

October 28, 2008

Ms. Anne Caldas  
Director, Procedures and Standards Administration Accreditation Services  
American National Standards Institute  
25 West 43rd Street, 4th Floor  
New York, New York 10036

Dear Ms. Caldas:

On behalf of the Biotechnology Industry Organization (BIO), I am writing in support of the United States Department of Agriculture's (USDA) September 11, 2008, appeal to ANSI requesting a review of the status of the Leonardo Academy (Leonardo) as an ANSI-Accredited Standards Developer with respect to its handling to date of the draft standard for sustainable agriculture (SCS-001), a process initiated in April of 2007.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

We believe that the appeal raises a number of concerns that we share, which are not likely to be resolved in the course of the deliberations of the Leonardo-Academy-constituted sustainable agriculture Standards Committee.

While the Leonardo-appointed Standards Committee did act in September to set aside the draft standard, SCS-001, which purported to cover the entirety of American agriculture, including its environmental and fair labor practices, the Committee itself was selected in light of the coverage of the standard, and therefore its prospective operations will be biased in favor of such an outcome. Therefore, the original damage to stakeholder interests that arose because Leonardo exceeded the scope of activity authorized by its accreditation can only be compounded as the process moves forward.

This is particularly the case with respect to the draft standard's equation of organic and sustainable agriculture. Requiring organic agriculture as the sole qualifying agricultural production technology effectively eliminates at least 95 percent of production agriculture in the United States from being able to obtain certification under the standard. The Committee formed to progress such a standard cannot be expected to fairly represent balanced stakeholder interests in the future.

Likewise, the Committee lacks other essential stakeholder voices. It appears that Leonardo Academy considers the single vote of the California Seed Association to represent all the other inputs denied a seat at the table. These include agrichemical producers, fertilizer producers, and biotechnology providers. Major sectors of agriculture are also un-represented. These include livestock, aquaculture, biofuels and cotton producers, and other sectors being considered for treatment in the Annexes.



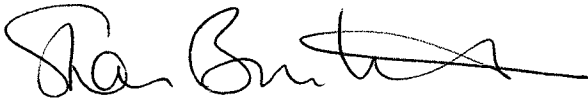
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Even though this Committee has chosen to set aside the draft standard, fatal defects of this standards procedure remain. We hope that ANSI will seriously consider the issues raised by USDA and conclude that the lack of notice to materially affected stakeholders, the lack of promulgation of procedures to challenge registration of a draft standard for trial use, and the unbalanced composition of a standards committee clearly point to the fact that the process is so flawed that it should not continue as presently structured. We believe that to do so would seriously call into question the viability of ANSI's Essential Requirements to administer a fair and equitable standards-setting process.

Sincerely,

A handwritten signature in black ink, appearing to read "Sharon Bomer Lauritsen". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Sharon Bomer Lauritsen  
Executive Vice President  
Food and Agriculture

cc. Charles Martin, USDA