Abstract:
The food and beverage industry is beginning to focus on product reformulation as its key strategy to tackle obesity, and resource itself accordingly. In February 2019, Food Drink Ireland (FDI) launched a report ostensibly describing improvements in population-level dietary patterns in Ireland that resulted from industry-led reformulation initiatives. We sought to conduct a rigorous, objective assessment of this report. We found that it contains six fundamental flaws: it infers a causal relationship between industry-led food reformulation and decreases in sugar, salt, and...
saturated fat and energy intake; it selectively uses points of time and products, which leads to a high risk of selection bias; it blurs the difference between a marketing research report and a scientific report; it aggregates decreases in salt, sugar and saturated fats across categories and this masks the uneven nature of reformulation strategies; it introduces a status quo bias, normalizing the 2005 starting point; and it assumes that any progress in dietary change was solely as a result of industry voluntarism, demoting the work of public health and government policy. We think it is important that the limitations and weaknesses in the report are brought to the attention of the National Clinical Programme for Obesity and the Department of Health. We have provided a brief synopsis of international peer-reviewed research on industry-led reformulation strategies and consider the policy implications for the Irish Government.

**Keywords:** Industry-led food reformulation; obesity; corporate political activity; lobbying

**Primary discipline:** Health and Business Studies

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**Reformulating Reformulation:**

A Technical Appraisal and Policy Context for the 2019 FDI report on the Impact of Ultra-Processed Food Reformulation in Ireland
For

National Clinical Programme for Obesity

and

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15th May 2019
Summary:

The food and beverage industry is beginning to focus on product reformulation as its key strategy to tackle obesity, and resource itself accordingly. In February 2019, Food Drink Ireland (FDI) launched a report ostensibly describing improvements in population-level dietary patterns in Ireland that resulted from industry-led reformulation initiatives. We sought to conduct a rigorous, objective assessment of this report. We found that it contains six fundamental flaws: it infers a causal relationship between industry-led food reformulation and decreases in sugar, salt, saturated fat and energy intake; it selectively uses points of time and products, which leads to a high risk of selection bias; it blurs the difference between a marketing research report and a scientific report; it aggregates decreases in salt, sugar and saturated fats across categories and this masks the uneven nature of reformulation strategies; it introduces a status quo bias, normalizing the 2005 starting point; and it assumes that any progress in dietary change was solely as a result of industry voluntarism, demoting the work of public health and government policy. We think it is important that the limitations and weaknesses in the report are brought to the attention of the National Clinical Programme for Obesity and the Department of Health. We have provided a brief synopsis of international peer-reviewed research on industry-led reformulation strategies and consider the policy implications for the Irish Government.

Background:

In recent years, reformulation' has emerged as a potential strategy to mitigate the public health risks associated with unhealthy dietary patterns globally. To date, reformulation efforts have been largely voluntary and industry-led.

In February 2019, the industry lobby Food Drink Ireland (FDII) published a report which it commissioned from the Dublin-based market research agency Creme Global purportedly analysing the impact of reformulation on dietary patterns in Ireland. The report describes “decreases in sugar and saturated fat in Irish diets between 2005 and 2017 as a result of voluntary undertaking by food and drink companies”. Specifically, 15 companies contributed data to the report, including Coca Cola, Pepsi, Lucozade Ribena Suntory, Mars and Nestlé. Creme Global conducted a statistical modelling exercise in order to determine the impact of reformulation on Irish dietary patterns over five domains of nutritional intake: total fat, saturated fat, sugar, sodium and energy.
The report comes at a time when the dangers of obesity have never been clearer, in terms of increased cancer, diabetes, cardiovascular risk and mortality. Specifically, unhealthy dietary patterns are driving these problems. For example, sugar sweetened beverage (SSB) intake is associated with obesity in adults and children. SSB consumption increases diabetes risk, blood pressure, stroke and cardiovascular disease. SSBs contribute to early death: in Mexico they account for 12.1% of premature mortality and they lead to 8.5 million disability adjusted life years globally.

Most authorities agree that reformulation could be a meaningful and constructive strategy to influence dietary behaviours that give rise to chronic diseases. However, population health gains are likely to be determined by the scope and intensity of reformulation of unhealthy foods. Consistent with other population-wide interventions, mandatory reformulation could have a significant impact over time, even if differences in dietary behaviors and disease prevalence are not discernible at an individual-level in epidemiological studies. Reformulation may act to bolster other sugar, salt and fat reduction strategies such as taxes or improved product labelling. The Irish government’s sugar-sweetened drinks tax, for example, which was discussed from 2011, likely drove reformulation in the SSD industry as a preemptive strategy to develop products that were not liable for the tax.

Why the need for this assessment of the FDI reformulation report?

In writing this appraisal of the FDI reformulation report, our primary aim is not to criticise reformulation as a strategy per se, but to rigorously examine the technical aspects and scientific assertions within the report. It makes sweeping inferences around a causal relationship between reformulation and improvements in dietary patterns in Ireland. It has potentially important and influential policy implications and has received widespread and enthusiastic endorsement at the highest levels of government. Authoritative scientific policy documents such as this which are intended to influence our national population health strategies must be held to the highest levels of scrutiny and transparency, but they are rarely formally peer reviewed, as is the case with this one.

Six errors in the report:

1. The inference of a causal relationship between the introduction of reformulation and a reduction in unhealthy dietary intake in the population is not justified by the data presented in the report.
The most seriously flawed assertion in the report is that its findings provide evidence that reformulation is having a positive effect on dietary patterns in Ireland. It states “The difference in the nutrient intakes between 2005 and 2017 can be interpreted as a result of the voluntary undertakings of the food industry, namely food product reformulation. (page 13),” while the foreword on page 4 describes how “With this report, the food and drink industry makes a major contribution to the store of public knowledge on the impact of reformulation and other food industry activities on changes in intakes of sugar, salt, saturated fat, total fat and energy.” While reformulation might have had an important influence on dietary patterns over time, the study design and data here makes it impossible to draw this conclusion.

Moreover, this important limitation ought to be obvious to any scientific authority competent in the conduct of nutritional epidemiological studies. This report describes observational data from what is essentially a “natural experiment”. It is one thing to note changes in dietary patterns coinciding with reformulation. It is quite another to attribute the former to the latter. We point to two specific errors in the study design:

**A: Inadequate consideration of potential confounding factors:**

By necessity, the authors have made an assumption that confounding factors in the populations were similar in 2005 and 2017 (with the only difference being the “exposure” to reformulated food and drink products) when in fact it is very likely that other factors also influenced the consumption of these products. For example, there were significant national economic changes between 2005 and 2017 (GDP per capita rose from USD 41369 to USD 75538). A recent Danish study showed that unemployment is associated with increased unhealthy food intake\(^ {18}\), as was recession in the UK\(^ {19}\) and in Italy\(^ {20}\). Though speculative, if recessions cause a worsening of dietary habits, then economic recovery in Ireland might have contributed, at least in part, to the observed dietary improvements. Similarly, public awareness of obesity as a health risk and educational campaigns from Safefood and others may explain some or all of the changes observed. As Lawlor et al. described recently, “if associations are measured at the aggregated population level but interpreted as if they apply to individuals within the population, there may be bias due to the ecological fallacy.”\(^ {21}\)

**B: Inadequate study design to infer causality:**

While the findings described in the FDI report fulfil some of the Bradford Hill criteria on causal inference, such as temporality and biological plausibility, they fall well short of an adequately rigorous scientific interpretation of the data. They serve as a model of how not to reach a conclusion from a study which was never designed to address the scientific hypothesis under consideration in the first place. The conclusions drawn by the authors are unjustified, unsound and invalid and would not pass even a rudimentary peer review process for this reason alone.
2. **The risk of selection bias in the analytic approach and study design is extremely high.**

Several areas of the study are prone to selection bias – in other words, the use of time points and data for analysis that may not have been randomly chosen. Firstly, the selection of just two time points (2005 and 2017), rather than repeated measures over as many years as possible is at best a wasted opportunity to identify any true temporal trends and reduce the risk of observations occurring by chance. A significant risk with arbitrary selection of specific years in this way is that data could be manipulated, however unintentionally.

**A: Bias mitigation strategies have not been used.**

Again, these are well described considerations and limitations in observational nutritional epidemiological research\(^1\). Strategies to mitigate the risks of bias are well established and include comparing trends over more than two time-points, and examining other indicators of unhealthy dietary patterns (such as Kantar sales data, which is readily available), and not just self-reported dietary intake. The report does not acknowledge these limitations, but ought to.

**B: Omission and selection of members’ data:**

Mondelez, a member which was included in the 2016 report is excluded from the current analysis, with no reason stated. Given its product portfolio (Liga, Cadbury’s, Oreo and Toblerone products, among others), it seems clear that this could introduce further selection bias, particularly if the consumption of Liga biscuits and Crème eggs was higher in 2017 than in 2005. Moreover, the report only refers to 235 products, a small proportion of all products available, so the generalisability of the findings or the rationale for focusing on these specific products is not clear, but is likely to have introduced yet more selection bias. Lastly it is not clear from this report (even if IUNA cohorts have been described in detail elsewhere) how representative the study participants are of the general population. At the very least, information regarding numbers of participants in each group as well as their anthropometric data would be helpful in this regard.

3. **The report blurs the distinction between marketing research and scientific research.**
Marketing research has a client relationship with its research object, and food marketing research assists clients in extending their corporate strategies with their various stakeholders. In this report, that corporate agenda is manifest in a potentially misleading and distorted representation of progress. For example, tables in the report show reductions in mean nutrient intakes in the total population. The results indicate very small and inconsequential changes in Irish dietary intake over 12 years. Despite this, large visuals in the text amplify only the most positive aspects of these results and represent the data in obfuscating ways, however unintentionally. The image on page 16 states that 4219 kcal have been removed from the average Irish adult diet. It would be clearer to state that this represents just 11 calories per adult per day.

Elsewhere, “cropping” is evident, where a part of the picture is treated as the whole picture. The report decontextualizes information, and then makes inferences based on it, without referring to the entire context. Below are some recurrent examples.

**A: Portion sizes:**

Portion sizes are not accounted for in the report – how might portion size affect the results, if it was accounted for? What data are available from members on the overall increases in portion sizes, product innovations and market share? Consumer research has demonstrated that foods which are reformulated in some way (such as “diet” versions) can disinhibit consumers and cause them to reward themselves with high calorie treats, or make calorie estimation biases, such as assuming that reformulated products are entirely healthy.

**B: Reformulation in the face of category innovation:**

The report focuses on product reformulation of its members portfolios, but does not provide any context of its members’ product innovation in the same period. For example, page 32 states that “pre-schoolers were affected by a slight increase in saturated fat from desserts, biscuits, cakes, ice cream and confectionery of 0.3 g/day. The increase from desserts, biscuits, cakes, ice cream and confectionery may be attributable to the rising popularity of cereal bars, whose sales increased between 2005 and 2017 and may make up a larger proportion of pre-schooler diets.” Cereal bars are only one innovation to occur in the period in question. What is the effect of ‘gourmet’ categories in crisps, ice-creams or chocolate, or unpackaged display product like doughnuts, or variety changes, such as mini-versions (e.g. Celebrations by Mars)? A European policy institute, for example, found that a popular brand selling biscottes developed a ‘low in salt’ category while the salt level of its conventional products increased by 20% between 2007 and 2013.
a. **Selective use of references and weak evidence bases:**
The report makes use of a McKinsey report from 2014 to assert that taxation was the second least effective factor in reducing obesity at a population level. However, it ignores measures higher than reformulation in the same McKinsey document, including, at number 3, the need to curb ‘high calorie food availability’\textsuperscript{26}. The FDI reformulation report uses just 16 references in total and only 3 of these are peer-reviewed, published papers describing original scientific observations.

b. **Part-of-the-whole reporting:**
Industry-led reformulation permits the corporate actor to frame itself as part of the solution, and move its role in the causation of the problem to the background. For example, the report states that between 2005 and 2017, beverage companies removed 10 billion calories from the country’s annual diet and reduced the amount of sugar consumed from beverages by 10%. This is about 2,170 calories per person (assuming a mean population of 4.6 million), or 15 cans of cola. A truly scientific report would provide the context and state the proportion. (10 billion calories were removed out of how many in the national food system?)

4. **Data are aggregated and a fallacy of composition is made.**

A fallacy of composition happens when data from two incommensurate categories are collated to amplify an effect. Data from the two categories should be separated to better inform the reader of varying success levels across categories.

A: **Merging incommensurate food categories:** In the ‘optimistic scenario’ of mass reformulation, there is no absolute change in sugar intake from the ‘desserts, biscuits, cakes, ice-cream and confectionary’ category. The previous FDI report (2018) featured the breakdowns of nutrients \textit{per category} on the same page. This meant the reader could see in which category reductions had been achieved. In other words, in the 2018 report, the fat, sodium and sugar reductions across all categories were described. For example, the pasta category reportedly achieved a 43% reduction in sugar. This figure is weighted as being of \textit{equivalent importance} to the 4% in the biscuits and confectionery category, and then added together, distorting the uneven progress in categories by providing an unrepresentative average.

5. **The report creates a status quo bias.**
Status quo biases occur when a baseline is mistaken for an acceptable standard to strive towards. Such bias contributes to policy inertia, where it is imagined that the food system can be better organised by consumers exercising restraint within the industry frame.

A Status quo bias in sugar consumption: The baseline of sugar consumption (in grams per day) in 2005 and after reformulation, in 2017, below, is taken from the report. Recommended daily guidelines of added sugar are 25, 38 and 12-25g for women, men and children, respectively.37 Irish children are eating 101g of added sugar per day according to the data below. Sugar has apparently achieved ‘significant reductions’, noted on page 28 as “This change was most pronounced among children and teens, whose sugar intakes fell by 3.2g/day and 2.7g/day respectively. Adults and pre-schoolers also saw notable decreases of 0.8g/day and 2g/day respectively.” However, this is a tiny fraction of their markedly unhealthy excessive sugar intake at baseline. Taking 3g as the optimistic achievement within the report’s timeframe, it would take 300 years to reduce intake to 25g per day.

<table>
<thead>
<tr>
<th>Daily intake of added sugar (g)</th>
<th>2005</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>91.54</td>
<td>90.73</td>
</tr>
<tr>
<td>Teen</td>
<td>108.02</td>
<td>105.36</td>
</tr>
<tr>
<td>Children</td>
<td>104.91</td>
<td>101.67</td>
</tr>
<tr>
<td>Preschool</td>
<td>80.29</td>
<td>78.3</td>
</tr>
</tbody>
</table>

6. The report co-opts public health and government achievements.

The report frames the achievements of reformulation thus: “The difference in the nutrient intakes between 2005 and 2017 can be interpreted as a result of the voluntary undertakings of the food industry, namely food product reformulation, the promotion of healthy options and new product development and, of course, changes in consumers purchasing choices in those food categories over that period.” There is no mention of how other actors and methods might contribute to reductions in the burden of obesity, most notably the role of government and
public health through instruments such as policy and taxation. The authors seem to infer that any changes in dietary pattern over time can be attributed solely to industry reformulation strategies.

Lessons from studies on industry-led reformulation:

Our assessment is not a disapproval of sugary products or the people who make or consume them, nor is it an argument against the good idea that reformulation likely is. However, whether reformulation should be industry-led on a voluntary basis or whether it requires legislation with compulsory changes to unhealthy foods is unclear. The risk is that reformulation goals that are set by industry may lack sufficient depth and breadth to have an adequate influence on dietary behaviours to improve population health. Below, we raise some important, critical assessments from public health academics on the externality effects of industry-led reformulation.

1. **There is no such thing as healthy ultra-processed products.**

Modification of their nutrient profile, for example, by adding less salt, or replacing fats by starches or sugars or artificial sweeteners, makes ultra processed foods only somewhat less and sometimes trivially less unhealthy. Industry-led reformulation does not make products nutritious or healthy. Removal of trans-fats makes products relatively safe but also does not make them healthy.28

2. **Industry-led reformulation gives corporate actors a social licence to operate, endowing their reformulation efforts with dangerous health-halos.**

When the tobacco industry reformulated and heavily promoted ‘lowtar’, light’ or ‘mild’ cigarettes, the market share of these products rose from 2 to 83.5%29. A health halo occurs when a product from an unhealthy category is perceived as healthy, and causes overconsumption. This phenomenon has been amply demonstrated in empirical studies30. Industry-led reformulation has become a public relations strategy – a goodwill gesture that enhances the dominance and legitimacy of the ultra-processed food category31. This means that the ultra-processed category is not challenged, rather it is inadvertently promoted.
3. **Industry-led formulation leads to the ‘mal-substitution’ of ingredients.**

The sources of nutrients-to-limit in reformulated products may be replaced with other highly processed ingredients and additives, rather than with whole or minimally processed foods\(^3\),\(^3\), the so-called ‘mal-substitution’ of products. There is ample historical evidence for this: the introduction of trans-fats as a healthy replacement to other fats in the 1960s, or the introduction of sugar to create the low-fat category in the 1980s and 1990s. More recently, a US Department of Agriculture report documented a significant rise of saturated fat usage by the food industry in its bid to reduce trans-fats, salts and sugar\(^3\),\(^4\). There is emerging evidence that sheds light on some of the constitutive ingredients and processes that are proposed for reformulation strategies: highly refined flours and starches are linked to increased glycaemic load and they have detrimental impacts on blood cholesterol levels\(^3\),\(^5\). Animal studies suggest that dietary emulsifiers may impact the gut microbiota, promoting colitis and metabolic syndrome\(^3\). There is insufficient data to conclude that the replacement of trans-fat-rich, partially hydrogenated vegetable oils with vegetable oils that have been fully hydrogenated, fractionated and inter-esterified is beneficial to health and these processes may in fact cause harm.

4. **Industry-led reformulation allows non-policy makers to determine the targets, substitute ingredients, and dictate the processes of reformulation.**

Industry-led reformulation means that the ultra-processed food industry determines the pace of change: in Ireland, that is 11 calories per person per day between 2005 and 2017. A study of industry consultation on reformulation in the US shows the same arguments put forward as in the FDI report: justification is given for very slight changes, termed ‘step-wise’ changes, to accommodate consumers’ palates; that reformulated products offer consumers the choice to live healthily; and that reformulation is technically challenging and costly to companies\(^3\). ‘Research’ reports on the part of industry are designed to guarantee participation in the policy process, to influence the nutrition policy debate, to establish partnerships with government bodies, and to influence the interpretation of evidence on nutrition.

5. **There are technical limits to reformulation.**

This is readily conceded by the ultra-processed food industry and public health advocates alike. There is evidence to suggest that these limits are being reached in salt\(^3\). Mandatory,
government-led reformulation would help weed out any products that are so inherently unhealthy that their reformulation is impossible, unprofitable, and may lead to discontinuation of consumption of that product.

6. **Industry-led reformulation constrains and implicates government in a narrow, obfuscating and ineffective strategy.**

Reformulation endorsed by government implicitly sanctions the pace, targets and substitutions of ultra-processed foods. This is a well-known public relations strategy called ‘policy substitution’, namely attempts by the corporate actor to delay, undermine or frame as extreme more fundamental changes to the diets of the population\(^{38}\). Government compliance or endorsement of industry-led reformulation may inadvertently protect industry from future potential litigation.

7. **Reformulation might slightly alter consumption in the Global North, but will increase ultra-processed food consumption in low- and middle-income countries.**

There may be small beneficial population-level effects of reformulation in markets where the diet is already saturated with ultra-processed foods, if three criteria are achieved (i) if there is increased, industry-wide reformulation, (ii) if these reductions are not accompanied by increases in other unhealthy foods, (iii) if consumers swap ‘old’ for ‘new’ reformulations\(^{29}\). This progress has been slow and uneven\(^{39}\). However, in low- and middle-income countries, reformulation should not legitimise the further displacement of whole-grain, minimally processed food\(^{40}\). The report here aggregates the decreases in salt, sugar, saturated fat and energy across categories, masking the fact that the two categories (savoury snacks and confectionary) have pitifully small decreases overall. Meaningful reductions in sugar, salt and fat levels should apply to whole ranges of products, not just to a few.

**Policy development:**

In light of these findings, we offer the following policy implications on reformulation:
1. **Introduce a comprehensive and effective reformulation programme covering free sugars, fat and salt.** The programme should include an independent set of reformulation targets for industry, backed by regulation and which are measured, evaluated and time-bound. Compliance with these targets should be monitored and non-compliance should be backed by meaningful sanctions. Adopt an international goal for reformulation.

2. **Introduce a two-tier concept of reformulation.** That corresponds to (i) minimizing unhealthiness in the ultra-processed food category (a ‘nutrients-to-limit’ strategy\(^3\)), and a much more progressive ‘wholefood formulation’ strategy, which aims to reduce the processing of food (i.e. shifting national reliance on ultra-processed food category to processed and unprocessed categories).

3. **Separate policy development from policy implementation.** Industry is an important, vital part of the solution to obesity. We support current international policy which recommends moving from partnership and consensus-building models in policy development, to soliciting the support of industry for policy implementation only\(^4\).

4. **Focus on the two categories** which have made the least progress in the reformulation effort so far: (i) crisps and savoury snacks, and (ii) confectionary.

**Definition of ultra-processed:**

“Food processing is used for transforming whole food ingredients into food commodities or edible products. The level of food processing occurs along a continuum from unprocessed to minimally processed, processed, and ultra-processed. Unprocessed foods use little to no processing and have zero additives. Minimally processed foods use finite processing techniques, including drying, freezing, etc., to make whole food ingredients more edible. Processed foods combine culinary ingredients with whole foods using processing and preservation techniques. Ultra-processed foods are manufactured using limited whole food ingredients and a large number of additives. Ultra-processed snack foods are increasing in food environments globally with detrimental implications for human health”\(^1\).

**References:**


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Methodology / still to read:

