



Our ref.: GEG-197 -06

Docket No 198P-0724
RIM No 0910-AF12

Thursday, April 27, 2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Of our consideration:

The present document is subscribed by the members of the **NATURAL COLORS & EXTRACT COMMITTEE** that belongs to ADEX, which groups the exporter companies of Peru. The 7 existing Carmine & Cochineal Extract Peruvian manufacturers that represent in total more than the 90% of the World production are part of this committee; therefore we can affirm without any doubt that what is written below represents the 100% of the Peruvian manufacturers which mean practically the total world production.

Our comments:

- 1) We seriously question the fact of declaring carmine and the cochineal extract as a potentially allergenic product.

Among all the existing medical literature all over the world there are around 20 isolated cases of people having allergic reactions caused by the ingestion of carmine colored products or cochineal extract colored products. We understand that these numbers themselves are not enough to emit a valid conclusion about carmine and its declaration as an allergenic.

It is not being taken in consideration that the aliments colored with Carmine or cochineal extract have been consumed for more than the 70% of the world population for over 10 years now, our members produce and sell to almost 100 countries all around the world, the every year selling average reaches the 300,000 kg in total of the concentrated version of carmine, it is evident that this quantity is consumed around the world during a year; however only 20 cases of allergy have been found in particularly sensitive persons, besides these few people who have been diagnosed to be allergic to Carmine already had a particular congenic predisposition to develop an allergy to other aliments. It is logical to ask ourselves if it is valid to declare the carmine or the cochineal extract as an allergenic product. We think that this is not justifiable at all.

- 2) We ask you while taking the final decision, to take in consideration the costs in Peru that would imply any change made on the current legislation for the case of Carmine and cochineal extract.

98P-0724

... C12

"32 AÑOS PROMOVRIENDO LAS EXPORTACIONES"



... 2

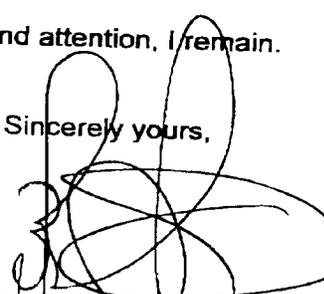
As per the numbers and statistical data on the agriculture ministry, about 20,000 families from the poorest rural zones of the country depend exclusively of the production and collection of cochineal as a way of daily survival, any change on the usage of this color additive will pose a real risk of detriment on the US demand which is the principal buying country of this resource, this will cause unavoidably less incomes and more poverty for these families who are mainly from the highlands.

It is certain that any change on the label legislation will produce a change in the demands since the final user would take this special treatment towards carmine as a warning of health risk despite the fact that this risk would be practically none, there will be an important fraction that will prefer other colorants that are not labelled.

Due to what is exposed we kindly ask you to take in consideration what has been said when any change is made on the legislation regarding labelling on carmine and cochineal extract.

Thanking you in advance for your kind attention, I remain.

Sincerely yours,


Alvaro Barrebechea Chávez
General Manager



"32 AÑOS PROMOVRIENDO LAS EXPORTACIONES"