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Review

Challenges and opportunities for increasing the effectiveness of food reformulation and fortification to improve dietary and nutrition outcomes

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ABSTRACT

Reformulation, a change to a food or beverage's processing or composition, can reduce potentially harmful ingredients such as salt, added sugar, and saturated and trans fats or increase potentially beneficial ingredients or nutrients such as fiber, protein, and micronutrients. Poor nutrition and health outcomes of populations have stimulated programs and policies to reduce the intake of salt, added sugar, and unhealthy fats and increase healthy nutrients and ingredients to meet recommended targets of a healthy diet. Alongside promoting the consumption of whole, nutritious foods (e.g., fruits, vegetables, and whole grains), reformulation, including fortification of processed foods, has been utilized by food industry manufacturers to contribute to improving diets and aligning with national dietary guidelines. This paper summarizes a literature review and twenty semi-structured interviews with experts on food product reformulation and fortification to highlight the challenges, limitations, and opportunities for increasing their effectiveness. While studies have shown that reformulation could have beneficial public health impacts, such as iodized salt, there are a dearth of rigorous evaluations, particularly for some types of reformulations. Importantly, some evidence suggests that ultra-processing has significant adverse health effects independently of nutrient adequacy. To improve population health, reformulation should be complemented with a range of approaches, including food taxes and subsidies, public food procurement, restrictions on food advertising and marketing, front-of-pack labeling, and changes to food environments that improve availability, affordability, and demand for whole and minimally processed foods.

1. Introduction

There is growing evidence on the detrimental effects of unhealthy diets on nutrition and health outcomes, including non-communicable diseases (NCDs) such as cardiovascular disease, diabetes, and some types of cancers (Afshin et al., 2019). According to the 2019 Global Burden of Disease Study, unhealthy diets are one of the leading risk factors of disease burden and global mortality resulting in 348 million and 447 million deaths in females and males, respectively (Murray et al., 2020). Unhealthy diets tend to be low in fruits, vegetables, whole grains, legumes, nuts, and seeds, with poor micronutrient, essential fatty acid, and fiber content, and high in foods laden with excessive sugar, salt, unhealthy fats, and other additives (Afshin et al., 2019; Imamura et al., 2015; Swinburn et al., 2019; Willett et al., 2019).

With poor diets on the rise and deteriorating nutrition among vulnerable segments of the global population, there has been significant investments in programs and policies which aim to reduce micronutrient deficiencies, as well as the intake of salt, added sugar, and unhealthy fats (Herforth et al., 2019; Springmann et al., 2020). Several global and national commitments have been critical to improving diets and nutrition. For example, Sustainable Development Goals 2 and 3 provide broad targets to end all forms of malnutrition and reduce premature mortality from NCDs by 2030. Furthermore, the World Health Organization (WHO) Global NCD Action Plan 2013–2020 aims to reduce premature mortality from NCDs by 25 % by 2025 by providing key nutritional recommendations. Within this plan, the WHO recommends limiting salt intake to 5 grams per day, added sugar intake to 10 % of total energy (with even more significant benefits if lowered to 5 %), and

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total fat intake to 30 % of total energy. For fat intake, saturated fats should be limited to 10 % of total energy, and industrial *trans*-fatty acids (TFA) should be eliminated from the diet (WHO, 2014a). In alignment, national fortification policies have been enacted worldwide to increase the micronutrient content of highly consumed staple foods. Ninety-one countries have mandatory wheat flour fortification, while 126 countries have mandatory salt fortification policies (Global Fortification Data Exchange, 2023).

Reformulation is a critical strategy to meet these global goals, with an additional focus on ensuring that reformulated foods are affordable and accessible for all (WHO, 2014b; WHO, 2012). Reformulation is the process of altering the processing or composition of a food or beverage to improve the product's nutrition profile. This is achieved by reducing the content of harmful ingredients or increasing the amount of potentially beneficial ingredients or nutrients in a food product (Scott et al., 2017). Examples of reformulation include reducing sodium, added sugars, saturated and TFA, and energy density; increasing, adding, or substituting healthier ingredients to replace unhealthy ones; or enhancing the healthfulness of products with dietary fiber or protein. Similarly, food fortification adds essential vitamins and minerals to commonly consumed foods such as maize and wheat flour, edible oil, rice, and salt. Fortification may be undertaken to replace micronutrients lost during processing, such as milling of cereals, or to address micronutrient deficiencies in the population (Das et al., 2019). Because the global population ubiquitously consumes staple grains, oils, and salt, fortifying these foods with essential micronutrients allows for a broad reach without requiring major dietary behavior shifts.

Both reformulation and fortification strategies often rely on nutrient profiling or ranking foods based on their nutrient composition (Drewnowski, 2017; WHO, 2010). Industrial food and beverage manufacturers (ranging from small companies to multi-national food and drink processing conglomerate corporations) use this profiling to align their products with national food-based dietary guidelines, labeling mandates, and other governmental policies to improve public health (Lehmann et al., 2017). Products are also reformulated in response to government policy or public demands for reduced sugar, salt, or fat; the omission of certain additives; or to increase the healthfulness of their food products to improve health and nutrition outcomes.

The primary objective of this paper is to appraise the food product reformulation landscape and highlight the challenges and opportunities of altering foods and their contribution to healthy diets and improved nutrition. To a lesser extent, we also examine fortification as another strategy to improve the nutrient content of foods. In this paper, we use existing literature and stakeholder interviews to highlight: (1) how and why reformulation and fortification are implemented, including voluntary and mandated strategies from industrial food and beverage manufacturers and governments; (2) the technological and political challenges and opportunities of reformulation and fortification; and (3) the public health impact of these approaches.

2. Methods

We conducted a literature review and 20 semi-structured interviews with individuals with public health expertise in the government, private sector, and academia who engage with reformulation and fortification issues. The literature review consisted of performing literature searches (restricted to articles in English) in PubMed and Google Scholar with the following keywords: reformulation; reformulation and public health; reformulation and nutrition; reformulation and sodium; reformulation and salt; reformulation and sugar; reformulation and fat; reformulation and saturated fat; reformulation and TFA; reformulation and fiber; reformulation and sustainability; reformulation and environment; reformulation and consumer; fortification; and alter food.

Studies were considered eligible if they were published before September 2022 and addressed voluntary or mandatory food reformulation and fortification strategies aimed at reducing harmful nutrients

(e.g., salt, added sugar, saturated and TFA, energy density, or artificial ingredients) or increasing the content of beneficial nutrients (e.g., fiber, protein, micronutrients, unsaturated and omega-3 fats, whole grains, fruits, and vegetables) in processed food products. As a result, 167 peer-reviewed and grey literature articles were found to be relevant and included in this paper.

Twenty semi-structured interviews were also conducted with those who engage with issues of reformulation and fortification, including those in public health, in research and academia who have studied reformulation and fortification in various facets, industrial food manufacturer employees and technical food specialists. Interviews were conducted by phone, Zoom, and Skype between August and November 2019. Using a purposive sampling strategy, we selected individuals identified through the literature review. We asked interviewees whom they considered most central in reformulation and fortification within academia and public and private sectors. Key informants were from high-, middle-, and low-income countries, representing various organizational affiliations with expertise in food systems and nutrition. Due to the selected sampling strategy, the results may be prone to selection bias. However, a purposeful effort was made to include a balanced reflection of perspectives from those engaged in both public and private sectors, as well as researchers in the nutrition and public health fields. We continued interviewing new informants until we reached theoretical saturation—the point at which all major themes have been identified and additional interviews are unlikely to reveal new information.

The interviews lasted approximately one hour on average and were recorded and transcribed with permission from the key informants. We obtained informed consent from all research participants. The study protocol was determined to be exempt from the requirements of policies for protecting human subjects by the Institutional Review Board at Johns Hopkins University on 07/22/2019 because it posed no risk or minimal risk to subjects (IRB #00009719). All interview transcripts and notes were anonymized and secured in password-protected documents to ensure respondent confidentiality. Drawing on the findings from the literature review, questions focused on the purposes, intents, successes, and challenges of reformulation and fortification. We tailored questions to each interviewee's expertise.

We conducted a thematic analysis in Microsoft Word to analyze the results, drawing on information from key informant interviews and collected literature. We initially coded the data under broad categories of purpose and intent, challenges, opportunities, and strengths of reformulation and fortification. To minimize bias and validate the accuracy of the findings, two authors coded the data simultaneously, and the data sources were triangulated, always corroborating information from interviews with written sources.

3. Findings

3.1. The multiple purposes of reformulation and fortification

Food companies have been reformulating products since the 1970s and fortifying food since the 1920s, increasing the number of choices people have in the marketplace (Mejia, 1994; Nestle, 2013). While the dialogue on reformulation has focused on its potential to improve public health and nutrition, other purposes were also discussed in the interviews. In interviews with food industry, reformulating food is pursued to decrease costs and increase profits, meet people's changing preferences for healthier products, tap into new markets, offset declining sales, comply with formal regulatory directives where they exist, or a combination of these drivers. Reformulation can also change a company's overall image from an increasingly irrelevant or irresponsible player to an innovative, responsive one. One interview with a food industry employee discussed how the intent of a product's first reformulation is usually to decrease the cost and make the product more profitable by changing a high-priced ingredient or the production process, such as reducing the cooking time to lower energy costs and save

time. Likewise, in two interviews with academics, they perceived that food manufacturing companies' substantial motive to reformulate is to increase profit. While food corporations leverage technology to make foods healthier, they must also consider shareholder profits in doing so. They respectively stated,

“At the business level, a brand might be reformulating for a higher purpose and to cooperate, but that is a psychological description. A more technical description would be at a corporate level, a brand is legally obliged to maximize shareholder value, and there is no getting away from that. So, recognizing that there are different marketplaces where there are consumers who desire reformulated food and consumers who do not, and developing countries that have lax regulation and so-called developed countries that have tighter regulation, a company is driven to reformulate for profit maximization reasons. That is it. It is profit - if it were for any other reason, it would be very suspect.” (Academic Respondent)

“As far as policy options go, it is the lesser of evils for them, and it shows that they are being proactive, it shows that they are part of the solution, it means that they can join these public-private partnerships which lend a lot of credibility to them as political actors and there are a lot of benefits it brings to them, and that is probably the real reason why they are doing it. I think they are definitely trying to avoid some reputational damage by taking corrective steps.” (Academic Respondent)

Interviews with food and beverage companies often cited public health as the primary reason to reformulate, with cost, consumer demand, and environmental sustainability as secondary reasons. One interview with a food industry employee typified this, articulating,

“The first [reason] is public health, we very much use reformulation to address over and undernutrition... and certainly reducing the levels of sugar, sodium, trans fats, etc. is very important... the second reason is consumer demand. We have to also consider what consumers are looking for. It is a marriage of the two, and that is where we as nutritionists come in because we would say there is a demand for more flexitarian and vegetarian diets, for example, so let us look at more plant-based foods and of course we also look at the environment - we could use that as the third reason - the environmental impact. As we are doing that, we are also saying as nutritionists that is great but make sure it is nutritionally sound, that the nutrients are meeting public health recommendations and that it is a nutritious product.” (Industry Respondent)

3.2. Types of food reformulation and fortification

While highly (or as it has been termed, ultra-) processed foods often receive the most attention from public health practitioners because of their potential detrimental impacts on health (de Oliveira et al., 2022; Federici et al., 2019; Langellier et al., 2022; Scrinis and Monteiro, 2022), minimally processed foods can be reformulated as well (e.g., decreasing the amount of salt in frozen or canned vegetables or added sugar in dried

or canned fruit). Reformulation can also include removing, adding, or substituting multiple ingredients. Table 1 shows the types of reformulations of unprocessed, basically, or moderately processed, or highly processed foods.

In addition, companies will often add a new portfolio of products by introducing brand extensions that are considered healthier. By introducing these novel products, companies can respond to emerging public demands and achieve market growth, while avoiding losing consumers due to a change in the taste or texture of existing popular products.

3.3. Removing harmful ingredients

Most reformulation has focused on reducing the amount of sodium, added sugar, saturated and TFA, and other harmful ingredients, as well as decreasing the energy density in processed foods. Unfortunately, reformulation can suffer from mal-substitution or replacing one ingredient with another, which may be worse for health, making the product unhealthier (Campbell et al., 2019; Scrinis, 2016; Scrinis and Monteiro, 2018). As industrial food scientists indicated in interviews, identifying substitution ingredients for those that are harmful while maintaining product appearance, taste, texture, shelf-life, cost, and other attributes can be a technological challenge. Removing ingredients may cause many unintended changes to processed foods, making food science and chemistry even more complex.

3.4. Sodium reductions

Excessive sodium consumption is a risk factor for high blood pressure and stroke (Graudal et al., 2020; Mozaffarian et al., 2015, 2014). A 10 % reduction in sodium consumption over ten years would avert 5.8 million disability-adjusted life years (DALYs) per year related to cardiovascular disease alone (Pearson-Stuttard et al., 2018; Webb et al., 2017). Forty-seven percent of countries have voluntary or mandatory legislation to reduce sodium intake to meet the voluntary WHO NCD target of reducing sodium intake by 30 % (WHO, 2017). Reductions have primarily been achieved through slow, incremental reformulation of food products, allowing consumers to change their sense of taste, and become accustomed to less salty products (National Heart Foundation of Australia, 2012).

Of the 96 national, multi-faceted salt reduction initiatives, 68 include food reformulation as one of the main strategies in collaboration with food companies (Santos et al., 2021). Of those 68 countries, 11 countries had voluntary agreements to lower sodium levels in foods, and 57 countries had established targets, with 19 of these countries enacting mandatory salt restrictions in food. No countries that have implemented salt reduction targets have achieved the WHO's target of 30 % reduction, with only three countries finding a substantial (greater than 2 grams/day) decrease in salt intake (Santos et al., 2021).

There are vital lessons to be learned from countries attempting to

Table 1
Types of Reformulations by Food Processing.

	Unprocessed foods	Basically or moderately processed foods	Highly processed foods	
Examples	Vegetables, fruits, eggs	Dried vegetables and fruits, grains, dairy products, seafood	Breads, breakfast cereals, dairy products	Sugar-sweetened beverages, chips, crackers, cookies, cakes, confectionary
Remove negative ingredients and nutrients	Not needed	Lower or remove salt from frozen or canned vegetables and fish, lower or remove added sugar from dried or canned fruits and dairy products	Lower or remove salt, added sugar, and unhealthy fats from all foods in this category	Lower salt, added sugar, and unhealthy fats from all foods in this category but these foods should still be limited in the diet, beware of unhealthy ingredient substitutions and marketing these reformulated foods as 'healthy' or 'healthier'
Add positive ingredients and nutrients	Biofortification	Biofortification, fortification with vitamins and minerals, reformulation with added fiber, protein, and healthy fats	Fortification with vitamins and minerals, reformulation with added fiber, protein, and healthy fats	Not recommended (the jellybean rule)

Source: Adapted from HLPE 2017 Report.

reduce salt intake. The United Kingdom (UK) created the Public Health Responsibility Deal to decrease sodium by 20 to 30 % in food products, which resulted in a 15 % decrease in dietary salt intake among adults between 2003 and 2012 (Buttriss, 2013). These data suggest that this reduction in salt intake was mainly from reformulation, not from education or behavior change (Griffith et al., 2017; Jaenke et al., 2017). This initiative was cited as one of the major successes in several interviews, with one informant stating,

“There is strong evidence from the UK that the salt reduction reformulation program led by the government successfully reduced salt in products and that had knock-on positive effects on public health.” (Academic Respondent)

Another study examined factors that attempted to reduce sodium intake through reformulation in Argentina, Mongolia, South Africa, and Vietnam. Findings suggested that while sodium reduction legislation was introduced in Argentina and South Africa, implementation challenges included leadership changes or poor funding. Mongolia and Vietnam instituted voluntary reformulation approaches that also faced difficulties. Mandatory legislation is one of the more sustainable options for reducing intake, but for these initiatives to be effective, countries need to have the capacity for rigorous monitoring and enforcement of the legislation (Webster et al., 2022).

3.5. Sugar reductions

A high intake of added sugar is considered a risk factor for obesity, type 2 diabetes, and dental caries (Yang et al., 2014). One study in the United States (U.S.) found that a 20 % and 40 % reduction in sugar from packaged foods and beverages respectively, could prevent 2.48 million cardiovascular disease events; 490,000 cardiovascular deaths; and 750,000 diabetes cases (Shangguan et al., 2019). While some have argued that the same successes seen with salt are not possible with sugar due to complexities in the chemistry of sugar substitutes (including non-nutritive sweeteners, polyols, fibers, and maltodextrin) (Hashem et al., 2019a, 2019b; Yeung et al., 2017), much can also be learned from how countries have attempted to reduce the sugar content of foods through reformulation.

The UK set a voluntary goal to reduce added sugars in food products to 5 % of total energy by 2020 (Gibson et al., 2017). Leading up to the deadline, an expert panel concluded the UK was unlikely to meet this goal, and more gradual reductions were needed (Gibson et al., 2017). Canada too aimed for a 5 % reduction of added sugar content in packaged foods and beverages. However, from 2013 to 2017, there was no overall change in the sugar content of these foods and beverages due to a cancellation effect, whereby 12.4 % of products were reformulated to lower their sugar content, while 11 % were reformulated to be higher in sugar (Bernstein et al., 2020).

There have been successful campaigns, such as the Union of European Beverages Associations' voluntary goal to decrease added sugar in beverages by 10 % from 2015 to 2020. They successfully met this goal, with a 2020 independent audit concluding that they had reached an 11.9 % reduction by 2017 (Goryakin et al., 2019). While unprompted voluntary reformulation should still be part of a sugar reduction strategy, an interview with an academic respondent argued that labeling and taxes would be more effective in incentivizing reformulation more forcefully.

3.6. Saturated fat reductions

Saturated fat is a controversial topic in the field of nutritional sciences, with much debate about whether it is associated with increased coronary heart disease and mortality (Krauss and Kris-Etherton, 2020; Teicholz, 2023). Some studies suggest that higher saturated fat intake can increase the risk of cardiovascular events (Hooper et al., 2020; Zong et al., 2016).

One UK modeling study demonstrated that a 20 % reduction in saturated fat across all manufactured and out-of-home foods would reduce energy intake by 67 kcals/person/day and the prevalence of obesity by 5 % over five years (Alessandrini et al., 2021). Food manufacturers argue that reducing or removing saturated fats in food is technologically challenging because they are solid at room temperature and do not oxidize easily, posing high costs for reformulation (Bruce, 2020). In an interview with an academic, they discussed this difficulty,

“There are a lot of functional properties that fats provide in products, and it is hard to get fat substitutes that meet the functional needs of these ultra-processed products and that are also okay for public health and also okay from an environmental and sustainability point of view. They are going to have a real challenge trying to figure out what to put in these products.” (Academic Respondent)

Additionally, to make these products palatable, food companies often add more sugar or replace saturated fats with TFA, creating negative health manifestations and increasing the incidence and prevalence of obesity, diabetes, and other NCDs (Murray et al., 2020; Temple, 2018).

3.7. Trans-fatty acid reductions and eliminations

Another critical and ongoing global food reformulation strategy has been the reduction of TFA through voluntary action by industrial food manufacturers and legislative mandates. Globally, more than 500,000 deaths in 2010 were attributed to an increased intake of TFA (WHO, 2019). While their removal from food products can have positive health impacts at the population level (Mozaffarian et al., 2010, 2006), there are a few technical barriers for industry. In an interview with an academic, they agreed, explaining,

“Trans fats are in another category, the evidence on the impact of reformulation on health and cardiovascular outcomes, is the strongest by far and that is because there is a big signal-to-noise ratio and it is detectable, and the evidence is strong.” (Academic Respondent)

A systematic review of studies conducted in high- and middle-income countries found that TFA reduction policies, such as bans, voluntary reductions, or labeling, significantly reduced cardiovascular events and deaths (Downs et al., 2017). Voluntary reformulation decreased TFA by 20 to 38 % and mandatory labeling by 30 to 74 %, with bans nearly eliminating TFA from the food supply. The review concluded that bans were the most effective, economical, and equitable, as compared to other measures which led to increased health disparities (Downs et al., 2017). For example, voluntary reformulation allows for more TFA to remain in cheaper products, while mandatory labeling relies on consumer knowledge. In an interview with an academic, they agreed with the conclusion that bans are the best course of action, stating,

“Trans fats are in a territory all on their own; it is quite different from the others, there are a handful of major industry players that create the trans fats, there is very powerful evidence showing its [health] impacts, there are very plausible alternatives that do not affect consumer palatability, and it is totally appropriate and plausible for governments to regulate it out of existence as a lot of them have. The major problem we have with trans fats is in low and middle-income countries where you have the big players who do not give a rat's ass about it and just want to sell products and say, ‘Oh, but they demand it, and therefore, we are going to produce it.’” (Academic Respondent)

In addition to sodium, the UK Public Health Responsibility Deal aimed to also reduce TFA. However, the pledge was only signed by 11 groups, only one of which was a food manufacturer. The others included catering, pub chains, universities, and entertainment companies. Knai et al. (2017) concluded that the pledge failed because of limited participation and its voluntary nature. Therefore, mandatory regulatory

approaches—limits, bans, and labeling—are more effective (Knai et al., 2017).

Regulatory interventions, such as limiting permitted levels or mandating labeling, have reduced TFA in foods through reformulation compliance (Hendry et al., 2015). In 2018, the WHO released a plan to remove TFA from the global food supply by 2023 (WHO, 2018b). A 2023 WHO progress report noted that mandatory TFA policies are currently in place for 60 countries, with 43 having “best practice policies” to eliminate TFA from the food supply (Fig. 1). Most countries with strong policy actions against TFA have been high-income countries (HICs). However, since 2021, India, the Philippines, Bangladesh, and Ukraine have all passed best practice legislation to remove TFA (WHO, 2023).

In removing TFA, healthy oils higher in monounsaturated fatty acids or polyunsaturated fatty acids (PUFAs) are often selected as replacements. Unfortunately, some products have replaced TFA with palm oil, which is high in saturated fat (Downs et al., 2017) and has both potentially harmful health and environmental impacts such as deforestation and biodiversity loss for large-scale monoculture plantations. One interview with a researcher discussed the problems with palm oil, stating,

“They probably will start to get some pressure to reformulate their products to remove palm oil. And of course, the reason palm oil is in there in the first place is because they reformulated out the trans fats which were in there to replace the saturated fats. So, you can see this vicious cycle, reformulation for the latest craze.” (Academic Respondent)

3.8. Other ingredient reductions

Reformulation can also remove other ingredients, including artificial colors, flavors, and preservatives, and replace these with natural alternatives. People’s demands for clean labels—foods without any artificial ingredients—have driven some reformulation efforts but can limit food manufacturers’ options for substitutions (van Gunst et al., 2018). As an industry respondent articulated,

“Consumers want to know what is in products, they want to know what they are eating, they want to know where things are sourced from. And there has also been a rise in either food allergies or intolerances. Our commitment to the consumer and their demands is very high and it is important to make sure that we can satisfy that because it is a highly competitive market, and we want to be a responsible producer of goods and to satisfy what consumers want.” (Industry Respondent)

Reformulation has also removed ingredients that some people cannot consume due to intolerances or allergies, such as lactose and gluten. Interestingly, improvements in taste and texture of these products have led to as much as 90 % of purchases to be from consumers without these conditions (Munday and Bagley, 2017).

3.9. Improving nutritional and health content

Another primary reason to reformulate food is to add or substitute ingredients to increase healthy components such as fiber or protein and

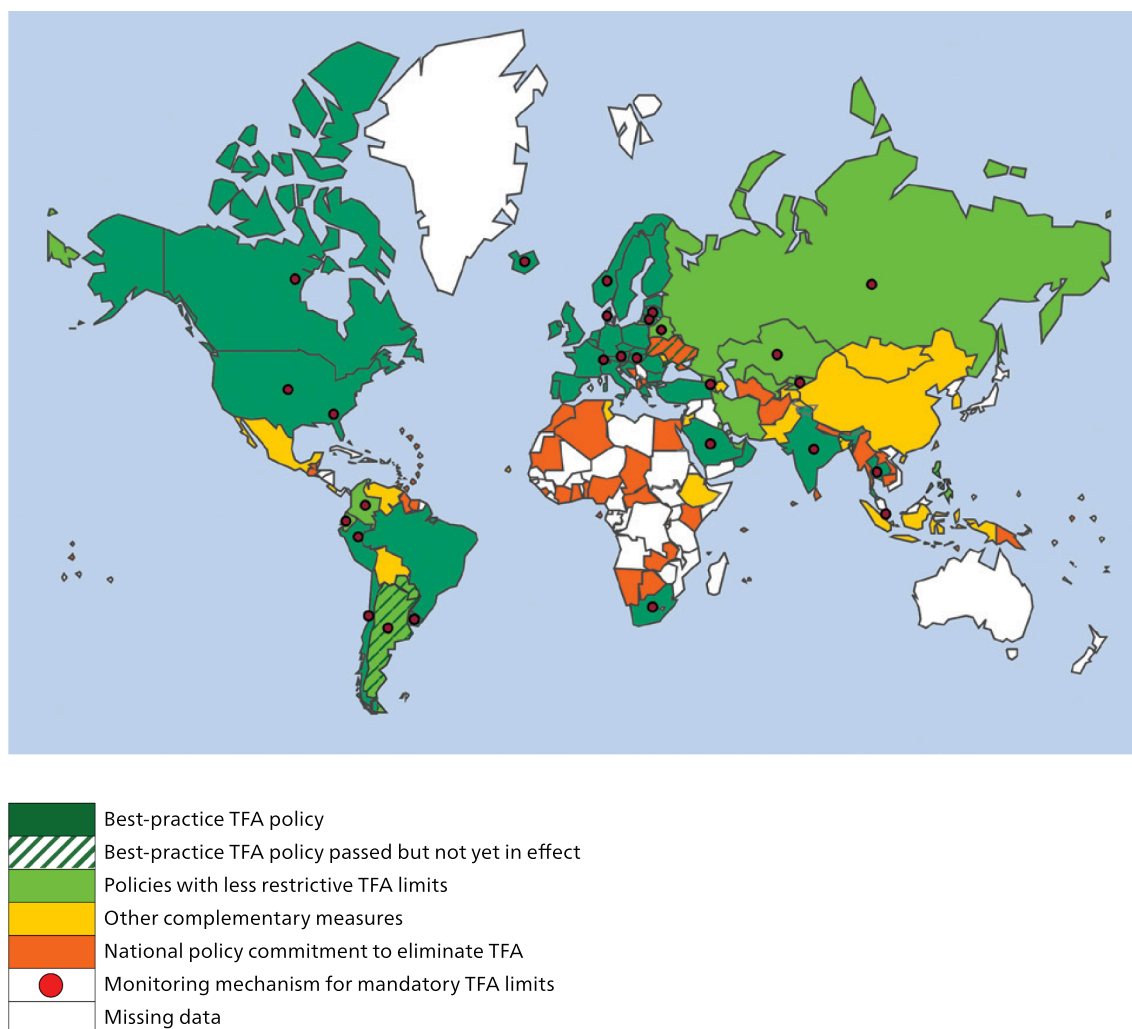


Fig. 1. Trans Fatty Acid (TFA) Policies and Commitments Around the World.

to produce a more healthful food product. Examples of improving products in this way include:

- Adding whole grains or other fiber to snacks, breakfast cereals, breads, and other products
- Altering dairy cow diets to improve the fatty acid profiles of milk, butter, and other dairy products
- Adding healthy oils to butter spreads
- Adding herb extracts to cooking oils to delay degradation and improve health properties
- Adding vegetables to chips, breads, and other products to increase their fiber, vitamins, and phytochemicals
- Adding phytochemicals to foods, such as betalains (pigments derived from fungi), which have strong antioxidant properties

3.10. Fortification

Fortification is often adopted to improve staple foods or vehicles, such as flour, oils, or condiments that are ubiquitously consumed by the population and have a public health good. For example, salt iodization programs have reduced the risk of goiter, cretinism, low cognitive function, and iodine deficiency in countries worldwide (WHO, 2014). Food fortification with micronutrients through a variety of vehicles has been successful in improving the hemoglobin and iron status of women and children (Bogard et al., 2015; Das et al., 2019; Klassen-Wigger et al., 2018; Kumar et al., 2022).

However, it is essential to consider the food vehicle for fortification and its intended effect on improving public health. Sometimes healthy ingredients are added to what are deemed unhealthy foods, so they are perceived to be more beneficial. The *jellybean rule* emerged in the U.S. in the 1990s by the Food and Drug Administration (Title 21 Code of Regulations Part 101), prohibiting companies from fortifying unhealthy, highly processed foods with the intent to classify them as healthy.

The issue of which foods are appropriate to fortify has resurfaced and has been a source of recent controversy. One assessment in Latin America showed that advertising ultra-processed foods fortified with micronutrients created a healthy halo effect that led consumers to overconsume these foods (Kroker-Lobos et al., 2022). Another example emerged in Nepal, where ultra-processed instant noodles that are nutrient-poor, but widely consumed, especially by young children, led to a fortification effort. President Bidya Devi Bhandari supported the Baliyo Nepal project, funded by the Chaudhary and Gates Foundations, to fortify noodles to address micronutrient deficiencies. However, many public health practitioners have criticized the move. One of the country's lead nutritionists, Dr. Aruna Uprety, resigned over the controversy, stating, "I am ashamed to have been part of the vested interest of a company that promotes junk food," and continuing, "This has seriously harmed my years-long initiatives against the promotion of junk food" (Poudel, 2019). Adding to the controversy, the Chaudhary Foundation is the philanthropic arm of the Chaudhary Group, which makes Wai-Wai instant noodles.

This question of which foods to fortify is an emerging challenge included in most of the interviews. Many academic and industry respondents agreed this is not a long-term solution to address public health. Thus, there is a critical need to be thoughtful and selective about which foods are reformulated and fortified and for what purpose.

3.11. Fiber inclusions

Fiber is an essential component of healthy diets and is linked to positive health outcomes, including the mitigation of cardiovascular disease, diabetes, and some types of cancers (Keenan et al., 2002; Lairon et al., 2005; Liu et al., 1999; Montonen et al., 2003; Steffen et al., 2003; Whelton et al., 2005). While the health impacts are notable, many people do not consume the necessary portions of fruit, vegetables, and whole grains to meet daily fiber requirements. As these foods are often

less affordable, increasing their availability, affordability, and demand is essential.

Dietary fiber is one of the most common beneficial ingredients added in reformulation. Fiber is usually a plant-based addition consisting of soluble and insoluble fibers, including cellulose, lignin, pectin, and beta-glucan. However, adding fiber to foods is challenging because it often drastically alters the texture and taste of a product (Evans, 2020). Despite the challenges, there have been some notable successful efforts. In Denmark, the Whole Grain Partnership was a voluntary reformulation initiative to increase fiber intake by setting standards for the content of whole grains in products and limits for sodium and sugar. If a food product met these standards, it received a certification logo on its packaging. This certification and partnership increased fiber intake from 36 grams/day in 2007 to 63 grams/day in 2014 (Goryakin et al., 2019).

3.12. Healthy oils swapping

Monounsaturated fats and PUFAs are inversely associated with cardiovascular disease risk. Omega-3 fats are especially valued for their health benefits (Hooper et al., 2006; Shahidi and Ambigaipalan, 2018). Many products, including processed meats and baked goods, have been reformulated to include PUFAs. Several studies have examined the impacts of oil swaps on taste, texture, shelf-life, and other food product properties as well as people's acceptance after these reformulations (Boncinelli et al. 2021; Barros et al. 2021; Gutiérrez-Luna et al., 2020; Martins et al. 2019; Gómez-Estaca et al., 2019; Barros et al. 2018; De Lamo and Gómez, 2018; Shan et al. 2017; Jiménez-Colmenero et al. 2001). However, further research is needed to determine if these reformulation strategies have positively impacted health.

3.13. Probiotic additions

An increased interest in the human microbiome has led to probiotics, or live microorganisms, being added to more food products. The global retail value of probiotics was estimated at over 49.4 billion USD in 2018, although this includes supplements, and is expected to increase to 69.3 billion USD by 2023 (Markets and Markets, 2019). The specific probiotic strains added are often chosen for their health benefits, such as improving gastrointestinal function, relieving bloating or constipation, increasing immune function, and improving allergies and asthma. However, the evidence behind many of the claims is limited. While probiotics naturally occur in unpasteurized fermented foods, they are also added to yogurt and other dairy products. Probiotics have also been added to bottled smoothies and juices, snack bars, chips, brownies, and cookies.

4. How reformulation and fortification are implemented and enforced

Reformulation and fortification are implemented voluntarily by the food industry or through regulatory mandates, including labeling, food taxes, and limiting or banning certain ingredients.

4.1. Industry-led measures

To date, most reformulation has been voluntary, with industrial food manufacturers deciding what products to reformulate, how, and when. There is a wide array of voluntary and self-regulated reformulation initiatives, for example, "quasi-regulatory public-private partnerships with government institutions, co-regulatory mechanisms in partnership with non-profit or non-governmental organizations, voluntary corporate pledges initiated by alliances of food and beverage companies, and codes of conduct or commitments at individual food and beverage companies, some of which are also participating in collective corporate reformulation pledges/alliances"—in which corporations seek to influence policy decisions and the regulatory environment (Scott et al., 2017). These

approaches may be motivated by competition with other food companies that are also reformulating their products in order to posture the corporation as an advocate for better health and the environment. They may also be inspired by the need to improve food products in terms of their appearance, taste, texture, cost, shelf-life, or other attributes, as well as the need to change products in response to a shortage or increase in the cost of ingredients. One interview addressed this, stating,

“There are factors that influence reformulation and reformulation options like supply, availability of alternative raw materials and ingredients, the functionality of ingredients that are being taken out or added and the impact on texture, mouthfeel, and taste – which are only part of those functionalities – the element of the label that is one of the key aspects, you do not want to replace an ingredient with a few different ingredients and make the label more complex, the impact that those ingredients have on the stability and; therefore, the shelf-life, and the safety during that shelf-life of the food product.” (Industry Respondent)

Many interviews with industrial food manufacturers maintained that reformulation should be voluntary, with some arguing that governments are unaware of the technical processes and challenges and thus, are ill-equipped to set mandates. One interview with an industry employee suggested that reformulation should be voluntary with a cap-and-trade approach, allowing industrial food manufacturers to decide which products to reformulate that have the potential to make the most considerable impacts (e.g., usually food products with the largest sales). This respondent continued, stating,

“We know the sales volumes. You know the averages. You can tell us at this point in time how much sodium we have to remove. Period. That’s the target, that much sodium; not that much from Brand A, Brand B, and Brand C. Do not tell me how to run my business.” (Industry Respondent)

This same interviewee argued that voluntary reformulation could occur much faster. Food manufacturers often repeat this argument, as voluntary reformulation does not require preceding political action. Voluntary reformulation allows industrial food manufacturers to set the agenda as well as monitor and evaluate themselves. They can decide how many products to reformulate, at what levels, over what periods, and whether to leave un-reformulated products on the shelf (Vandevijvere and Vanderlee, 2019). Some have argued that industrial food manufacturers have too significant a conflict of interest to be genuine partners in making these decisions (Kaldor, 2018).

With voluntary reformulation, food manufacturers can establish their own targets, which may or may not align with public health targets. Additionally, what may appear as a significant decrease, may be misleading for food products with high baseline levels of harmful ingredients. For example, if a breakfast cereal has 30 % added sugar, a 20 % reduction still results in a product with 24 % added sugar (Scrinis, 2016). There is also little accountability for whether these targets are met. This results in food companies continuing to sell unhealthy products, both those that have been reformulated and those that have not (Campbell et al. 2019). In fact, a qualitative comparative analysis suggests that when industry is involved in policy creation, public health impacts can be diminished (Ngqangashe et al., 2021).

Voluntary reformulation also leads to uneven coverage, with some products from certain brands being reformulated and others not; therefore, consumers still have the option to buy products with high levels of salt, sugar, and unhealthy fats. One interview with a food industry employee discussed how people could switch from a reformulated product to one that has not been changed, stating,

“One of the things that you cannot do in these efforts that are very well-supported by science and very well-meaning is alienate your consumers, because the risk is two-fold. There is not only a commercial risk, but if you try to do something that you believe is good for the health of your consumers and you do it in the wrong way or too quickly and they don’t follow you, you have lost not only a commercial opportunity, but also an

opportunity to do good on the health of your consumers. And I do not think that even people who talk about nutrition understand how this intricate dynamic between somebody who puts food out there in the marketplace and the consumers that end up consuming it is fundamental to how quickly you can move the needle.” (Industry Respondent)

Another contributing factor to uneven coverage is that after a company reformulates a product for one market, such as Europe, it can continue to sell the original product in other markets with less demand or regulations around reformulation. Additionally, if products that are not consumed in large quantities are reformulated, even significantly, there may not be impacts on dietary intake and public health. One interview with an academic described this, saying,

“There is a tendency for the media to see foods outside of the context of their contribution to diets. This then influences policymakers. It is thus essential that target foods be identified based on their contribution to the intake of the target nutrient. You can reformulate Christmas pudding, but its public health impact will be near zero. On the other hand, a small change in the sodium content of bread will have a significant impact on sodium intake. Bread is a significant contributor to sodium intake and bread has a high population diet penetration.” (Academic Respondent)

Independent evaluations have questioned the accuracy of industry reports of successes with voluntary reformulation. For example, the Healthy Weight Commitment Foundation—an organization of 16 food and beverage companies (e.g., Kellogg, the Coca-Cola Company, PepsiCo) committed to preventing childhood obesity in the U.S.—claimed to have removed 6.4 trillion calories from the food supply; however, an independent verification found that calories were already declining and may have reached this same level without the group’s efforts (Mozafarian, 2014; Ng et al., 2014).

Another example from Food Drink Ireland reported its successes with product reformulation from 2005 to 2017 (Food Drink Ireland, 2017). The report compiled voluntary industry data submissions and claimed a 28 % reduction in salt, an 8 % reduction in sugar, a 10 % reduction in saturated fat, and a 1.6 % reduction in calories. However, this was only for 235 unidentified and voluntarily reported products. They also reported no change in dietary salt intake. When explaining this discrepancy, the report said, “One possible explanation is that the products submitted by the participating companies do not include many of the biggest contributors to salt intake in Irish diets” (International Food Information Council Foundation, 2018).

One interview with an academic discussed how it is problematic for industrial food manufacturers to choose the indicators and measurement tools for monitoring and evaluation. Industrial food manufacturers can then use “a very subtle shaping of measurement tools that are acceptable” (Academic Respondent) to distort results. One interview with a researcher discussed many of these shortcomings of voluntary action, stating,

“In terms of why voluntary reformulation does not drive the kinds of changes that would lead to public health benefits, it has to do with it not being a level playing field, not all companies do it and there are competitive reasons not to reformulate their best sellers because they do not want to lose out on market share to somebody who has not reformulated their product. We also see things happen in a voluntary initiative where companies can set their own product portfolio targets in such a way that they can meet their targets primarily through obtaining new products that are healthier than their existing products. You could argue that is a good thing, that they are shifting, and their business model is diversifying, but they are not changing the nutritional composition of their bestsellers and those are what people are consuming the most of, the small niche brands that they are buying are not the big sellers.” (Academic Respondent)

Another critical shortcoming of voluntary reformulation is it allows food and beverage companies to shift the conversation away from mandatory regulation (Koplan and Brownell, 2010; Scott and Nixon,

2018b, 2018a). A recent review found that voluntary actions in low- and middle-income countries (LMICs), which included reformulation, do not effectively promote or protect public health and their implementation often results in weak policy responses, and sometimes, substitutions (Erzse et al., 2022). For voluntary measures to be impactful, they must engage governments and an external, comprehensive monitoring mechanism is necessary to assess impacts on nutrition and health.

4.2. Restrictive or mandatory regulations: Labeling, taxes, limits, and bans

Other measures not considered voluntary, nor mandatory either, include pressure and legislation from governments and organizations such as the WHO to mandate and advocate respectively for labeling, taxes, limits, or bans of ingredients or nutrients. These measures exist on a spectrum from optional nutrition labeling to mandatory ingredient bans. While measures on the voluntary end of the spectrum share similar limitations discussed above, they may lead to more voluntary reformulation by the food industry to avoid further government action.

4.3. Front of the pack labeling

Labeling is a stimulus for industrial food manufacturers to reformulate, particularly if the labeling constitutes a warning on food products. Simple, easy to interpret front-of-pack (FOP) labels that include stars, traffic lights, or other assessments of nutrition and health, as well as warning labels are also increasing within the market. Manufacturers may choose to reformulate products to avoid a low rating or warning label (Vandevijvere and Vanderlee, 2019).

In 2012, Chile passed the Law of Food Labeling and Advertising (Law 20.606). The law specifies limits for salt, sugar, saturated fat, and calories and requires packaged foods that exceed these limits to carry a FOP warning label. Additionally, foods with warning labels are prohibited from being sold or offered at schools and daycares and cannot be marketed to children under 14 years old (Kanter et al., 2018). Prior to the law, there was some reformulation, but fewer than 2 % of products were reformulated to avoid a warning label (Kanter et al., 2019). Additionally, while there were similar absolute declines in purchases of foods with warning labels, despite differences in education levels, there were higher relative declines in purchases for households with higher education due to lower baseline purchase levels and higher health literacy. Thus, this policy could increase health disparities and the study advocated for more research in this area (Taillie et al., 2020).

Australia and New Zealand introduced the voluntary FOP label, the Health Star Rating (HSR) system in 2014, which assigns food products up to five stars, and as low as a half star, based on a calculation of healthy and unhealthy ingredients. One study examined the composition of 252 packaged foods aimed at children in Australia in 2013 before the HSR system was introduced and then again after in 2016. Their findings suggest that 65 % of the products that adopted the HSR were reformulated. Products with the HSR had less saturated fat and calories and more fiber and protein. However, as the HSR was voluntary, very few products adopted the label and overall, the packaged foods were considered healthier in 2016 as compared to 2013 (Morrison et al., 2018). A 2016 study in New Zealand also looked at packaged foods and found that only 5.3 % of packaged foods adopted the HSR, but of these products, 83 % were reformulated to reduce salt and energy density and increase fiber (Mhurchu et al., 2017).

In addition to these empirical accounts, a U.S. study modelled the expected effect of mandating labels, with and without reformulation to reduce added sugar by 25 % in 9 % of products over three years. The researchers found that mandatory labeling alone was expected to prevent 354,400 cases of cardiovascular disease and 599,300 cases of diabetes. In comparison, labeling and reformulation were expected to prevent 708,800 cases of cardiovascular disease and 1.2 million cases of diabetes between 2018 and 2037. These large differences illustrate that

while mandatory labeling can change consumer behavior and dietary patterns, reformulation is also important, and together these are even more effective (Huang et al., 2019).

Despite these efforts, reformulation can introduce leanwashing or misleading health and nutrient content claims, that are vague and often not legitimate. Labels such as ‘all natural’ or ‘superfood’ offer a perceived healthfulness of a food product, though these labels are largely undefined within regulatory instruments across the world. Given the growing market size of health and wellness food products, future research should explore the nutritional composition of these food products, as well as consumer health benefit attitudes to justify their legislation (Campbell et al., 2023; Rahman et al., 2020).

4.4. Food taxes

National and local taxes on sugar-sweetened beverages and unhealthy foods have been introduced in over 40 countries with varying impacts (Andreyeva et al., 2022; Nakhimovsky et al., 2016; Niebylski et al., 2015; Teng et al., 2019; Thow et al., 2014). Taxes can stimulate reformulation, with food manufacturers reformulating foods to avoid or limit their taxes. Mexico was one of the first countries to implement a volume-based tax on sugar-sweetened beverages in 2014. At one peso per liter, or a 10 % volumetric tax, evaluation studies showed reductions in taxed beverage purchases by all socioeconomic groups and geographically (4 % in rural areas and 6.3 % in urban areas) after one year (Salgado Hernández et al., 2023). Similarly, in 2018, the UK implemented a tax on beverages with more than 5 g/100 mL of sugar. A year after the tax went into effect, companies reformulated beverages resulting in a 34 % reduction in the number of beverages above this threshold (Scarborough et al., 2020). While these examples provide impetus for other countries to follow suit, their effectiveness varies and is highly dependent on a range of factors including geography, local politics, advertising, income, and the competitiveness of the local retail sector, to name a few (Cawley and Frisvold, 2023). Importantly, taxes implemented in isolation are likely not significant enough to drive changes to food systems and public health, due to substitution for other foods and cross-border purchases (Cawley and Frisvold, 2023). Therefore, mutually reinforcing policies, including subsidies on unprocessed and minimally processed foods, are critical to change purchasing and dietary patterns. In an interview with an industry employee, they argued that taxing sugar by gram would lead to greater reformulation efforts, as this would provide a financial incentive for companies to reduce sugar in these drinks, stating,

“If you tax [sugar] at a penny a gram, it is massive what just a half gram reduction would deliver. It is a few million dollars and that is pure profit. And if you do the math on the profit side you usually triple that to get to the sales figure. So, one million dollars in gross profit typically has to mean about three to four million dollars in sales. So, it is that incentivization to drive those kinds of changes that really, really makes a difference.” (Industry Respondent)

4.5. Ingredient and nutrient limits and bans

There are examples of mandatory reformulation in which governments have placed limits or bans on certain ingredients such as salt and TFA. This approach has the advantage of allowing the health sector to set meaningful targets, timelines, and penalties for noncompliance that are based on public health goals. One interview with an academic discussed the importance of restricting food manufacturers from setting these targets and goals, stating,

“It is not the industry that we should be looking to lead reformulation. By all means, we can work with industry but the notion that they would be partners in defining the standards for healthy food is a flawed one and it

leads to anemic, inadequate, attenuated, and ineffective reformulation strategies.” (Academic Respondent)

Mandatory reformulation often requires all companies to reformulate all products, taking the burden off the public. This also creates a level playing field, which some food manufacturers have supported. A study that interviewed employees from 17 Dutch food companies about their agreement to reduce salt, sugar, saturated fat, and energy density found that companies wanted more government regulation to force all companies to reformulate (van Gunst et al., 2018). Similarly, this was a point made in several interviews with industry, with one stating,

“[We have] been reformulating, but if we are competing with companies that have not, and it is not a level playing field, and particularly if we put that on our labels but other companies do not, sometimes consumers have not been educated and maybe think, ‘Oh, well that is not going to taste good.’ To make a public health impact, we need everyone to do it. That is the important thing, and the other important thing is that when you are reducing salt and fat and sugar, it can impact taste, and that is why we all need to be doing it together.” (Industry Respondent)

Another benefit is that products that cannot be reformulated to meet mandatory targets could be removed from shelves, improving the food supply (Scrinis, 2016). One report estimated that mandatory reformulation for salt in Australia would be 20 times more effective than voluntary reformulation (National Heart Foundation of Australia, 2012). An interview with an academic described how mandatory reformulation would be an effective path forward for salt and added sugar, stating,

“The sugar and salt are in the same basket in that we have human taste for salt and sugar, which the industry exploits, and there are some food products where sugar and salt are fundamental to the composition of the product, you cannot have chocolate without sugar, you cannot have salami without salt, so you cannot always have salt and sugar free products, you cannot completely get it out of the food system. But what do you do about it in a regulatory sense and what do you do about it in a monitoring and a policy goal sense? So, the easiest thing to regulate by far is to have maximum salt and sugar levels in particular products. And yes, an individual company can be responsible and monitored and pinged for having a product which is too high in salt or sugar.” (Academic Respondent)

While there are few disadvantages from a public health standpoint, food manufacturers have argued that there are challenges to mandatory reformulation. The reformulation process can be difficult, long, and expensive for industry with some companies claiming that it may not be technologically feasible to reformulate all their products to meet certain targets and it does not guarantee consumer acceptance (Komitopoulou and Gibbs, 2012). An interview with an industry employee also argued that mandatory reformulation would be a disadvantage to small-scale food producers as they have less money for research and development and would face more difficulty in reformulating. They stated,

“That is one of the reasons why only large organizations can deal with regulatory issues on an industrial basis, meaning dealing with 100 different regulations at a time for any single product, and why small startups are better-suited initially to concentrate on one or two targeted markets, but it is an immense issue, and it drives significant cost within these organizations because it is so disharmonized outside that you have to harmonize it inside the company, and to do that is a massive effort.” (Industry Respondent)

Mandatory reformulation has also been criticized for being paternalistic and limiting people’s freedom, as well as interfering with free markets. However, an ethical analysis found no difference on the impact of freedom of choice when comparing voluntary and mandatory reformulation (Kaldor, 2018). The same study also argued that the market for food is more complex and involves an interplay of the state, industry,

and the public and that the ‘free market’ is already being shaped by the food industry and governments to impact demand. The study concluded, “reflecting free market ideals, governments’ preference for industry schemes is likely to persist. But, given the increasing evidence linking greater state involvement with more successful food reformulation outcomes, a default preference for the ‘voluntary’ may start to require a stronger justification” (Kaldor, 2018).

4.6. Fortification mandates

Food fortification is considered one of the most cost-effective and scientifically evidenced nutrition interventions that is readily available to address vitamin and mineral deficiencies (Keats et al., 2019). Fortification spreads the burden of intervention and cost between the public, private sector and the consumer. While food manufacturers are responsible for fortification, governments can create a more enabling environment for manufacturers by enacting legislation by setting standards to ensure adequate and safe levels of nutrients are added and enforcing compliance. Moreover, when fortification is mandatory, there is no reliance on consumer behavior change. Therefore, there is greater likelihood for a public health benefit because there is no need for people to actively identify and choose to purchase fortified food (Nazeri et al., 2015; Rodrigues et al., 2021; Slagman et al., 2019; van der Pols et al., 2021).

5. Market demand measures

Food manufacturers can be incentivized to reformulate through market demand mechanisms in response to changing consumer preferences, increasing priorities for nutrition and health, and environmental sustainability awareness. Companies are responding to these new demands in both HICs and LMICs to make premium or superior products more accessible and affordable, while ensuring these are tailored to consumer demographics. One interview discussed changing demands, stating,

“The millennials (and gen Zs) really want to change the way that they eat compared to their parents, they are much more open to different tastes, and they want innovation even if it’s not very good as long as it’s okay enough for what they expect.” (Industry Respondent)

The 2019 Health and Wellness Progress Report published by the Consumer Goods Forum (a global organization of over 400 consumer goods companies that work collectively together on sustainability issues related to supply chains) stated that food manufacturers want to empower consumers to lead healthier lives through reformulation. The report highlights that 320,000 food products have been reformulated to limit salt and sugar since 2015 and 98 % of companies have reformulated at least some of their products in 70 countries (Consumer Goods Forum, 2018). Positioning reformulation as an important action by food industry players is beneficial, not only for their reputation, but could also provide gains in their consumer base. A report found that 81 % of consumers in India wanted food companies to make products healthier, whereas only 3 % believed that companies already offered enough healthy foods (IGD, 2019). This alone should incentivize food manufacturers to improve the healthfulness of their products.

Food manufacturers are also responding to market demand for more sustainable products in the face of the climate crisis. However, sustainability criteria to reformulate is still in its infancy. Spieldecker and van der Horst (2018) suggest that reformulating to address environmental sustainability comes with a cost and much of this is passed onto consumers. As consumers are largely concerned about the value for money, the perception and desirability of sustainable food products are mixed. Product success, therefore, will require encouraging consumer acceptance as well as convincing and opportunistic marketing (Spieldecker and van der Horst, 2018).

6. Challenges and opportunities for reformulation and fortification

6.1. Supply challenges and opportunities

6.1.1. The necessity of certain ingredients

Reformulation poses challenges for food manufacturers to reduce or remove ingredients or nutrients from their products. Given the many actors across the value chain, it can be difficult to find acceptable replacements at the right price point, to incorporate into production. Thus, ingredients need to be replaced in a way that maintains the food product's characteristics, such as appearance, taste, texture, shelf-life, as well as, food safety (Buttriss, 2013; Gibbs et al., 2012; van Gunst et al., 2018).

While salt adds flavor, it is also a preservative that has an important role in shelf-life and food safety. Salt, for example, is functionally critical for the gluten structure in bread making (Munday and Bagley, 2017). The flavor of salt can be replaced using potassium chloride, though this results in a slightly bitter taste that is unfavorable at higher levels, and consumers may be skeptical with an unfamiliar ingredient on the label (Buttriss, 2013).

Similar to salt, sugar and fats also serve many functions in food besides adding flavor, from texture to bulk, as well as preservation and others. The sweetness of sugar can be replaced with non-nutritive sweeteners such as acesulfame-K, aspartame, neotame, saccharin, sucralose, and steviol glycosides. However, given the minute quantities needed due to their sweetening potencies, they do not have the same properties for texture and bulk as sugar and may reduce consumer acceptance since most are considered artificial (Gibson et al., 2017).

An interview with an industry respondent described several reformulation failures that came from trying to remove ingredients. They described how reducing salt in hot dogs resulted in a liquefied center and reducing salt in cheese prevented it from melting in grilled cheese or on cheeseburgers. They also described the attempt to remove saturated and TFA from crackers but due to packaging and storage, this resulted in an uneven distribution of fats and product texture.

6.1.2. Sustainable goals and practices

With climate change presenting a global challenge, many companies are considering how to reformulate foods by sourcing ingredients produced in sustainable ways. However, environmental sustainability has become a social responsibility tool for marketing purposes as well. Many food companies have sustainability goals and discuss using reformulation to meet these. There is a potential risk that food and beverage companies will misdirect the focus and derail more meaningful action on sustainability by greenwashing unsustainable practices.

6.1.3. Fortification challenges

While the public health impact of fortifying foods has been well documented, there are a variety of challenges in scaling up fortification programs including technical, capacity, and quality assurance challenges (Chadare et al., 2019). This is particularly true for LMICs, given their limited resources (Mkambula et al., 2020).

6.2. Demand challenges and opportunities

6.2.1. People's acceptance of new products

The largest reformulation challenge as cited by many food manufacturers were concerns around consumer acceptance of altered foods (van Gunst et al., 2018). For food manufacturers, reformulated products must be indistinguishable from the original, not just equally preferable. Failing to maintain the taste, texture, or other characteristics of a food can motivate consumers to switch to another product. One interview with an industry employee stated,

"We have faced some failures of reformulations of products that were not accepted by consumers. We did all the reformulation work, we put the

product on the market, and then we had very big disappointments with very sharp decreases of sales by 30 % in three weeks that were obliging you to go back to the previous formula." (Industry Respondent)

People are accustomed to the levels of salt, sugar, and fat in packaged foods, and even more specifically in their favorite brands and products. Additionally, not only do these ingredients influence the taste and texture, but they can also change even more subtle factors such as the weight of the product. One approach to reformulation is to do so through stealth or silent reformulation. Stealth reformulation decreases the amount of an ingredient either suddenly or incrementally, but without making claims on the product packaging of this change (Jensen and Sommer, 2017). There is no marketing of these changes to the public, as any indication of change may spur disapproval (Lacy-Nichols et al., 2020; Popkin and Kenan, 2016). Several interviews with food manufacturers echoed this as being more effective approach to minimize complaints and maintain a consumer base. Regan et al. (2017) argue that "health by stealth" strategies should include consumer views and their buy-in to avoid reaching thresholds in which the palatability of their favorite food products is diminished.

This stealth strategy has been successfully used for the reduction of sodium. For example, in the UK, the food industry slowly reduced sodium over time. Over a 20 year-period, sodium in bread decreased by 40 % and in breakfast cereals by 60 % (Buttriss, 2013). Several of the key informant interviews from both academia and industry stated that while salt requires this slow, stepwise reduction, it is easier to reduce sugar faster as other ingredients can mask the change. Another study examined sales data from a Dutch retail chain and found that adopting stealth reformulation to lower the energy density of their products contributed to a reduced calorie intake in the population and losses in retailer's sales revenues (Jensen and Sommer, 2017).

Several of the interviews with industry explained that it was easier to make new products with lower levels of salt, sugar, and unhealthy fats than to change the composition of existing products; however, there are different challenges with new products.

"Understanding where [reformulation] stops and where innovation plays a role, and for each brand you have a role for both, and typically that is how you do what we call brand planning and strategic planning. So, you would ask what your renovation pipeline looks like, and then what does your innovation pipeline look like, and if you are starting from scratch, it is much, much easier. If you look at our new recipes around the world, they are much lower in sugar, they tend to have the cleanest labels, they have lots of fortification. But launching a new brand or launching a new food is very difficult and you do not have the volume, if you think about the millions of boxes that we sell of an established brand versus something that is new to the market, it takes quite a while to pick up speed, but there is a role for that for sure." (Industry Respondent)

6.2.2. Cost of reformulated food products

Reformulation can be very expensive. The 2014 U.S. Food and Drug Administration's Reformulation Cost Model (as cited by Muth et al., 2019), estimated the cost to be between five thousand and four million USD per product. These costs may then be passed onto the consumer. One study looked at reformulation of foods aimed at children and found an increase of three to twelve cents more per serving (Muth et al., 2019). This may make it difficult for the food industry to reformulate without increasing prices and losing sales.

6.2.3. Emerging demand trends

Despite the challenges discussed above, consumers are now demanding healthier food products and are closely inspecting labels for health information and sustainability practices before purchasing. A 2018 survey of almost 1600 individuals in the U.S. found that 93 % want to eat healthy at least some of the time and 63 % most or all the time. The number of U.S. citizens interested in specific health claims had increased

by 20 % since 2016. The survey also found that people were interested in “natural” foods with much higher demand for foods without artificial ingredients. Additionally, up to 70 % of people said they were willing to pay a premium for foods that were all-natural, ethical, enhanced, or had been reformulated to have lower levels of harmful ingredients, up 10 % from 2016 (L.E.K., 2018). This gives food companies a chance to gain new customers, while staying ahead of market trends (van Gunst et al., 2018).

This is particularly important in emerging economies, where incomes are increasing along with demands for new and diverse foods. For example, in much of Latin America and Southeast and East Asia, there is evidence of growth in purchasing and eating away from home, as well as reliant on processed foods for changing lifestyles (Baker et al., 2020; Baker and Friel, 2016; Popkin and Reardon, 2018; Reardon et al., 2021b, 2021a, 2014). With the double burden of malnutrition rising in LMICs (Khan et al., 2015; Popkin et al., 2020; Popkin and Ng, 2021), there is opportunity and demand for reformulation of unhealthy ultra-processed foods that are currently expanding in market share (Baker and Friel, 2016; Khonje and Qaim, 2019; da Silva et al., 2020).

Additionally, as environmental sustainability becomes a priority in both LMICs and HICs, there is an increased demand for plant-based proteins, including plant-based burgers and milks, made from legumes, grains, and nuts. One interview with a researcher mentioned this, stating, “in the rich countries it’s going from animal to plant, but the overwhelming global trend is from plant to animal, of course. So, the protein transition is two-phased.” (Academic Respondent).

7. Public health impacts of reformulation and reformulation

Reformulation, along with food taxes and subsidies and individual behavior changes, potentially provides the opportunity, to improve diets and nutrition by decreasing the salt, added sugar, saturated fats and TFA, and energy density of certain foods in the food supply. While only one tool, reformulation offers a pathway to improving diets without requiring people to change their eating behaviors (Muth et al., 2019; Spiteri and Soler, 2018; Vandevijvere and Vanderlee, 2019). In addition to reformulation, large-scale food fortification is widely recognized as a cost-effective public health intervention to reduce micronutrient deficiencies such as those of iodine, vitamin A, folate, and iron (Keats et al., 2019; Osendarp et al., 2018).

7.1. Impacts on public health

Has reformulation and fortification impacted public health overall? Establishing causation is difficult due to the limited number of reformulation program evaluations conducted on short- and long-term health effects. Evaluating the population impact of specific reformulation initiatives is especially difficult because of the multifactorial and distal nature of chronic diseases from baseline measurement. For reformulation, the evidence is mixed for reductions in salt, sugar, and unhealthy fats. In a systematic review examining reformulation on individual behaviors, nutrient intake, and health impacts, the authors found that in 73 % of studies, reformulation was associated with increased nutrient intake. In addition, reformulation was associated with a salt reduction of -0.57 grams/day and a reduction of -1.2 for TFA intake (Gressier et al., 2021). Another systematic review and meta-analysis found that product reformulation decreased sugar intake by 91 grams/day and reduced body weight by 1 kilograms. (Hashem et al., 2016). On the other hand, a recent review found voluntary reformulation strategies were largely ineffective in improving public health (Erzse et al., 2022).

Fortification through single or multiple nutrient approaches has beneficial outcomes. A Cochrane review by Das and colleagues suggested that multiple micronutrient fortification reduces iron deficiency anemia and micronutrient deficiencies including iron, vitamin A, vitamin B₂ and vitamin B₆ (Das et al., 2019). Fortification has also been critically important for women and children’s micronutrient status in

LMICs (Das et al., 2013). Large-scale fortification programs have shown reductions in anemia (34 %), goiter (74 %), and neural tube defects (41 %) (Keats et al., 2019).

Taking a closer look at country case studies, in Colombia, voluntary industry measures resulted in reduced sugar content and calorie density in drinks (Lowery et al., 2020). In the UK, a 5.1 % decline in salt intake was attributable to product reformulation (Jaenke et al., 2017). In Finland, reformulation led to a 3 gram/day reduction in dietary salt intake between 1978 and 2002. This corresponded to a 10 mmHg decrease in blood pressure and a 60 to 80 % decrease in mortality from cardiovascular disease and stroke (National Heart Foundation of Australia, 2012). In Mauritius, reformulation of products with soybean instead of palm oil led to a reduction in energy from saturated fat by 3.5 % and an increase in energy from PUFAs by 5.5 %. This further led to a decrease in population total cholesterol by 0.79 to 0.82 mmol/L (National Heart Foundation of Australia, 2012). In Denmark, the ban of TFA in 2004 led to a 3.2 % decrease in deaths from cardiovascular disease per year in the three years after the policy was enacted (Restrepo and Rieger, 2016; Vandevijvere and Vanderlee, 2019).

Though several studies have modeled the potential health impacts of reformulation, modelling relies on a priori assumptions. With reformulation, there are many unknowns about which food products would be reformulated, what ingredients would be changed, how many people would eat these reformulated food products, and for those who would no longer eat them, which foods they would eat instead. Despite these limitations, modeling is still useful to evaluate potential scenarios. A review of 33 studies demonstrated positive health impacts from reformulation, with salt reduction producing the greatest impact on public health, and less so for sugar and unhealthy fats (Federici et al., 2019). Another modeling study in 42 countries found that reformulation could lead to 1.1 million fewer cases per year of cardiovascular disease, diabetes, and cancer; leading to a gain of four million DALYs, 3.1 million life years annually, and increasing the life expectancy by 2.9 months. In terms of cost-effectiveness, these impacts could save 13.2 billion USD purchasing power parities by decreasing health care spending by 0.21 %, increasing the gross domestic product of those 42 countries by 0.51 % per year (Goryakin et al., 2019).

In France and the U.S., a modeling study found that reformulation could promote population adherence to dietary guidelines, as well as decrease current socioeconomic disparities in diets (Gressier et al., 2017). In France, reformulation was estimated to prevent between 2408 and 3597 deaths per year, which was a 3.7 to 5.5 % reduction in mortality. More of these preventable deaths were for low-income groups, illustrating that reformulation could reduce health disparities. In addition to this, the reduction of saturated fat had the greatest health impact with 1897 deaths avoided, followed by sugar and salt, with 746 and 608 deaths avoided, respectively (Leroy et al., 2016). Another modeling study from Australia found that if salt was reduced in processed foods by 15 to 25 % over ten years, it could prevent 5800 to 9700 heart attacks and 4900 to 8200 strokes (National Heart Foundation of Australia, 2012).

7.2. The controversy of ultra-processed foods

To implement policy actions that promote healthy dietary behavior, the health potential of food needs to be assessed by a nutritional classification system. The way foods are classified is highly contested conceptually and technically, with a variety of approaches including nutrient-based (such as nutrient profiling), food-based, or dietary-pattern-based (Dickie et al., 2022).

One type of food classification system, known as NOVA, categorizes the levels of processed foods and their relationship to nutrition and health (Monteiro et al., 2019). Ultra-processed foods are a broad category of foods that are generally made from highly processed and industrialized ingredients not found in home or restaurant kitchens. These foods are designed to be hyper-palatable, often conveniently

ready-to-eat, shelf-stable, transportable, strongly marketed, and ultimately, highly profitable (Lawrence and Baker, 2019; Scrinis and Monteiro, 2018).

Ultra-processed foods, such as sugar-sweetened beverages, sweet and savory packaged snacks, and reconstituted meat products now comprise a significant share of diets around the world. Between 20 and 30 % of the energy consumed in HICs is from ultra-processed foods, and middle-income countries are catching up – where consumption of ultra-processed food is increasing by 10 % per year (Monteiro et al., 2019). The 2018 Global Nutrition Report revealed that Europe, North America, and Oceania purchase the highest volumes of ultra-processed foods, although sales growth is stagnant or declining. In contrast, regions with the highest population density globally—Asia and Africa—are experiencing significant growth in sales, albeit from a lower baseline. Globally, total per capita sales volumes of packaged food rose from 68 kg per capita in 2005 to 77 kg per capita in 2017 (Development Initiatives, 2018).

While the trend in packaged food sales is relatively clear, an increasing body of evidence indicates the adverse health effects associated with the consumption of these foods. Ultra-processed foods fail to contribute to a nutritious diet in the way that unprocessed and minimally processed foods do due to their high energy density and limited nutrient content. As the consumption of ultra-processed foods increases, there is less space in diets for wholesome, nourishing foods and instead, diets move towards an “ultra-processed dietary pattern” (Scrinis and Monteiro, 2022).

Several systematic reviews and meta-analyses point to an association between the consumption of ultra-processed foods and chronic diseases including obesity, dyslipidemia, hypertension, gastrointestinal disorders, and some cancers (Beslay et al., 2020; Cascaes et al., 2022; Figueiredo et al., 2022; Hall et al., 2019; Hecht et al., 2022; Honicky et al., 2022; Schnabel et al., 2018; Smit et al., 2022; Werneck et al., 2022; Whatnall et al., 2022). It has been estimated that replacing half of the ultra-processed foods consumed in the UK with minimally processed ones would result in 14,235 fewer coronary deaths and 7820 fewer stroke deaths by 2030 (Moreira et al., 2015).

However, there are counterarguments within the literature questioning the real impact of reformulation on public health (Federici et al., 2019). For example, Monteiro and colleagues argue for ultra-processed foods, “nutritional reformulation is not likely to make them healthy foods” (Monteiro et al., 2019a). Thus, simply changing the nutrition profile of foods may not go far enough, particularly in ultra-processed foods. Some argue the food industry has focused on what is called “nutritionism”—a narrow view of food quality based on “good” or “bad” nutrients that have defined dietary guidelines, and other technological solutions such as reformulation that targets nutrients instead of overall healthfulness of dietary patterns (Clapp and Scrinis, 2017; Sturdy, 2014). As Monteiro articulated, “Reformulated ultra-processed foods would be especially troublesome if promoted as “premier” or “healthy” products. They would remain partly, mainly, or solely formulations of chemicals” (Monteiro and Cannon, 2022).

Dicken and Batterham argue that ultra-processed foods have degraded food matrices and adversely altered nutrient bioavailability. Thus, altering the “nutrient content of ultra-processed foods is insufficient to decrease their adverse effects on human health” (Dicken and Batterham, 2022). Additionally, even if some ultra-processed foods are slightly improved in their nutritional composition through reformulation, the category of ultra-processed foods is still harmful for health and, given its dominance in diets, this outweighs improvements in individual food products (Scrinis and Monteiro, 2022). Several studies have maintained that reformulation aimed at reducing the quantities of harmful ingredients—salt, added sugar, saturated and TFA, and total energy density—has limitations, especially in ultra-processed foods where these may make up the bulk of the ingredients. One researcher from the public health sector stated:

“If you implement 100 % of the reformulation agenda you probably do not have junk food any longer because you have to reduce sodium, sugar, and saturated fats. Having only one piece of the reformulation agenda is not going to work, it has to be much more comprehensive, and has to change the ingredients... It is very difficult to improve junk foods.” (Public Health Respondent)

Mal-substitution is a risk with ultra-processed foods where the ingredients used in substitution are also likely to be highly processed, and therefore function similarly to the ones removed, often with unknown health impacts (Campbell et al., 2019). For example, the push to replace saturated fats with added sugar or TFA were later found to have detrimental health impacts (Scrinis, 2016; Scrinis and Monteiro, 2018). Another concern is that by focusing on just one, or a few ingredients to remove, many other ultra-processed ingredients are left behind that may also have harmful impacts on health (Scrinis and Monteiro, 2018).

While reformulation has been described as a win–win by many—a win for public health and a win for industrial food manufacturers—others have questioned or disputed this. In one interview with an academic, they stated that a win–win was not achievable and argued that reformulation enables food manufacturers to portray themselves as actively addressing the issue and implementing sufficient measures, even though their efforts yield little effectiveness. They argue that this is more dangerous than doing nothing at all, stating,

“[Reformulation] leads to delayed action, policy inertia, and massive halo effects of so-called socially responsible firms going out and apparently voluntarily doing something that is making a difference. The disaster comes from a little bit of difference. From the psychological reasons I have just outlined. Action has to be reframed in policy making because a little bit of action is more dangerous than inaction... and in actual fact, all you are doing is propagating a myth that something effective is being done when nothing effective is being done. And the risks are huge.” (Academic Respondent)

Additionally, this interviewee discussed some examples of negative public health impacts that can result from reformulation. They describe licensing effects, wherein people think they are making a healthy choice by eating a reformulated product and then reward themselves by eating more of it or eating other unhealthy foods. Moreover, there is calorie underestimation bias when consumers notice that a food has been reformulated and believe it has fewer calories, thus consuming more of it. Another interview with an academic acknowledged the potential benefits of reformulation but argued there was still the need for broader dietary changes, stating,

“In the intermediate, where we are, reformulation is a positive thing, we need to start shifting people away from eating loads of sugar and fat, but it is not getting us on the pathway towards the large dietary shifts that we need both for health and for sustainability reasons.” (Academic Respondent)

8. Discussion and conclusion

Reformulation has the potential to improve diets and nutrition and make significant impacts on public health by improving the nutrient profile of processed foods. As discussed earlier, fortification has been an important intervention to improving public health, particularly for women and children living in LMICs and is a common strategy for staples in HICs.

Despite this, the promise of reformulation is not a panacea for diets and nutrition, and its ability to promote public health is limited to a certain extent. In fact, even the most extensive reformulation will not transform ultra-processed foods into nutritious ones. Changing the nutrient composition is not enough for foods that are of poor nutritional quality and are riddled with additives, artificial colors, and other synthetic ingredients. Perhaps regulating the sales of ultra-processed foods

should be the end goal, instead of reformulating these foods to make them healthier. Significant action is needed if we want to witness real gains in public health.

The present review suggests that which measures are taken to spur reformulation matter. While food manufacturers push for voluntary, industry-led reformulation, this is ultimately driven by profits and falls short of what is needed to improve public health. This was observed in the interviews, with most industry respondents advocating for voluntary reformulation and arguing this path is faster and more effective since governments may not have the knowledge or political will to successfully set mandates. On the other hand, many academic and public health respondents argued that mandatory reformulation would be more effective.

The public's concern for the healthfulness of their food choices, as well as the environmental and labor implications of food production, is increasing. As a result of this market demand, the food industry will need to engage in reformulating food products. However, a comprehensive, government-led strategy that includes mandatory labeling, taxes, limits, and bans informed by public health and sustainability evidence is required. This was the approach supported in many of the interviews with academic and public health respondents. This allows for more ambitious targets to be set, enforced, and applied to all foods from all companies, leading to more meaningful and larger improvements in public health. There is also a need for independent monitoring and evaluation and repercussions for missed targets by a larger body such as the WHO. The food industry should be involved in implementing reformulation policies but not in their design.

Challenges, from both food supply and market demand aspects, should not be underestimated. According to food manufacturers, reformulating foods is not an easy, inexpensive task. Simply reducing or removing sodium or sugar can have significant ramifications on the taste, architecture, consistency, and shelf-life of foods. Meeting government mandates can be significant and, at times, impossible for companies to achieve in keeping with what consumers expect from their favorite brands.

While reformulation has potential health benefits, it will not solve the issues with diet quality that exist across the world. With three billion people unable to afford a healthy diet, and food prices and inflation surging (Bai et al., 2022), processed foods can be important in filling macro- and micro-nutrient gaps for those who are most acutely impacted by the deepening food crisis. While it would be ideal for everyone to have access to a diverse range of animal source foods, vegetables, fruits, and other nutrient-dense foods, for many of those struggling to make ends meet, this is a formidable challenge. Ultra-processed foods are convenient, have a long shelf-life, and are less expensive for households with little disposable income or purchasing power (de Oliveira et al., 2022; Monteiro et al., 2019).

The interviews carried out as part of this work highlight some of the ways that public health, academic, and food manufacturers differ in their views on reformulation; however, the interviews also show some areas of overlap. While food manufacturer interviewees were more likely to cite public health and environmental sustainability as their motivations for reformulation, public health and academic respondents pointed to profits as the driving factor. Public health and academic interviewees were more likely to support government led, mandatory efforts while most food industry respondents advocated for reformulation to be industry led, although a few industry respondents were in support of leveling the playing field through mandatory efforts. One area of agreement across the interviews was around avoiding fortifying unhealthy foods (adhering to the jellybean rule). Seeing these patterns emerge across the interviews may increase understanding of the different views of reformulation, informing the way forward.

One significant limitation of our review is that most of the included papers draw on research in HICs. Further research is needed in LMICs to ensure that evidence and key lessons on reformulation are more inclusive, contextualized, and relevant for various settings. Given the lack of

representation from researchers living in LMICs, it would be valuable for future studies concerned with reformulation to interview these actors as a means of further corroborating our findings. It will also be important to use those findings to better design policies and programs to improve diets in those specific contexts with a prioritization of how reformulation impacts populations living in resource-constrained settings. In countries where public funds to invest in scaling-up technology and regulation remain inadequate, philanthropic institutions and bi-lateral agencies should provide funds to support governments, and multi-lateral organizations, such as the United Nations (WHO, UNICEF, and FAO) and continue to set forth guidelines and rules of engagement with food industry.

A larger shift in diets towards unprocessed and minimally processed foods is needed for nutrition and health. For this to occur, policies and actions—in both LMICs and HICs—are needed to improve the availability, affordability, and demand for all types of nutritious foods, including fresh, unprocessed, and minimally processed foods such as fruits, vegetables, nuts and seeds, whole grains, and legumes. Therefore, reformulation should not be undertaken in isolation but rather in conjunction with broader-scale, comprehensive efforts to improve access to healthy, diverse, and safe diets.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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