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14 December 2012

Food and Drug Administration  
Department of Health  
No. 161-2, Kunyang St, Nangang District  
Taipei City 115-61  
Taiwan (ROC)  
Email: [hylin@fda.gov.tw](mailto:hylin@fda.gov.tw)

Re: WTO Notification G/SPS/N/TPKM/271

To whom it may concern:

The International Association of Color Manufacturers (IACM) is the trade association that represents the manufacturers and end-users of coloring substances that are used in foods, including natural and artificial colors. We are writing to offer further information and express our concerns with recent proposal DOH No. 1011302921 of 16 October 2012 to limit the scope and application standards for caramel color. IACM does not support this proposal and encourages the Taiwan Department of Health to continue to classify caramel as a “natural edible colorant.”

However, if the DOH reclassifies Caramel as a “color-food additive” then IACM is concerned that Taiwan would limit the use of caramel colors in certain food categories such as soy sauce and tea beverages. In the case of reclassification, IACM encourages Taiwan to set appropriate limits, such as those that exist under Codex. IACM is a non-government observer organization of Codex and generally supports global harmonization with Codex standards.

IACM understands that the Taiwan DOH is concerned about the presence of 4-Methylimidazole (4-Mel) in caramel colors. The State of California did include 4-Mel on its Proposition 65 list of possible carcinogens. However this inclusion does not signify that the presence of 4-Mel should impact the safety of a food product as 4-Mel is formed naturally in the process of cooking, roasting, broiling or grilling food of every sort — chicken, beef, vegetables, other meats, and even coffee beans. Trace 4-Mel is found in hundreds of home-cooked or store-bought foods that people have been consuming for generations and is not an additive.

California’s decision, which was made by a regulatory agency without any public hearing or review of other research, was based on two inconclusive and contradictory studies — one study in rats, after they were fed large amounts of 4-Mel, showed a reduction of tumors and the same study in mice showed an increase in lung tumors. There has never been a study that showed any connection between 4-Mel and cancer in humans.

Caramel color has undergone complete food safety testing more than 20 times in the past 35 years. It meets rigorous food safety standards around the world. There has never been a study that showed any health risk from caramel color. In 2011 the European Food Safety Authority (EFSA), the U.S. Food and Drug Administration (FDA), and other food authorities reaffirmed that caramel color is a safe color additive. Caramel also has Generally Recognized as Safe (GRAS) status with the FDA.

We remain at your disposal to provide any additional information concerning the strong safety record of all caramel colors that are produced or used by our member companies, including the scientific evidence that our colors are safe. We strongly urge that the scientific evidence that caramel colors are safe be considered in a manner consistent with other government bodies and harmonized international standards.

IACM thanks you for considering these comments.

Sincerely,

A handwritten signature in cursive script that reads "Sarah A. Codrea".

Sarah A. Codrea  
Executive Director