



# Efficacy of front-of-package nutrient labels designed for mandatory implementation in the USA: an online randomised controlled trial

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## Summary

**Background** In 2025, the US Food and Drug Administration (FDA) proposed a mandatory single front-of-package label (FOPL) listing low, medium, or high descriptors and the percent Daily Value (%DV) for saturated fat, sodium, and added sugars. Effects of this scheme (referred to as Nutrition-Info-%DV) on consumer understanding, perceptions, and behaviours are largely unknown; thus, this study aims to compare the FDA's proposed label against potential alternatives.

**Methods** This online randomised controlled trial recruited a national sample of US adults aged 18 years or older who reflected US demographics. Participants were randomly assigned (1:1:1:1) via the Qualtrics randomiser to view products labelled according to one of five conditions: (1) a no-label control; (2) the FDA's proposed scheme (Nutrition-Info-%DV); (3) a Nutrition-Info scheme with no %DV and High highlighted in red (Nutrition-Info-Red); (4) a single label scheme listing all nutrients contained in a high amount (High-In); or (5) a multilabel scheme with separate labels for each nutrient contained in a high amount (Multi-High-In). Participants were masked to the study objectives. Primary outcomes included consumer understanding (ie, correct identification of products with the healthiest and least healthy nutrient profiles, correct assessment of high nutrient content) and perceived healthfulness of unhealthy products (high in one, low in two nutrients). This study was registered with ClinicalTrials.gov (NCT06903403).

**Findings** A total of 15 582 participants were randomly assigned (3121 assigned Nutrition-Info-%DV, 3115 assigned Nutrition-Info-Red, 3117 assigned High-In, 3116 assigned Multi-High-In, and 3113 assigned no-label control), with recruitment and data collection occurring April 1–25, 2025. 1653 participants were excluded, yielding an analytical sample of 13 929 (7021 [50%] women, 6851 (49%) men, and 57 (<1%) identifying another way (eg, gender non-conforming or non-binary). All FOPLs improved consumer understanding compared with the control. Nutrition-Info-Red outperformed Nutrition-Info-%DV for participants correctly identifying the healthiest (5.4 percentage points; 95% CI 4.1–6.8;  $p < 0.0001$ ) and least healthy (3.3; 1.8–4.9;  $p < 0.0001$ ) nutrient profiles. Multi-High-In outperformed Nutrition-Info-%DV for participants correctly identifying the least healthy nutrient profiles (1.7; 0.1–3.3;  $p = 0.038$ ). Both Nutrition-Info-Red (2.3; 1.6–3.0;  $p < 0.0001$ ) and Multi-High-In (0.9; 0.2–1.5;  $p = 0.014$ ) outperformed Nutrition-Info-%DV in correct assessment of high nutrient content. Nutrition-Info-Red and Nutrition-Info-%DV resulted in higher perceived healthfulness of unhealthy products than Multi-High-In. Multi-High-In outperformed all schemes in reducing the selection of high-in foods (range= -7.7 to -5.0 percentage points) and quickly identifying nutrient profiles (range= -31.6 s to -4.5 s).

**Interpretation** FOPLs that only highlight high amounts of nutrients of concern, like Multi-High-In, outperformed the FDA's proposed scheme and should be considered for implementation to help consumers quickly identify and make healthier dietary choices.

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## Introduction

Packaged foods are the leading source of added sugars,<sup>1</sup> sodium,<sup>2</sup> and saturated fat in US diets.<sup>3</sup> Overconsumption of these particular nutrients of concern increases risk for chronic diseases,<sup>4–6</sup> and the *Dietary Guidelines for Americans 2020–2025* (DGAs) recommends limiting their consumption.<sup>7</sup> Front-of-package labels

(FOPLs) hold promise for reducing consumption of these nutrients, improving consumer understanding and dietary choices, with the potential benefit of preventing chronic diseases.<sup>8</sup> Although the USA lacks a mandatory FOPL system, the US Food and Drug Administration (FDA) has begun the regulatory process to mandate one<sup>9</sup> and has researched label designs (*Quantitative Research on*

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### Research in context

#### Evidence before this study

We searched PubMed for studies testing front-of-package labels (FOPLs) published between Jan 1, 2010, and Dec 31, 2024, using the search terms (“nutri\*” OR “warning” OR “high”) AND “label\*” AND “pack\*” AND “food” AND “random\* controlled trial”), with no language restrictions. This search identified 46 relevant publications based on titles and abstracts. Experiments comparing labelling schemes have found that interpretive labels, and particularly High-In labels for high nutrient content, outperform quantitative or numeric labels in improving consumer understanding and behaviours. Policy evaluations also suggest that High-In labels are effective at improving behaviours.

#### Added value of this study

In January, 2025, the US Food and Drug Administration (FDA) proposed a mandatory FOPL called the Nutrition Info box that lists low, medium, and high descriptors and percent Daily Value. The FDA’s proposed label is novel compared with other

currently implemented labels, and evidence is limited on its effects on consumer understanding, perceptions, and behaviour. To our knowledge, our study is one of the first to compare the FDA’s proposed label against a no-label control and alternative labels the FDA could consider in place of the Nutrition Info label.

#### Implications of all the available evidence

We found that two alternative designs outperformed the FDA’s proposed label in consumer understanding. In particular, a multilabel High-In design resembling labels currently implemented in several Latin American countries (ie, Argentina, Chile, Colombia, Mexico, Peru, Uruguay, and Venezuela) yielded largest improvements in behaviour and quickest response. These findings, together with other experimental and observational evidence, suggest that the FDA and policy makers in other countries should prioritise multilabel FOPLs that indicate high contents of nutrients consumed in excess instead of Nutrition-Info labels.

*Front of Package Labeling on Packaged Foods*; Office of Management and Budget control number 0910-0920).<sup>10</sup> Based on this research, in 2025, the FDA published a proposed rule to mandate a so-called Nutrition Info box scheme, listing nutrients of concern alongside low, medium, or high descriptors and percent Daily Value (%DV;<sup>9</sup> hereafter called Nutrition-Info-%DV).

The FDA’s proposed scheme is unique among FOPL systems internationally. First, it contains both qualitative (eg, low, medium, or high) and quantitative (eg, %DV) information, whereas most mandatory FOPLs contain only qualitative information. Qualitative labels outperform quantitative labels in improving consumer understanding<sup>11,12</sup> and purchasing intentions and behaviours,<sup>13,14</sup> suggesting the FDA’s proposed label could be improved by removing the quantitative information. Second, the FDA has proposed a single label resembling the FDA’s Nutrition Facts label, contrasting with multilabel designs that display one label for each nutrient contained in high amounts in a product, such as the so-called High-In labels used in several Latin American countries.<sup>15</sup> Experiments<sup>13,16,17</sup> and policy evaluations<sup>18,19</sup> show that multilabel, High-In schemes improve the healthfulness of food and beverage selections and spur product reformulation.<sup>20</sup> Thus, testing a multilabel, High-In design in the US context is essential for developing informed policy recommendations. Shifting to a multilabel, High-In scheme or making other changes to the FDA’s proposed label (eg, removing quantitative information and specifically highlighting nutrients that are contained in a high amount) might improve consumer understanding and the healthfulness of purchases, but this idea has not been tested before. Moreover, the FDA’s

research on potential FOPLs had important limitations that this study aims to address, including ambiguously worded outcome measures (ie, asking participants to evaluate nutrient profiles without defining the phrase); labels tested in isolation of products or only on mock packages of healthy foods, rather than actual products sold in the USA; no testing of labels on products with substantially (also known as severely) mixed nutrient profiles (ie, low in one nutrient and high in another), which represents about 40% of purchased packaged foods;<sup>21</sup> and a confounded experimental design (eg, use of different nutrient profiles for different experimental conditions).<sup>10</sup>

In this study, we seek to address the aforementioned limitations and compare the FDA’s proposed Nutrition-Info-%DV to alternative FOPL schemes and a no-label control, examining effects on consumer understanding (eg, correct identification of the healthiest nutrient profiles), perceptions of products, reactions to labels, and behaviour (ie, food selections).

## Methods

### Study design

We conducted an online randomised controlled trial (RCT) that used a between-subjects design with five conditions (four FOPL schemes and a no-label control); the protocol and analysis were preregistered (ClinicalTrials.gov, NCT06903403; appendix p 20), and the trial is closed. The UC Davis Institutional Review Board deemed this study exempt from a full committee review. No adverse events were reported during the study, and a Data and Safety Monitoring Board was not required. There was no participant or public involvement in the study design, conduct, or reporting.

See Online for appendix

## Participants

A national sample of adults reflecting US distributions of sex, age, race and ethnicity, and education<sup>22</sup> was recruited with Prime Panels<sup>23</sup> between April 1 and 25, 2025. Participant demographics were self-reported. Eligibility included living in the USA and being age 18 years or older. Participants were compensated modestly with varying amounts depending on what they agreed upon with their platform for their time by Prime Panels. Participants provided informed consent electronically.

## Randomisation and masking

In an online RCT, participants were randomly assigned with a simple allocation ratio (1:1:1:1:1) via the Qualtrics randomiser to one of five conditions: (1) no-label control; (2) FDA's proposed Nutrition-Info-%DV (black and white, low, medium, or high descriptors, with %DV for each nutrient); (3) Nutrition-Info-Red (low, medium, or high descriptors, with High highlighted in red, and %DV removed); (4) High-In (black and white single label developed by the FDA, listing any nutrients present in high amounts); or (5) Multi-High-In (multiple black rectangle labels; one for each nutrient present in a high amount; similar to Chile's FOPL scheme<sup>15</sup>). Although other schemes with evidence of efficacy exist, such as summary schemes (eg, Health Star Rating, NutriScore),<sup>15</sup> we only tested scheme types the FDA has vetted and studied (ie, Nutrition-Info and High-In),<sup>10</sup> as these are the ones the FDA would most plausibly consider in its final rule. These scheme types also have high legal viability in the USA<sup>24</sup> and align with existing US regulations that use %DV thresholds. Participants saw the same FOPL scheme on real (ie, branded) products. Participants were masked to the study aims and were informed that the study was about packaged foods.

## Procedures

Participants first completed an initial hypothetical shopping task in which they selected an item they wanted for themselves among eight frozen meals labelled according to assigned condition. Then, participants answered a series of questions. We used these responses to assess noticing, recall, reported label use, and food selection. Food selection in this first task was included as an exploratory outcome to assess the behavioural impact of labels before their assigned schemes were explained.

Second, participants assigned to an FOPL scheme received a brief explanation of their assigned scheme. They then viewed four sets (desserts, yogurts, frozen meals, and sandwiches) of three products (each with different nutrient profiles) labelled according to assigned condition. For each set, participants were asked to identify which of the three products had the healthiest and least healthy nutrient profiles. To clarify the meaning of nutrient profile, the survey item asked participants to consider saturated fat, sodium, and added sugars in their evaluations.

Third, participants viewed nine products (seven foods, two beverages) labelled according to assigned condition one at a time and rated each on perceived healthfulness. Products belonged to one of three categories: (1) unhealthy products high in one and low in two nutrients of concern (beef jerky or carbonated, sweetened, soft drink [also known as soda in the USA]), sweets (known as candy in the USA); (2) high-added-sugar products with different amounts (low and medium) for each remaining nutrient of concern (cereal, yoghurt, sports drink); and (3) unhealthy products not high in any nutrients of concern but that the 2020–25 DGAs recommends limiting (white bread, cheese corn puffs, hot dogs).<sup>7</sup>

Fourth, participants viewed five products (four foods, one beverage) one at a time that were labelled according to assigned condition and indicated if the product was high in sodium, saturated fat, or added sugars.

Fifth, participants completed a second shopping task to assess behavioural response to the label. In this task, participants selected one of 12 snack foods, labelled according to their assigned condition, for themselves and (if applicable) their youngest child aged 2 years or older. To encourage real-world behaviours, participants were informed that 20 people would be randomly chosen to receive their selected item.

Finally, while viewing their assigned labels in isolation of products, participants reported perceptions of their assigned label: the extent to which it discouraged consumption of products high in nutrients of concern,<sup>17</sup> ease of understanding the label; and ease of using the label to compare products. The latter two measures on ease were similar to those used in the FDA experiment.<sup>10</sup> Participants then provided sociodemographic information (appendix pp 25–27, 63–67).

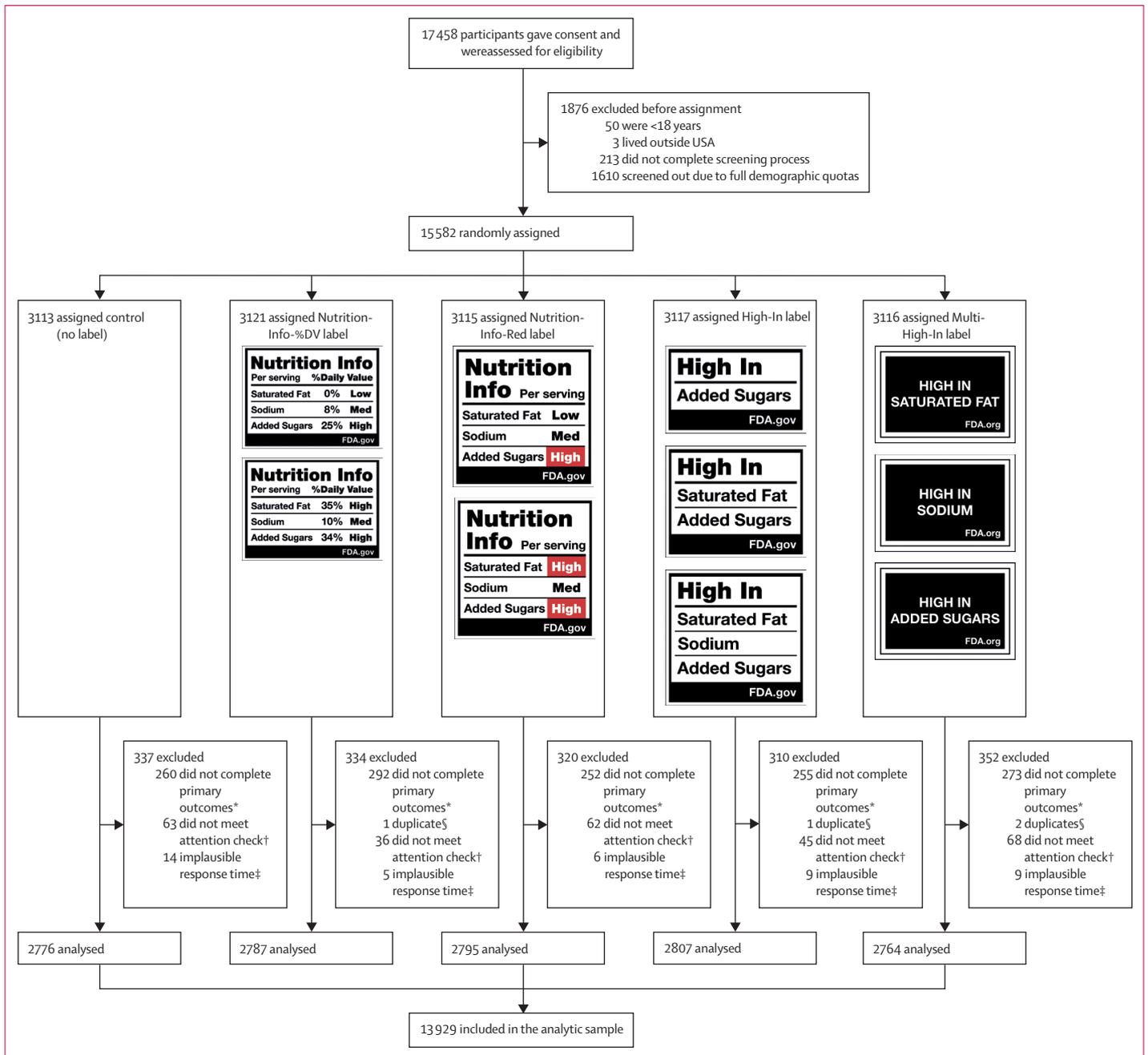
Products displayed (appendix pp 2–3) were chosen to represent popular brands, major sources of nutrients of concern (eg, sandwiches, desserts), or products explicitly discouraged by the 2020–25 DGAs (eg, carbonated, sweetened, soft drinks and processed meats).<sup>7</sup> The display order of products and categories (or shopping task shelf order) was randomised via the Qualtrics randomiser. Response times were captured by Qualtrics.

## Outcomes

The primary outcomes were correct identification of the healthiest and least healthy nutrient profiles; perceived healthfulness of unhealthy products high in one and low in two nutrients of concern; and correct assessment of whether products were high in each nutrient of concern. These primary outcomes were selected to align with the FDA's priorities of improving consumer understanding,<sup>10</sup> which support the agency's mission of providing accurate science-based information.<sup>25</sup>

Secondary outcomes included perceptions (ie, perceived healthfulness of unhealthy products that contained different amounts for each nutrient and of unhealthy

For more on Qualtrics see  
<https://www.qualtrics.com/>



**Figure 1: Trial profile**

%DV=percent Daily Value. FDA=US Food and Drug Administration. Nutrition-Info-Red=high descriptor highlighted in red. High-In=black and white single label listing any nutrients present in high amounts. Multi-High-In=multiple black rectangle labels; one for each nutrient present in a high amount. \*Incomplete primary outcomes: identification of healthiest and least healthy nutrient profiles, high nutrient assessment, perceived healthfulness of products high in one nutrient of concern (exclusion preregistered). †Attention check question assessed the current month (exclusion preregistered). ‡Completed survey in less than a third of the median completion time (exclusion preregistered). §Second response from the same individual.

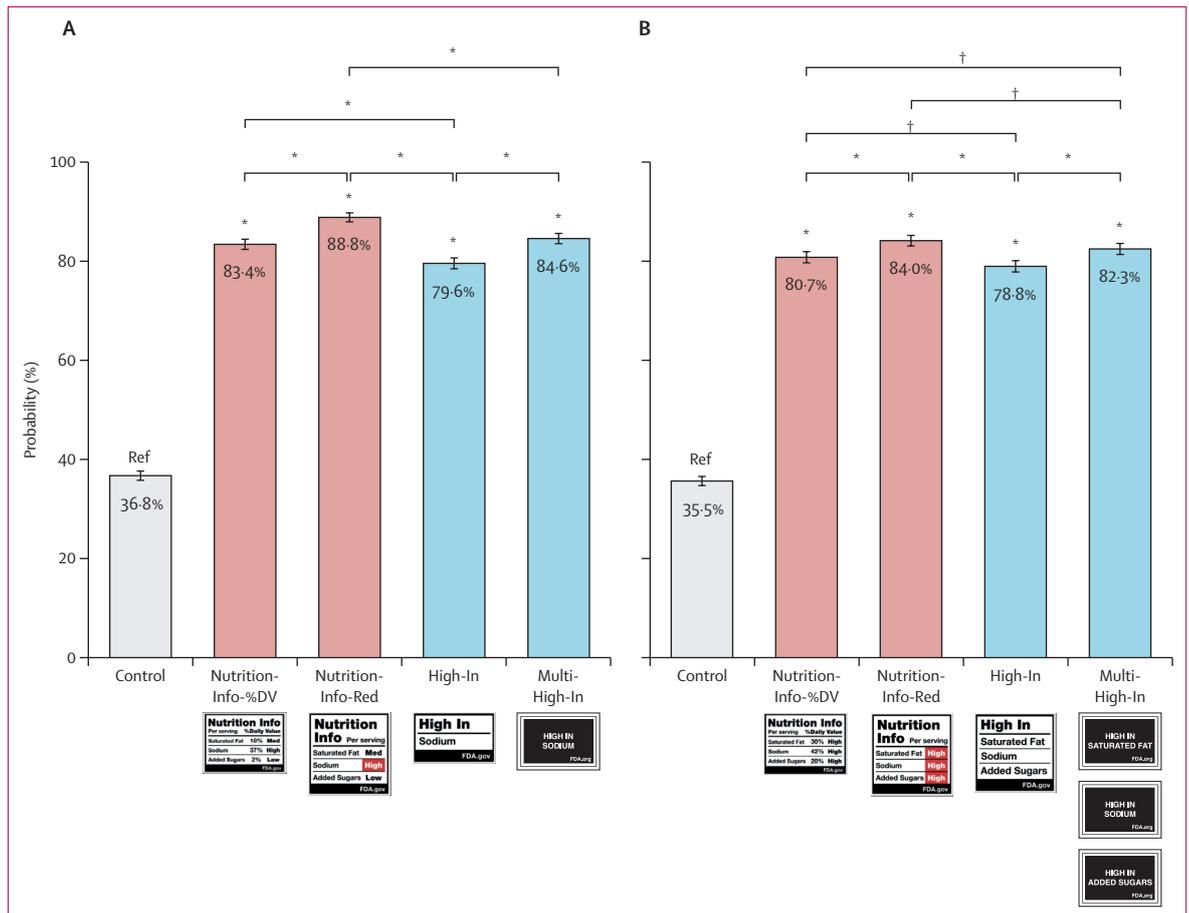
products not high in any nutrient, perceived discouragement of consuming products high in nutrients of concern); reactions (ie, noticing a label, recall of label content, reported label use); behaviours (ie, selection of a food high in nutrients of concern in the second shopping task [after label information was provided to

participants]); and response times. For comparable analysis, we used the same method as the FDA did to examine response times in their experiment:<sup>10</sup> for response time outcomes only, we further excluded the top and bottom 2% of times in the main analytical sample, analysing all other times, including incorrect

	Overall (N=13 929)	Control (n=2776)	Nutrition-Info-DV (n=2787)	Nutrition-Info-Red (n=2795)	High-In (n=2807)	Multi-High-In (n=2764)
<b>Age</b>						
18–34 years	4163 (30%)	857 (31%)	835 (30%)	809 (29%)	854 (30%)	809 (29%)
35–54 years	4409 (32%)	867 (31%)	901 (32%)	872 (31%)	872 (31%)	897 (32%)
≥55 years	5357 (38%)	1052 (38%)	1051 (38%)	1114 (40%)	1081 (39%)	1059 (38%)
<b>Gender</b>						
Woman	7021 (50%)	1383 (50%)	1428 (51%)	1384 (50%)	1421 (51%)	1406 (51%)
Man	6851 (49%)	1380 (50%)	1352 (49%)	1401 (50%)	1372 (49%)	1346 (49%)
Identify another way (eg, gender non-conforming or non-binary)	57 (<1%)	13 (<1%)	7 (<1%)	10 (<1%)	14 (1%)	13 (<1%)
<b>Education</b>						
Lower than some college*	5616 (40%)	1109 (40%)	1130 (41%)	1118 (40%)	1130 (40%)	1130 (41%)
Some college†	4189 (30%)	830 (30%)	849 (30%)	818 (29%)	847 (30%)	845 (31%)
Bachelor's degree or higher	4124 (30%)	837 (30%)	808 (29%)	859 (31%)	830 (30%)	790 (29%)
<b>Race and ethnicity‡</b>						
Hispanic, any race	2497 (18%)	481 (17%)	514 (18%)	488 (17%)	493 (18%)	521 (19%)
Non-Hispanic Asian alone	678 (5%)	141 (5%)	113 (4%)	153 (5%)	147 (5%)	124 (4%)
Non-Hispanic Black alone	1795 (13%)	334 (12%)	377 (14%)	375 (13%)	341 (12%)	368 (13%)
Non-Hispanic, more than one race	340 (2%)	73 (3%)	74 (3%)	68 (2%)	62 (2%)	63 (2%)
Non-Hispanic Pacific Islander, American Indian, Alaskan Native, or other Indigenous or First Nations Peoples alone	241 (2%)	42 (2%)	54 (2%)	39 (1%)	63 (2%)	43 (2%)
Non-Hispanic White alone§	8378 (60%)	1705 (61%)	1655 (59%)	1672 (60%)	1701 (61%)	1646 (60%)
<b>Income (US\$)</b>						
≤\$35 000/year	5033/13 528 (37%)	1012/2705 (37%)	1013/2708 (37%)	975/2706 (36%)	988/2717 (36%)	1046/2692 (39%)
\$35 001–65 000/year	3757/13 528 (28%)	743/2705 (27%)	742/2708 (27%)	787/2706 (29%)	788/2717 (29%)	697/2692 (26%)
\$65 001–95 000/year	2103/13 528 (16%)	413/2705 (15%)	414/2708 (15%)	423/2706 (16%)	444/2717 (16%)	409/2692 (15%)
≥\$95 001/year	2636/13 528 (19%)	537/2705 (20%)	539/2708 (20%)	521/2706 (19%)	498/2717 (18%)	541/2692 (20%)
<b>Have children who are ≤18 years</b>						
Does not have children	9685 (70%)	1899 (68%)	1886 (68%)	1986 (71%)	1984 (71%)	1931 (70%)
Has children	4244 (30%)	877 (32%)	901 (32%)	809 (29%)	823 (29%)	834 (30%)
<b>Nutrition literacy (Newest Vital Sign score)</b>						
0	2728/13 053 (21%)	533/2605 (20%)	588/2619 (22%)	524/2603 (20%)	542/2638 (21%)	541/2588 (21%)
1	2868/13 053 (22%)	579/2605 (22%)	583/2619 (22%)	590/2603 (23%)	528/2638 (20%)	588/2588 (23%)
2	2687/13 053 (21%)	523/2605 (20%)	538/2619 (21%)	533/2603 (20%)	555/2638 (21%)	538/2588 (21%)
3	2536/13 053 (19%)	495/2605 (19%)	503/2619 (19%)	506/2603 (19%)	540/2638 (20%)	492/2588 (19%)
4	2235/13 053 (17%)	475/2605 (18%)	407/2619 (16%)	450/2603 (17%)	474/2638 (18%)	430/2588 (17%)
<b>Frequency of household food shopping</b>						
All the food shopping	7480/13 506 (55%)	1502/2701 (56%)	1507/2704 (56%)	1465/2701 (54%)	1495/2713 (55%)	1511/2687 (56%)
Most of it	263/13 506 (20%)	539/2701 (20%)	521/2704 (19%)	525/2701 (19%)	528/2713 (19%)	525/2687 (20%)
About half of it	2311/13 506 (17%)	444/2701 (16%)	473/2704 (17%)	488/2701 (18%)	469/2713 (17%)	437/2687 (16%)
Only a little of it	840/13 506 (6%)	169/2701 (6%)	157/2704 (6%)	179/2701 (7%)	159/2713 (6%)	177/2687 (7%)
None of it	238/13 506 (2%)	47/2701 (2%)	46/2704 (2%)	44/2701 (2%)	63/2713 (2%)	38/2687 (1%)
<b>Region¶</b>						
Northeast	2501 (18%)	501 (18%)	476 (17%)	508 (18%)	514 (18%)	502 (18%)
Midwest	2915 (21%)	561 (20%)	579 (21%)	584 (21%)	602 (21%)	589 (21%)
South	5704 (41%)	1149 (41%)	1166 (42%)	1149 (41%)	1120 (40%)	1121 (41%)
West	2804 (20%)	564 (20%)	566 (20%)	551 (20%)	570 (20%)	553 (20%)
US territory	4 (<1%)	1 (<1%)	0 (0%)	2 (<1%)	1 (<1%)	0 (0%)

Data are n (%) or n/N (%). Missing data were not included in the calculation of percentages. %DV=percent Daily Value. Nutrition-Info-Red=high descriptor highlighted in red. High-In=black and white single label listing any nutrients present in high amounts. Multi-High-In=multiple black rectangle labels; one for each nutrient present in a high amount. \*Post-secondary education (also called higher education) with enrolment in the USA at around age 18 years. †2-year degree (called associate's degree in the USA) or attended college or university without receiving a degree. ‡Race and ethnicity were combined due to the high proportion of Hispanic residents in the USA who identify as Hispanic or Latino, Latina, or Latinx for both their ethnic and racial background.<sup>29</sup> §Includes Middle Eastern and North African for consistency with the US Census. ¶US Census defined regions.

**Table:** Participant characteristics



**Figure 2: Impact of front-of-package label conditions on probability of correctly identifying the healthiest (A) and least healthy (B) nutrient profiles**  
 Significance based on corrected p values. %DV=percent Daily Value. FDA=US Food and Drug Administration. Nutrition-Info-Red-high descriptor highlighted in red. High-In=black and white single label listing any nutrients present in high amounts. Multi-High-In=multiple black rectangle labels; one for each nutrient present in a high amount. \*p<0.0001. †p<0.05.

responses. Exploratory outcomes included other perceptions (ie, ease of understanding and use of the label) and selection of a product high in nutrients of concern in the first shopping task (before label information was provided). We sought to align many of our measures with those used in the FDA’s study (appendix p 4).

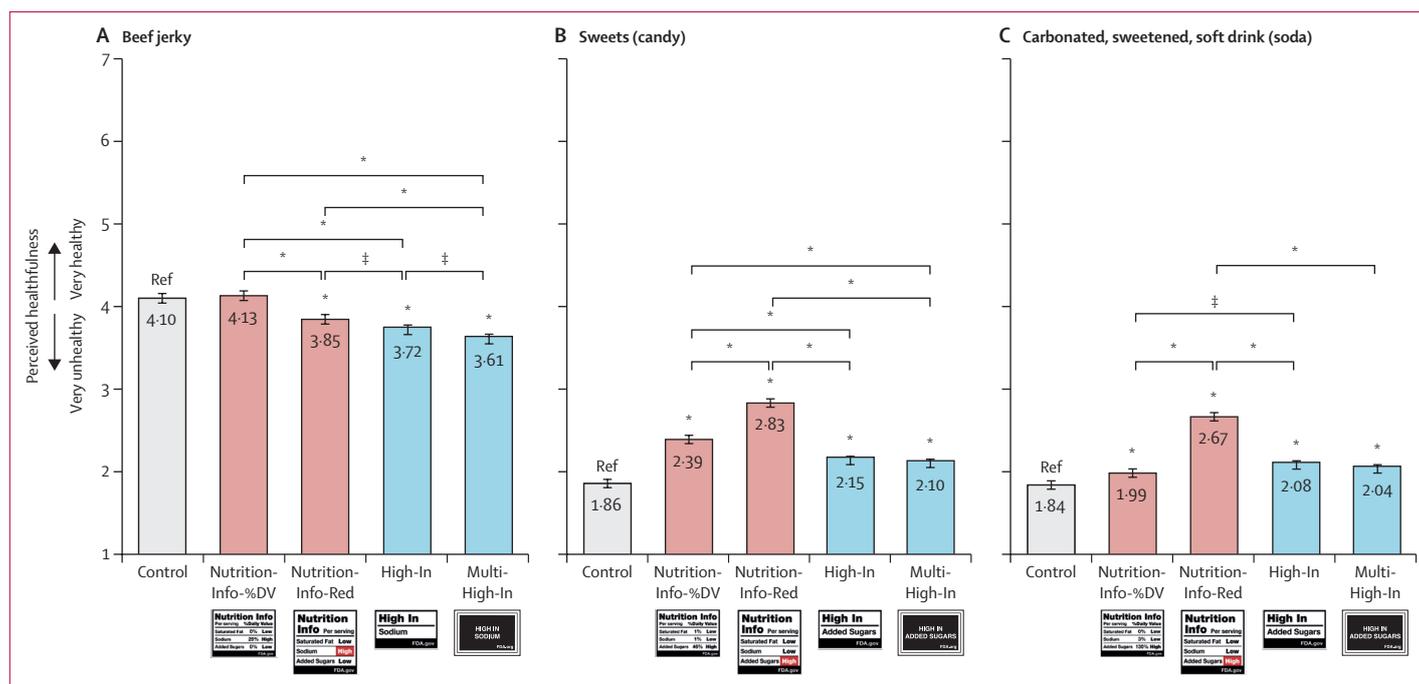
**Statistical analysis**

The target sample size of 13 000 participants was expected to yield more than 80% power to detect a 2-percentage-point difference or larger in correct assessment of the healthiest nutrient profile (appendix p 19).

We used bivariate models, regressing outcomes on indicators for experimental condition with the control as the reference. We analysed multiresponse dichotomous outcomes (ie, identification of healthiest and least healthy nutrient profiles, assessment of whether products were high in nutrients) using mixed effects Poisson regressions with robust standard errors, treating the intercept as random to account for repeated measures.

Single response dichotomous outcomes (eg, food selection) were also analysed with Poisson regression with robust standard errors. We used Poisson regression with robust standard errors (as preregistered) because this method provides a direct and unbiased estimate of probability ratios, unlike logistic regression.<sup>26</sup> Continuous outcomes (eg, perceptions) were analysed with ordinary least squares regression. We used regression models to calculate average differential effects (ADEs; ie, differences between conditions expressed as percentage point differences for dichotomous outcomes and mean differences for continuous outcomes) and marginal means.

For all outcomes, we compared labels using post-hoc contrasts, with comparisons to the FDA’s proposed Nutrition-Info-%DV being of primary interest. We corrected p values using the Benjamini–Hochberg procedure (not preregistered in the protocol) considering ten tests (four against control, six between labels) or six tests when the control group was not assessed. We used the Benjamini–Hochberg correction to control



**Figure 3: Impact of front-of-package label conditions on perceived healthfulness of unhealthy products high in one nutrient of concern and low in two nutrients of concern**  
Significance based on corrected p values. %DV=percent Daily Value. FDA=US Food and Drug Administration. Nutrition-Info-Red=high descriptor highlighted in red. High-In=black and white single label listing any nutrients present in high amounts. Multi-High-In=multiple black rectangle labels; one for each nutrient present in a high amount. \* $p<0.0001$ . † $p<0.01$ .

the false discovery rate while maintaining power.<sup>27</sup> Throughout, we report corrected p values.

We used interaction terms to explore effect modification of experimental condition on the primary outcomes by nutrition literacy (measured with the Newest Vital Sign<sup>28</sup>), education, primary shopper, and having children (preregistered).

In sensitivity analyses of primary outcomes (not preregistered), we included all randomly assigned participants who had been excluded from the analytical sample due to preregistered criteria. All tests (two-sided  $\alpha=0.05$ ) were done with Stata/MP 16.1.

### Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

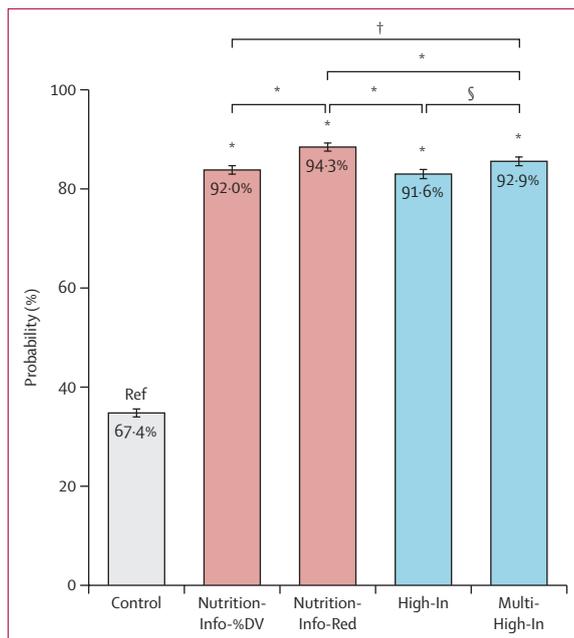
### Results

Of the 17 458 participants recruited between April 1 and 25, 2025 and assessed for eligibility, 15 582 were randomly assigned, and 13 929 were included in the analytical sample (figure 1, appendix p 5). All exclusions (eg, attention check failure, implausible response time) were preregistered. The mean (SD) age was 47.7 years (18.5), and 7021 (50%) were women, 6851 (49%) were men, and 57 (<1%) identified another way (eg, non-conforming or non-binary; table). The sample had similar distributions of race, ethnicity, and education to the US population (table).

All pairwise differences between FOPL schemes are shown in figures 2–4 and in the appendix (pp 7–12). We highlight differences compared with the control and Nutrition-Info-%DV conditions. Probability ratios of FOPL schemes compared with the control are available in the appendix (p 6).

For correct identification of the healthiest nutrient profiles, all FOPL conditions (Nutrition-Info-%DV [83.4% correct; 95% CI 82.4–84.4], Nutrition-Info-Red [88.8%; 87.9–89.7], High-In [79.6%; 78.5–80.7], and Multi-High-In [84.6%; 83.5–85.6]) outperformed the control (36.8%; 35.8–37.7; ADE range vs control: 42.8–52.1 percentage points; all  $p<0.0001$ ; figure 2). Multi-High-In did not differ from the Nutrition-Info-%DV scheme (ADE: 1.2 percentage points; 95% CI  $-0.3$  to  $2.6$ ;  $p=0.117$ ). However, Nutrition-Info-Red did better (5.4; 4.1 to 6.8) and High-In worse ( $-3.9$ ;  $-5.3$  to  $-2.3$ ), than the Nutrition-Info-%DV scheme (all  $p<0.0001$ ).

For identifying the least healthy nutrient profiles, all schemes (Nutrition-Info-%DV [80.7% correct; 95% CI 79.5–81.8], Nutrition-Info-Red [84.0%; 82.9–85.1], High-In [78.8%; 77.7–80.0], and Multi-High-In [82.3%; 81.2–83.4]) outperformed the control (35.5%; 34.6–36.5; ADE range vs control: 43.3–48.5 percentage points; all  $p<0.0001$ ; figure 2). Both Nutrition-Info-Red (ADE: 3.3 percentage points; 95% CI 1.8–4.9;  $p<0.0001$ ) and Multi-High-In (1.7; 0.1–3.3;  $p=0.038$ ) performed better than Nutrition-Info-%DV. Conversely, High-In ( $-1.8$ ;  $-3.4$  to  $-0.2$ ;  $p=0.031$ ) did worse than the Nutrition-Info-%DV scheme.



**Figure 4: Impact of front-of-package label condition on probability of correctly assessing a product as high in a nutrient**

Significance based on corrected p values. %DV=percent Daily Value. Nutrition-Info-Red=high descriptor highlighted in red. High-In=black and white single label listing any nutrients present in high amounts. Multi-High-In=multiple black rectangle labels; one for each nutrient present in a high amount.

\* $p < 0.0001$ . † $p < 0.05$ . § $p < 0.001$ .

For beef jerky (high in sodium, low in saturated fat and added sugars), Nutrition-Info-%DV did not differ in perceived healthfulness from the control condition; by contrast, participants in all other FOPL conditions perceived beef jerky as less healthy than those in the control condition (all  $p < 0.0001$ ). Additionally, Nutrition-Info-Red (ADE:  $-0.29$ ; 95% CI  $-0.37$  to  $-0.20$ ), High-In ( $-0.41$ ;  $-0.49$  to  $-0.33$ ), and Multi-High-In ( $-0.52$ ;  $-0.61$  to  $-0.44$ ) participants perceived beef jerky to be less healthy than Nutrition-Info-%DV participants (all  $p < 0.0001$ ; figure 3).

For both sweets (candy) and carbonated, sweetened, soft drinks (high in added sugars, low in saturated fat and sodium), participants in all FOPL conditions perceived these as healthier than did those in the control condition. Additionally, compared with Nutrition-Info-%DV participants, Nutrition-Info-Red participants perceived sweets (ADE:  $0.44$ ; 95% CI  $0.37$ – $0.51$ ) and carbonated, sweetened, soft drinks ( $0.68$ ;  $0.61$ – $0.75$ ) as healthier (all  $p < 0.0001$ ). For sweets (candy), both High-In and Multi-High-In participants perceived them as less healthy than did Nutrition-Info-%DV participants. For carbonated, sweetened, soft drinks, compared with Nutrition-Info-%DV participants, High-In participants perceived the item as healthier whereas Multi-High-In participants did not differ in perceived healthfulness (figure 3).

Compared with the control (67.4% correct; 95% CI 67.0–67.9), all schemes (Nutrition-Info-%DV [92.0%;

91.6–92.5], Nutrition-Info-Red [94.3%; 93.9–94.8], High-In [91.6%; 91.1–92.1], and Multi-High-In [92.9%; 92.4–93.4]) increased the likelihood of correct assessment of high nutrient content (ADE range *vs* control: 24.2–26.9 percentage points; all  $p < 0.0001$ ; figure 4). Nutrition-Info-Red (ADE: 2.3 percentage points; 95% CI 1.6–3.0;  $p < 0.0001$ ) and Multi-High-In (0.9; 0.2–1.5;  $p = 0.014$ ) further outperformed the Nutrition-Info-%DV scheme in correct assessment. However, High-In did not ( $-0.4$ ;  $-1.1$  to  $0.3$ ;  $p = 0.24$ ).

Nutrition-Info-%DV did not differ from the other FOPL schemes in participants noticing a nutrition label. However, compared with those in the Nutrition-Info-%DV group, High-In (ADE: 4.6 percentage points; 95% CI 2.8–6.4;  $p < 0.0001$ ) and Multi-High-In (8.9; 7.1–10.7;  $p < 0.0001$ ) participants had higher label content recall, but only Multi-High-In participants had higher reported use (14.0; 9.9–18.0;  $p < 0.0001$ ). Nutrition-Info-Red and Nutrition-Info-%DV did not differ in label content recall or reported use (appendix p 7).

For high-added-sugar cereal, white bread, cheese corn puffs, and hot dogs, participants in all FOPL conditions perceived the items as healthier than did those in the control condition. For the high-added-sugar yoghurt and sports drink, participants in all FOPL conditions perceived these as less healthy than did those in the control group. Compared with Nutrition-Info-%DV, participants in the Nutrition-Info-Red group perceived the high-added-sugar yoghurt and sports drink, white bread, and hot dogs as healthier, but perception did not differ for the cereal or cheese corn puffs. Both High-In and Multi-High-In participants perceived the cereal, cheese corn puffs, and hot dogs as less healthy, and High-In participants perceived white bread as less healthy, than did the participants in the Nutrition-Info-%DV group. For the high-added-sugar yoghurt and sports drink, participants in High-In and Multi-High-In perceived the items as healthier than did those in the Nutrition-Info-%DV group (appendix p 8).

For the main behavioural outcome, participants in all FOPL conditions (Nutrition-Info-%DV [ADE:  $-5.3$  percentage points; 95% CI  $-8.0$  to  $-2.7$ ], Nutrition-Info-Red [ $-8.0$ ;  $-10.6$  to  $-5.4$ ], High-In [ $-6.1$ ;  $-8.8$  to  $-3.5$ ], and Multi-High-In [ $-13.0$ ;  $-15.6$  to  $-10.5$ ]) were less likely to select a snack food high in a nutrient of concern for themselves than were the control group participants (all  $p < 0.0001$ ; appendix p 9). Similarly, when selecting a snack food for their youngest child, participants for all FOPL conditions were less likely to select an item high in a nutrient of concern than the control group (appendix p 9). Additionally, Multi-High-In reduced the likelihood of participants selecting a snack food high in a nutrient of concern for themselves (but not their child) compared with Nutrition-Info-%DV ( $-7.7$ ;  $-10.2$  to  $-5.1$ ;  $p < 0.0001$ ) and the other schemes (*vs* High-In:  $-6.9$ ;  $-9.4$  to  $-4.4$ ;  $p < 0.0001$  and *vs*

Nutrition-Info-Red:  $-5.0$ ;  $-7.6$  to  $-2.5$ ;  $p=0.0001$ ). There were no other differences in snack food selection compared with the Nutrition-Info-%DV group.

Nutrition-Info-Red resulted in higher perceived discouragement from consuming products high in nutrients of concern than did the Nutrition-Info-%DV scheme, whereas Multi-High-In did not differ from the Nutrition-Info-%DV scheme. Conversely, High-In resulted in lower discouragement ratings than the Nutrition-Info-%DV scheme (appendix p 10).

For the response times, when identifying the healthiest and least healthy nutrient profiles, the Nutrition-Info-Red (ADE:  $-27.1$  s; 95% CI  $-30.8$  to  $-23.3$ ), High-In ( $-23.9$  s;  $-27.7$  to  $-20.1$ ), and Multi-High-In ( $-31.6$  s;  $-35.4$  to  $-27.8$ ) schemes were all quicker than the Nutrition-Info-%DV scheme (all  $p<0.0001$ ). This outcome is equivalent to Nutrition-Info-%DV being 21–30% slower than all other schemes. Differences compared with the control were of similar magnitude, and Nutrition-Info-%DV did not differ from the control (appendix p 11). By contrast, Multi-High-In was quicker than all other schemes in identifying nutrient profiles (ADE range:  $-31.6$  s to  $-4.5$  s). A similar pattern of differences between schemes and the control (with smaller magnitudes of differences) was observed for the time spent assessing products as high in nutrients of concern (appendix p 11).

In the first shopping task, before receiving information about their FOPL scheme, all FOPL conditions reduced the likelihood of selecting an item high in a nutrient of concern compared with the control condition (appendix p 12). Only the Multi-High-In group (ADE:  $-4.0$  percentage points; 95% CI  $-5.3$  to  $-2.7$ ;  $p<0.0001$ ) had a lower likelihood of selecting an item high in a nutrient of concern than did the Nutrition-Info-%DV group.

For perceptions that the label was easy to understand and easy to use to compare products, both Nutrition-Info-Red and Multi-High-In had higher scores than did the Nutrition-Info-%DV group (appendix p 10). High-In did not differ from Nutrition-Info-%DV for easy to understand but scored lower for easy to use to compare.

All labels tended to be more efficacious at improving consumer understanding among those with lower educational attainment, those with lower nutritional literacy, and those who were primary household food shoppers, but were less efficacious among participants with children (appendix pp 13–14). For the primary perceived healthfulness outcomes, all labels were similar across demographics (appendix pp 15–16).

Finally, results did not differ in sensitivity analyses of primary outcomes with data from all randomly assigned participants (appendix pp 17–18).

## Discussion

In this large online RCT, compared with the control, all FOPL schemes substantially improved consumer

understanding of products' nutrient content and reduced selection of products high in nutrients of concern. Multi-High-In and Nutrition-Info-Red schemes outperformed Nutrition-Info-%DV on multiple outcomes, suggesting that a label design that emphasises when products are high in nutrients of concern improves consumer outcomes over the proposed FDA design.

Among the label formats tested, Multi-High-In did well across a range of outcomes, which might reflect that for this design, the number of labels provides a quick and intuitive sense of product healthfulness. A previous study found that a multilabel High-In design outperformed single-label High-In designs in helping consumers identify products high in sodium and saturated fat.<sup>17</sup> The Multi-High-In label also yielded the highest recall of label contents, highest reported use, and lowest likelihood of selecting a product high in nutrients of concern in both shopping tasks. For the shopping tasks, the Multi-High-In scheme strongly outperformed the Nutrition-Info-%DV scheme: it was even more effective at reducing selection of a snack high in nutrients of concern for the participant compared with the Nutrition-Info-%DV (difference:  $-7.7$  percentage points) than Nutrition-Info-%DV was compared with the control ( $-5.3$  percentage points). Furthermore, Multi-High-In was least likely to increase perceived healthfulness of unhealthy products relative to the Nutrition-Info schemes. Multi-High-In resulted in lower perceived healthfulness than did Nutrition-Info-%DV in five of nine unhealthy products and in eight of nine unhealthy products when compared with Nutrition-Info-Red. Finally, Multi-High-In had the quickest response times when evaluating products, consistent with studies of similar labels,<sup>30</sup> whereas Nutrition-Info-%DV had the slowest response times (21–30% slower than all other schemes for identifying nutrient profiles). Together with previous studies, these results suggest that the Multi-High-In label is likely to be more effective than the FDA's proposed Nutrition-Info-%DV scheme.

Nutrition-Info-Red resulted in the most accurate consumer understanding of product nutrient profiles. It might have outperformed Nutrition-Info-%DV because highlighting High in red and removing numeric information could have made label contents easier to read and more salient. Additionally, Nutrition-Info-Red uses the concept of a traffic light without green and yellow, which might improve consumer understanding, given that a mix of colours can be confusing, and green can contribute to an unintended so-called health halo.<sup>31</sup> However, even without green and yellow, Low or Med (for medium) on labels might produce a health halo, indicated by our finding that the Nutrition-Info-Red condition exhibited, to the greatest extent among FOPL schemes, the unintended consequence of perceiving unhealthy foods as healthier. Specifically, Nutrition-Info-Red had the highest—or tied with Nutrition-Info-%DV for the highest—perceived healthfulness for six of

nine unhealthy products. Although previous research suggests red labels can decrease unhealthy food selections,<sup>32–34</sup> our findings suggest red colouring alone might not adequately mitigate the health-halo effect of the low descriptors for products with substantially (also known as severely) mixed nutrient profiles (high in one nutrient and low in another). Because 40% of purchased packaged foods have substantially mixed nutrient profiles, an unintended health-halo effect of Nutrition-Info schemes could have widespread consequences.<sup>21</sup>

Although the single-label High-In scheme underperformed Nutrition-Info-%DV for identification of the healthiest nutrient profile by 3.9 percentage points and least healthy nutrient profile by 1.8 percentage points, the outcome was the same for assessment of high nutrient content and food selections, and better for High-In for recall of label content, reported label use, and response times. High-In labels have been observed to correct misperceptions of products' healthfulness that can arise from misleading claims or imagery<sup>35</sup> and lead consumers to think more about the nutrient content of their food.<sup>36</sup>

In contrast to the present study, the FDA found that single High-In designs (the FDA did not test a multilabel version) produced the slowest response times, moderate consumer understanding (70–88% accuracy), and lower perceived usefulness, understandability, and noticeability compared with Nutrition-Info schemes.<sup>10</sup> Differences between our findings and the FDA's<sup>10</sup> might be due to limitations of the FDA's experiment, which this study addressed. First, the FDA's identification task showed FOPLs in isolation rather than on food packaging, reducing external validity. Second, the FDA's primary outcome measure did not specify the meaning of overall nutrient profile, so participants might have considered nutrients besides those listed by the FOPL. Third, different nutrient profiles were used for High-In versus Nutrition-Info schemes (eg, all High-In profiles were high in one or more nutrients but only one Nutrition-Info profile was high in nutrients), confounding outcome comparisons. Fourth, the FDA did not provide participants with information about their FOPLs (eg, did not explain that High-In would only appear on products high in nutrients of concern), reducing external validity because consumers would quickly gain familiarity with a mandatory FOPL. Finally, many of the Nutrition-Info (but not High-In) schemes contained potentially more efficacious elements (eg, colours, icons), but analyses aggregated all Nutrition-Info schemes together and all High-In schemes together, confounding results by these design elements.

To the best of our knowledge, our study is the first to test the FDA's Nutrition-Info label as proposed (with %DV) against alternatives, including a Nutrition-Info scheme with only High highlighted and a multilabel High-In scheme. Strengths of this study also include use of a randomised controlled design, recruitment of

a large national sample, and use of behavioural measures and measures adapted from those used in the FDA's research,<sup>10</sup> allowing for comparison, but with improvements expected to increase external and internal validity.

Limitations include that we assessed hypothetical (not actual) food selections, and only assessed two scheme types (Nutrition-Info and High-In); future studies could include in-person food selections and other schemes, such as summary schemes, which have been observed to improve food selection.<sup>37</sup> Furthermore, this study used real products, which increased external validity, but might have influenced results due to brand recognition and familiarity. Moreover, participants were instructed to focus on saturated fat, sodium, and added sugars when evaluating nutrient profiles to reduce ambiguity in the measure. However, baseline consumer perceptions about the healthfulness of these nutrients might have influenced how they responded. Additionally, the order of tasks might have increased the perceived healthfulness of unhealthy products across FOPL conditions because in the preceding task, some of the nutrient profiles deemed to be healthiest were high in one nutrient. Finally, differences between label conditions were modest for consumer understanding outcomes, which might reflect that participants in this online setting probably focused more closely on the labels than would be typical in a real shopping trip. In real-world shopping environments, where consumers encounter many products and might be rushed, stressed, or fatigued, these differences might be more pronounced. Consistent with that possibility is our finding of larger differences between labels for the behavioural outcome when participants were selecting from multiple products.

This study contributes to evidence that could inform the FDA's final rulemaking. Nutrition-Info-Red and Multi-High-In outperformed the FDA's proposed Nutrition-Info-%DV in consumer understanding. However, Nutrition-Info-Red produced, to the greatest extent, the unintended consequence of higher perceived healthfulness of unhealthy products. Importantly, Multi-High-In had the largest behavioural effects, quickest response times, highest recall of label contents, and highest reported use. Label designs specifically highlighting products' high content of nutrients of concern, like Multi-High-In, outperformed the FDA's proposed label and should be prioritised for consideration in FOPL policies.

#### Contributors

BL: conceptualisation, methodology, data curation, software programming, formal analysis, investigation, data visualisation, writing of the original draft. AHG: conceptualisation, methodology. AM: validation. LMSM, LEA, SDB, LMP: methodology. AW: methodology, resources. JF: conceptualisation, methodology, investigation, resources, supervision, project administration, funding acquisition. All authors reviewed and edited the Article. All authors were responsible for the decision to submit the manuscript. BL, AM, and JF have access to the data.

**Declaration of interests**

We declare no competing interests.

**Data sharing**

De-identified data can be made available through request to the corresponding author for non-commercial research use purposes only and with a signed data use agreement.

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