



Food and Drug Administration
College Park, MD 20740

January 29, 2007

James Russell, Ph.D.
Consultant
2938 Jenks avenue
Panama City, FL 32405

Dear Dr. Russell:

This is in response to your letter of June 6, 2006, in which you expressed an interest on behalf of Pine Chemicals Association Inc., in having FDA recognize, in the CFR, Title 21 that the color of rosin is now normally reported in terms of the Gardner color scale rather than the outdated USRG scale.

In your letter of September 7, 1999, you requested that FDA regulations pertaining to rosin and its derivatives be amended to allow the use of the Gardner scale in addition to the current USRG scale, as a standard measure of the color of rosin and rosin derivatives. You state that the USRG scale, although still current, is rarely used in the industry.

Currently as specified in 21 CFR 178.3870 *Rosins and rosin derivatives*, the color of rosin is determined by ASTM method D509-70 "Standard Methods of Sampling and Grading Rosin" using the USRG scale.

In our response to your September 7, 1999 letter, we indicated that we have no objection to the use of the calculated Gardner scale value for specifying the color of rosin and rosin derivatives provided that the color values can be related to the USRG scale that is included in ASTM method D509. We also indicated that it would be inappropriate to eliminate Method D509 from 21 CFR 178.3870 as this method also includes methods for sampling rosins that are not included in method D6166. We further indicated that we would encourage the submission of a food additive petition to amend 21 CFR 178.3870 to include the Gardner color scale and ASTM method D6166 so that this more popular color reference could be used by the industry.

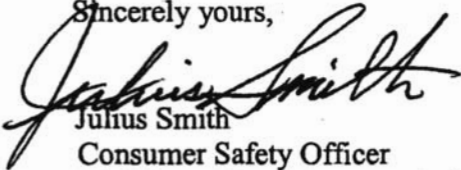
In response to our suggestion that a food additive petition be submitted requesting such an amendment, you state that 21 CFR 171.1 *Petitions* is not appropriate for your intended change/amendment in the regulation. You now ask if there is another citation that is more applicable to your situation or should you use CFR 171.1 and mark "not applicable" in the appropriate places and then include a detailed justification in the covering letter.

We have also concluded that a food additive amendment via the petition process would not be appropriate. However, as mentioned above, we have no objection to the use of the calculated Gardner scale value for specifying the color of rosin and rosin derivatives provided that the color values can be related to the USRG scale that is included in ASTM method D509.

Furthermore, we believe that our conclusion of no objection to the use of the Gardner Scale adequately addresses the subject of an acceptable method as a standard measure of the color of rosin and rosin derivatives and therefore, an amendment to 21 CFR 178.3870 *Rosins and rosin derivatives* is not warranted. We further believe that it would be inappropriate use of agency's resources to amend the CFR for use of a method that the agency has already concluded as currently acceptable for this use.

We trust that the content of this letter is responsive to your inquiry. If you have additional questions, please feel free to contact us.

Sincerely yours,

A handwritten signature in black ink that reads "Julius Smith". The signature is written in a cursive style with a large, sweeping initial "J".


Julius Smith

Consumer Safety Officer

Division of Food Contact Notification, HFS-275

Center for Food Safety and Applied Nutrition

June 29, 2000

Food and Drug Administration
Washington DC 20204

James Russell, Ph.D.
Consultant
2938 Jenks Avenue
Panama City, Florida 32405

Dear Dr. Russell:

This is in response to your letter of September 7, 1999, in which you requested that FDA regulations pertaining to rosin and its derivatives be amended to allow the use of the Gardner scale in addition to the current USRG scale, as a standard measure of the color of rosin and rosin derivatives. You state that the USRG scale, although still current, is rarely used in the industry. To support your request, you have submitted data from Dr. Mike Pointer of Tintometer Ltd. which allows the two scales to be correlated.

Currently as specified in 21 CFR 178.3870 *Rosins and rosin derivatives*, the color of rosin is determined by ASTM method D509-70 "Standard Methods of Sampling and Grading Rosin" using the USRG scale.

We note that ASTM method D509 calls for the use of the USRG (Rosin) scale to assess the color of rosin and rosin derivatives. The method requires that a solid lump of rosin be shaped into a 7/8" cube which is then analyzed for spectral transmittance. The transmittance value is converted to a letter value using a calibration scale.

ASTM method D1554 defines the Gardner color scale. This method determines the color of a sample solution and compares the value to a calibration scale which translates absorbance into Gardner color units. ASTM method D6166 describes a version of the Gardner method that is specifically applicable to Naval Stores (rosin and rosin derivatives).

Your submission included one graph which shows both systems of rosin color measurement plotted in "chromaticity space" demonstrating good correlation between the Rosin Scale and the calculated Gardner color values.

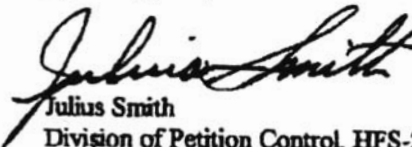
Additionally, Dr. Pointer observed that a different method of interpolation, such as cubic spline or Lagrange, might give different results than the linear interpolation he used, but any differences would be expected to be small.

We have no objection to use of the calculated Gardner scale value for specifying the color of rosin and rosin derivatives provided that the color values can be related to the USRG scale that is included in ASTM method D509. It would be inappropriate to eliminate Method D509 from 21 CFR 178.3870 as this method also includes methods for sampling rosins that are not included in method D6166. However, we would encourage the submission of a petition to amend 21 CFR

178.3870 to include the Gardner color scale and ASTM method D6166 so that this more popular color reference could be used by the industry.

We trust that the content of this letter is responsive to your inquiry. If you have additional questions, please feel free to contact us.

Sincerely yours,

A handwritten signature in black ink that reads "Julius Smith". The signature is written in a cursive style with a large, sweeping initial "J".

Julius Smith

Division of Petition Control, HFS-215
Center for Food Safety
and Applied Nutrition