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With regard to your concerns about Bovine Spongiform Encephalopathy (Mad Cow Disease) having any negative impact on beef gelatin, we would present the following information to allay them:

There are no Specified Risk Materials used in the production of gelatin. (This includes skulls, spinal cords, brains, eyes, tonsils, intestines, etc.)

All materials used in the gelatin production process are from animals that have been inspected by veterinarians from the respective agricultural ministries ante and post mortem and were found free from disease and fit for human consumption. Our suppliers provide us with this documentation, which is made available to the U.S.D.A. under the terms of our import agreement.

In addition, it is stated in the F.D.A. document "Guidance for Industry" dated July 1998 and updated March 5, 2001 (CFR 589.2000) that "... gelatin is exempt under the B.S.E. regulation. Data available to the F.D.A. suggests that gelatin does not transmit the transmissible Spongiform Encephalopathy agent. The conventional manufacturing process for beef hide gelatin has been demonstrated to inactivate in a significant way, any residual activity that may have been present in source tissues."

This process includes:

- 1) An alkali treatment that entails soaking hides at a pH of 12.5 for a period of 30-60 days or a treatment in sodium hydroxide at a pH of 14 for 4-6 days.
- 2) Hot water extractions in temperatures ranging from 55 °C to 90 °C.
- 3) Filtration at temperatures of approximately 55 °C.
- 4) Deionization at approximately 55 °C in an environment with a pH range as low as 2 and as high as 14.
- 5) A sterilization process that involves injecting steam directly into the gelatin to raise the temperature to 140 °C (4 - seconds UHTST) and vacuum flash cooling to cool liquid as rapidly as it was heated.
- 6) A drying process in which moisture is removed from the gelatin in 6 to 8 temperature stages of 45 °C to 65 °C.

A 2004 Dutch study published in the journal Biotechnology and Applied Biochemistry found that even when spiked with the B.S.E. agent, the alkaline or acid process used in the manufacture of gelatin reduced BSE infectivity to undetectable levels. These results were obtained in spite of worst-case conditions that did not reflect the type or quality of materials normally used in the gelatin manufacturing process.

In conclusion, considering that there are no Specified Risk Materials used in the gelatin manufacturing process, the animals used are documented to be healthy and from non B.S.E. affected sources, and also the harshness of the gelatin extraction-purification process, we find it inconceivable that gelatin can be anything but a safe and healthful product.

We hope that this information will be of help to you.

Sincerely,

Sheila Tenut  
Quality Assurance  
Gelatin Innovations