



GILLINGS SCHOOL OF
GLOBAL PUBLIC HEALTH

Nutrition

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July 12, 2023

Food and Drug Administration, HHS

RE: Quantitative Research on Front of Package Labeling on Packaged Foods OMB Control Number 0910–NEW

This will be a short letter emphasizing some points I feel are very important. **First, I applaud the FDA on recognizing that food high in added sugar, added sodium and added saturated fat (HSSFs) are to be minimized in the American diet.** While reducing added sodium is a simple clear win all around, as sodium replacements are often potassium salts and we need desperately to increase the potassium to sodium ratio in our diet. There will be controversies around the other two which I want to comment on:

1. Added sugar: this is often replaced by nonnutritive sweeteners (the diet sweeteners). WHO misread the literature on this category. They ignored the 25-35 randomized controlled trials which showed either no impact or a positive health impact. They focused on longitudinal studies. When a few of the studies, namely CARDIA and the Harvard cohorts each treated diet as an effect modifier all the adverse effects of non-sugar sweeteners (NSS) on cardiometabolic outcomes and weight disappears (the one time Harvard treated diet as an effect modifier) and showed significant cardiometabolic improvement (the CARDIA NIH funded cohort).^{1,2} I should add that all the rat studies are irrelevant as per gram of body weight rats and mice have 100 fold higher sweetness impact.
2. Saturated fat: while many saturated fats are fine to consume, the major saturated fat in packaged food is palm oil, the most dangerous of saturated fats.^{3,4} Palm oil has been found to have strong adverse impacts on health but the food industry loves this colorless odorless oil as these properties allow its ready usage.

In addition, it is critical to exclude various vitamins and other nutrients the companies want to add. They do not impact the healthfulness of these major items linked with obesity and so many other major NCDs.

Second, as of now Canada, Israel, Chile (higher income countries), and Mexico, Colombia, Peru, Brazil, Argentina, and Uruguay have warning labels. A number of other governments are now in the public response stage of introducing warning labels (e.g., South Africa, possibly India) and many more are considering this. The Industry fights all the labeling systems that work despite the fact that employment, profits and wage rates have not been impacted in evaluations published to date.⁵⁻⁷ And in publications to date these policies have a positive impact on reduction of added sodium and sugar, a lesser impact on reduction of saturated fats via reformulation⁸ and significant reductions in sugar-sweetened beverage and unhealthy food intake.⁹⁻¹¹ Forthcoming studies from Chile and Peru will show even larger positive impacts in terms of reducing intake of HSSF food. One last point is the warning labels in just the first year already deeply impacted Chilean children as our focus groups in lower income areas showed.¹²

Third, HSSF food comprises the majority of ultra-processed foods (UPF) in the US.

Globally, warning labels are shown along with taxation to be the most impactful policies linked with ultra-processed food.

Fourth, the science is not quite there in creating a simple readily followed definition of ultra-processed food. Research ongoing by several US, UK, Australian and other teams will show that additions of several FDA Codex classes of additives will allow us in later years to reduce UPF intake in the policy arena. Now the taxes and policies of Colombia that talk about reduction of UPF food in their titles really only use the HSSF cutoffs of PAHO or Chile.^{13,14}

Fifth, I have concerns about the warning labels used. The only options found to be impactful and used by countries are the octagon and one with words. The two colors used to date have been red and black. I worry not having the octagon as an option removes a potential strong option. Two countries tested the octagon vs. an information box and the latter also worked but no current country uses it. Warning labels with pictures on them should be considered to allow low level literacy individuals to read them. Pictorial warning labels are currently used in Israel, proposed in South Africa regulation and in process in India. It is important for these labeling RCTs to test low level literacy individuals of all ages, but as this proposed experiment is via computer it will likely not reach such individuals, and it would be wise to consider alternatives to include testing those with low literacy.

Sixth, the use of percentage of daily allowance will mislead the public. All studies of this show it does not have an impact. Also, daily allowance varies by age and gender. The use of each nutrient of concern with grams or mg per 100 grams is the global standard used in almost all FOPL thresholds and is the international codex requirement. PAHO uses energy density, but other WHO regional offices and most countries use grams or mg of the nutrient per 100 grams as the cutoff.

Finally, in many countries, such as Chile and Israel, the energy density threshold is used for food with added sodium, sugar or saturated fat. This is very important. If you want to capture even a small proportion of ultra-processed foods more effectively this should be added. Our team will provide more informed scientific justification for inclusion of the improved warning label based on tests in actual stores as well as in person and online RCTs. Our eye-tracking studies are not published yet. One important overview we did of the warning label process from the tobacco, alcohol and food literatures is noted here.

I congratulate you on moving forward with this. I think with a few changes, this proposed warning label will be the FDA's most important regulation to reduce NCDs other than the cigarette regulations.

Sincerely yours,



Barry M. Popkin

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