



MEMORANDUM OF TELEPHONE CONVERSATION

June 29, 2004

Between: Dr. Gerald McEwen
Vice-President - Science
Cosmetic, Toiletry, and Fragrance Association

and

Karen L. Carson
Deputy Director
Office of Plant and Dairy Foods, CFSAN, FDA

Subject: BSE Regulation

I asked Dr. McEwen several questions associated with the impact of a BSE regulation, as described in the FDA's January 2004 announcement that the agency intends to publish an interim final rule paralleling actions taken by USDA.

1. What proportion of the cosmetic industry is imported and what proportion is domestic?

Dr. McEwen asked if I wanted finished products or finished products and products made in the U.S. by foreign companies. I asked for only imported finished products. He said that roughly 10-20% of the U.S. market is imported products. He also said that these are weak numbers, but he would ask either Lou Santucci or Mark Pollack to call our economists with stronger numbers. I understand that Mr. Pollack later called and spoke with Clark Nardinelli, CFSAN/FDA, confirming the 10-20% number.

2. Would the impact of a regulation written along the lines of the January 2004 announcement be different for the import and domestic segments of the industry?

Yes, very different. There would be a far greater impact on the domestic industry than on the import industry because, for example, in Europe there is more following of individual cows than in the U.S. and they have been able to dispose of SRMs, etc. We don't have these

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systems in place. If a rule is published as outline in the January announcement, the impact will be greater for the domestic industry.

3a. Are much gelatin and collagen used in cosmetics? b. Will the rule as it affects gelatin and collagen be prohibitive to the industry?

- a. Yes, in certain products
- b. Dr. McEwen did not say that the rule would be prohibitive, but that manufacturers may have to reformulate to use other ingredients or have to find other sources of ingredients, which will incur costs. They do use quite a bit of porcine gelatin. However, the ingredient of greatest concern to the cosmetic industry is tallow and tallow derivatives ù far more of these are used in cosmetics than either of the other ingredients.

4. In a related question I asked whether a possible requirement that the industry demonstrate that cattle materials used did not come from dead or downer cattle would be prohibitive.

Dr. McEwen said that it is hard to say. The industry may need to reformulate or find non-beef sources of ingredients.

I thanked Dr. McEwen for his time and gave him the phone number of the economist, Clark Nardinelli and the regulation writer, Rebecca Buckner.



Karen L. Carson