

1 **Letter to the Editor**

2 **Comment on Amchova et al. 2015 review of food color safety**

3 A review by Amchova et al. on the safety of synthetic food colors is currently in press in the journal of  
4 Regulatory Toxicology and Pharmacology (Amchova et al., 2015). The authors of this review have  
5 attempted to provide an update on the status of safety evaluations of synthetic food colors, in light of the  
6 recent re-evaluations by the European Food Safety Authority (EFSA). Such a review is a worthy  
7 undertaking, provided that it accurately reflects the available scientific evidence. Regrettably, Amchova et  
8 al. have infused the review with popular sentiments, typically expressed in non-scientific literature sources,  
9 about perceived risks attributed to consumption of foods containing added colors.

10 There are multiple inaccurate statements within the review. These include the opening sentences such as  
11 “food colorant is *any* dye, pigment, etc.” or “*any chemical that reacts with another substance and causes*  
12 *the formation of color*”. While similar definitions may be seen in the US Food and Drug Administration  
13 (FDA) regulations, the generalization is taken out of context and ignores the fact that synthetic food colors  
14 are few and selected substances that have undergone multiple regulatory and scientific safety reviews. *Not*  
15 *any* dye that can be used in non-food applications such as painting, is approved for use as a food colorant,  
16 and there are specific regulations and a long history of safe use that govern the approval of food additives  
17 including colors in Europe<sup>1</sup>, the USA<sup>2</sup>, and elsewhere.

18 The authors appear to consider all listed food colors as “azo dyes” in Section 2 and Table 1, despite listing  
19 the proper chemical group in the individual paragraphs, indicating confusion about the proper chemical  
20 classification and the structure and function of color additives. The very generic description of the principles  
21 and application of toxicology in section 1.2 is too basic for the audience of this journal, not specific to the  
22 context of food additive safety evaluations and indicative of the rigor in the representation of the following

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<sup>1</sup> <http://www.efsa.europa.eu/en/topics/topic/foodcolours>

<sup>2</sup> <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm>

23 sections. Generally, the findings and conclusions of cited studies are simply reproduced as stated in the  
24 original publications and summarized rather uncritically.

25 The lack of critical review is evident throughout. As one example, the Lucova et al. (2013) study presents  
26 major limitations that render their conclusions invalid if one were to assess their findings quantitatively and  
27 critically (Codrea, 2013). Similarly, simply referring to the estimated intake of food colors as reported by  
28 Stevens et al. (2014) is insufficient. Amchova et al. failed to recognize the methodological limitations that  
29 led to a gross overestimation of intake (Bastaki and Codrea, 2014) that is inconsistent with the results of  
30 the analysis conducted by the US FDA (Harp et al., 2013). In addition, in descriptions of genotoxicity test  
31 results, the meaning of mitotic index is misinterpreted and high dose effects, despite acknowledgement as  
32 such, are still interpreted as indicative of risk of carcinogenesis (e.g. in the section for tartrazine).

33 In addition to the multiple inaccuracies and misinterpretations of toxicological findings, the review of  
34 multiple EFSA Scientific Opinions on color additives is highly repetitive and reproduces excerpts  
35 insufficiently often ignoring the rationale of EFSA's conclusions on food color safety. While the  
36 compilation of these Opinions and their accessibility in the peer reviewed literature could be helpful to  
37 readers, the review lacks substantive information about EFSA's scientific reasoning and interpretation of  
38 available scientific evidence, and adds little to the already publicly available (free of charge) Scientific  
39 Opinions. Amchova et al. brush over important literature in a patchwork that in our opinion does not inform  
40 the readership of Regulatory Toxicology and Pharmacology.

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## 42 **References**

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