives access to the records required under § 2904.9 for inspection and copying during normal Federal business hours.

Dated: July 17, 2009.

Pearlie S. Reed,

Assistant Secretary for Administration, U.S. Department of Agriculture.

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