

17 October 2011

Subject: Studies relevant to the evaluation of aluminum-containing food additives

We are writing to provide important information regarding the use and safety status of aluminum lake colour additives.

Background on the importance of aluminum lake colour additives

Aluminum lakes have specific technical applications that cannot be readily replaced by non-lake alternatives. The primary use of aluminum in food colourants is in the formation of aluminum lakes. For a small number of products, aluminum is also used as aluminum sulphate to stabilize the dye. These are primarily for anthocyanin colourants. In these applications, an aluminum lake is not considered to be formed. No alternative stabilizer has been found that could replace aluminum for these anthocyanin colourants.

Because aluminum lake colours have a higher cost in use than water-soluble synthetic colours, they are generally used only in circumstances where they give a technical advantage. Within that general food category they are most commonly found in confectionery, including chewing gum, and cake decorations, and to a lesser extent in certain snack seasonings, dairy products, and desserts. Aluminum lake colours are also used in food/dietary supplements.

Aluminum lake colour intake

Aluminum lake colours represent only one source of aluminum intake. In one study¹, the total average human exposure to aluminum from food sources, including contributions from contact with aluminum foil and aluminum cookware, was estimated to be roughly 50% of the newly-established PTWI of 2 mg/kg bw for typical consumers. In its recent evaluation, JECFA indicated that for some consumers at the 95th percentile, the PTWI may be exceeded for total aluminum intake, and emphasized that consumption of aluminum-containing food additives is not a health concern provided that total dietary exposure to aluminum remains below the PTWI.² Due to this, the Codex Committee for Food Additives (CCFA) will revise provisions for food additives containing aluminum within the Codex General Standard for Food Additives (GSFA). It is not anticipated that this exercise will focus on aluminum lake colours, since they represent a minor contribution to total aluminum intake.

While aluminum lake intake varies by age, sex and population, aluminum lakes contribute, in general, less than 10% of the total daily aluminum intake. Additionally, a more important measure of aluminum exposure is not that amount ingested from all sources, but that amount of aluminum that is absorbed. For this reason, it is critical to better understand the aluminum bioavailability.

¹ Pennington, J.A., and Schoen, S.A. 1995. Estimates of dietary exposure to aluminium. *Food Addit. Contam.* 12:119-128.

² <http://www.who.int/entity/foodsafety/chem/jecfa/summaries/Summary74.pdf>

JECFA: Recent Safety Evaluation

As mentioned above, aluminum (all sources) was recently re-evaluated at JECFA at their 74th meeting held in July 2011. At that meeting, JECFA established a new provisional tolerable weekly intake (PTWI) of 2 mg/kg bodyweight (bw). This was an increase relative to the previous PTWI of 1 mg/kg bw that was established in 2007, and the increase was on the basis of recent additional data that was submitted to JECFA, including new data on the bioavailability of aluminum from a representative aluminum lake colour additive.

Newly Available Data on Aluminum Bioavailability and Toxicology

The new data provides strong evidence that the aluminum from aluminum lake colour additives is very poorly bioavailable, and would therefore not be absorbed to any significant extent prior to excretion.

We sponsored a bioavailability study on FD&C Red No. 40 (allura red AC) aluminum lake in female rats using JECFA-recommended analytical methods.³ From the Red 40 lake bioavailability study, the fractional uptake of aluminum was roughly 0.0008. In other words, if 1 ng of aluminum is consumed as part of an aluminum lake, after 7 days the residual amount of aluminum in the rat is 0.0008 ng. This indicates that the bioavailability of aluminum is extremely low, and similar very low uptake has been shown in man, indicating that it is likely that the bioavailability of Al from Red 40 seen in this experiment would be the same for man. This study provides strong evidence that there is no chronic accumulation of Al from aluminum lakes.

In response to JECFA's call for data for aluminum from 2007, both the food industry and the aluminum industry have also conducted a number of studies.

These studies used state-of-the-art methods to assess the bioavailability of aluminum from a number of sources, and low bioavailability for food additives was observed. Industry-sponsored studies have also assessed the potential developmental and/or neurological effects of aluminum through a multi-generation study. In Japan, additional work addressed issues of aluminum bioavailability and potential developmental effects. **No significant neurological effects were found.** We believe that such studies, while performed on water-soluble aluminum salts, are directly relevant for other sources of aluminum, such as aluminum lake colours and sodium aluminum phosphate.

At its 43rd and most recent meeting in 2011, the CCFA noted that there are not provisions within the GSFA for aluminium lake colours, stating that:

“The Committee noted that the concern for the use of aluminium lakes of colours should be addressed by Members in the context of the procedure of prioritisation of substances for evaluation by JECFA.”⁴

In our opinion, it should be noted that this is not an indication of a safety concern, but rather is an indication that CCFA has not yet made a decision on how to best allocate aluminum exposure from the use of aluminum lake color additives.

³ Priest, N. (2010) The Bioavailability of Ingested Al-26 Labelled Aluminium and Aluminium Compounds in the Rat: FD&C Red No. 40. GNP-121100-REPT-001, Unpublished report to the International Association of Color Manufacturers.

⁴ [Codex 43th CCFA Report](#)

We remain at your service should you have additional questions or need further information.

Yours sincerely,

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