

June 15, 2018

European Commission
DG Health and Food Safety, Unit D2-Multilateral International Relations
Rue Froissart 101
B-1049 Brussels
Via E-mail: sps@ec.europa.eu

To whom it may concern:

The International Association of Color Manufacturers (IACM) is the trade association that represents the global color industry, comprised of manufacturers and end-users of coloring substances that are used in foods, including natural and synthetic colors. IACM appreciates the opportunity to provide the following comments on the Draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards Cochineal, Carminic acid, Carmines (E 120) via WTO notification G/SPS/N/EU/255.

IACM supports many of the proposed changes to the specification of E 120. However, we respectfully raise concerns over the proposed new purity limit for lead. This limit appears to be set without consideration of scientific justification or global trade implications. A level of not more than 1.5 mg/kg is significantly lower than both the US limit of not more than 10 ppm¹ as well as that of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which was set just in 2006, of 5 mg/kg². Additionally, there are other color additives, such as curcumin, chlorophylls, and chlorophyllins, with a European Union regulatory limit for lead of not more than 5 or 10 ppm.

In addition to not being scientifically justified, the new limit for lead will be extremely challenging for manufacturers to meet, due to natural occurrence. Commission Regulation (EU) No 231/2012³ states that “specific purity criteria currently applicable should be adapted by reducing maximum limits for individual heavy metals of interest where feasible and where the JECFA limits are lower than those currently in force.” In this case, the JECFA limit is not lower and to reduce the limit for lead for E 120 significantly below what JECFA set just over 10 years ago with no scientific justification to support this move is arbitrary and unwarranted, particularly since manufacturers have noted that compliance with stricter Union provisions would not be technically feasible.

From a safety perspective, the level of exposure to lead is miniscule considering the estimated intake of carmines in Europe. The 95% intake of carmines is estimated to be up to 4.7 mg/kg bw/day (toddlers age group) under the brand-loyal scenario (most conservative refined exposure scenario) and up to 6.7 mg/kg bw/day in the same age group using the regulatory MPL scenario. With lead levels of 5 ppm, the lead exposure from carmines is calculated to be

¹ 21 CFR 73.100

² http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/additive-108-m1.pdf

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012R0231&from=EN>

0.0235 $\mu\text{g}/\text{kg}$ bw/day or 0.032 $\mu\text{g}/\text{kg}$ bw/day, respectively. The conservative refined exposure estimate at the 95% intake level is 3.5% of the mean lifetime exposure to lead of 0.68 $\mu\text{g}/\text{kg}$ bw/day from all food and water intake based on middle bound lead occurrence, as published in the 2012 EFSA Scientific Opinion on lead intake.⁴ More appropriately, the mean intake of carmines calculated in the brand loyal intake scenario was up to 1.3 $\mu\text{g}/\text{kg}$ bw/day (also in toddlers) with a corresponding lead exposure of 0.0065 $\mu\text{g}/\text{kg}$ bw/day, which is <1% of the mean lifetime exposure to lead of 0.68 $\mu\text{g}/\text{kg}$ bw/day. Furthermore, the EFSA reported that the foods that contributed the most to lead exposure were “*grains and grain-based products (16.1%), followed by milk and dairy products (10.4%), non-alcoholic beverages (10.2%) and vegetables and vegetable products (8.4%)*”. This is understandable considering the natural occurrence of lead. Based on these findings, food colorants like carmines are not significant contributors to lead exposure through food and a limit of 1.5mg/kg is not scientifically justified.

Lastly, the contribution of food colors to lead (and other metals) exposure is significantly overestimated since the fractions of foods containing these colors are lower than 100% in each category and this is not considered in most exposure assessments, including the refined brand loyal scenario.

IACM appreciates the opportunity to provide feedback on the EU initiative to update the specifications for E 120. Please do not hesitate to contact me directly with any further questions.

Sincerely,



Sarah Codrea
Executive Director

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2831>