Chapter 12

Role of Meal Replacements on Weight Management, Health and Nutrition

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Additional information is available at the end of the chapter

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Abstract

Meal replacements are a safe and effective tool for weight loss and weight management and beyond. Recent research and concepts suggest that the category can provide additional metabolic and nutritional benefits not previously recognized. Recent studies indicate that use of protein-enriched meal replacements helps maintain lean body mass during weight loss, providing additional metabolic benefits in the form of improved insulin sensitivity and reduced inflammation. Depending on the formulation, meal replacements can have a low glycemic index and have a high nutrient density relative to energy density, the latter being an important aspect highlighted in government dietary guidance. While well defined in some markets, there is a need to establish clear regulatory standards in other key markets to ensure a level playing field and proper recognition of the category.

Keywords: meal replacement, weight loss, body composition, glycemic index, nutrient adequacy, regulation

1. Introduction

Globally, obesity rates remain high, and although incidence has plateaued in some countries (e.g., US men), rates of related comorbidities continue to escalate, such as, type II diabetes. Nutrition survey data suggest that populations are becoming overfed, yet undernourished, due to the poor nutrient density of the diet, contributing simultaneously to elevated rates of chronic disease and nutrient inadequacy. Meal replacements (MR)—a prepackaged, calorie-controlled product in a bar or powder mix that can be made into a shake or beverage—have long been validated as safe and effective tools for weight loss (and weight maintenance). More recent studies have indicated that high-protein MR are also effective at maintaining lean body mass and reducing visceral body fat during weight loss. This review focuses on MR that do not require medical supervision (those classified as medical foods).

Depending on the formulation, MR also possess the advantage of having a low glycemic index (GI) value; low-GI diets have been linked to improved weight maintenance and reduction in risk of diabetes and ocular disease. Many nutrition researchers and authoritative bodies around the world have highlighted the need to improve the nutrient density of diets as a means to reduce obesity while maintaining optimal nutrition status. MR also tend to be nutrient dense, meaning that they possess a high ratio of essential nutrients relative to calories.

Some markets have established clear regulatory standards and definitions for the composition and marketing claims for MR (e.g., Codex, Canada, EU, Brazil, Korea, Indonesia). However, several large markets (e.g., US, Mexico, China, Russia, India) still lack these important standards, in turn limiting research opportunities and recognition by governments, healthcare professionals and consumers of the value the category provides.

The aim of this chapter is to review the extensive body of literature validating the safety and effectiveness of MR as weight loss and weight maintenance tools; explore the benefits of MR beyond weight loss, including maintenance of lean body mass and low glycemic index; discuss the concept of nutrient density, its importance in nutrition and how MR fit into a nutrient-dense diet; and discuss the need for regulatory standards to be established in those countries that currently lack a definition for MR.

2. Meal replacements for weight loss and weight maintenance

According to the most recent global analysis, obesity rates continue to rise at an alarming level overall, reaching 50% of the population in some countries (**Figure 1**), with the prevalence in women rising faster than that for men. Globally, the prevalence of obesity now exceeds that of underweight (NCD Risk Factor Collaboration 2016). Although obesity rates in some developed countries appear to have leveled off (e.g., US men) [1], comorbidities, such as type II diabetes, continue to rise. The World Health Organization (WHO) estimates the prevalence of diabetes has doubled worldwide since 1980 and resulted in 3.7 million deaths in 2012, with combined direct and indirect costs estimated in the $billions annually [2]. With overweight and obesity recognized as the strongest risk factors for type II diabetes, the WHO recommends obesity prevention, through healthy diet and physical activity, as a key approach.

Few tools have been validated as safe and effective in the treatment or prevention of obesity and overweight. Bariatric surgery is effective at treating those who are morbidly obese, yet it is associated with substantial risks and postsurgery complications, including nutrient deficiency. While advances in science and technology have eventually provided several efficacious pharmaceutical drugs for obesity treatment, the effects are modest and associated with a myriad of side effects [3], and many FDA-approved prescription weight loss drugs have been subsequently withdrawn from the market due to safety concerns [4]. In contrast, nearly 150 studies demonstrate that use of MR (in various forms) safely reduces energy intake and results in sustainable weight loss (**Table 1**). A systematic review published concluded that

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MR safely and effectively produce sustainable weight loss [5]. The systematic review included six randomized, controlled MR intervention studies of at least 3 months duration, involving adults with a body mass index (BMI) ≥ 25 kg/m².

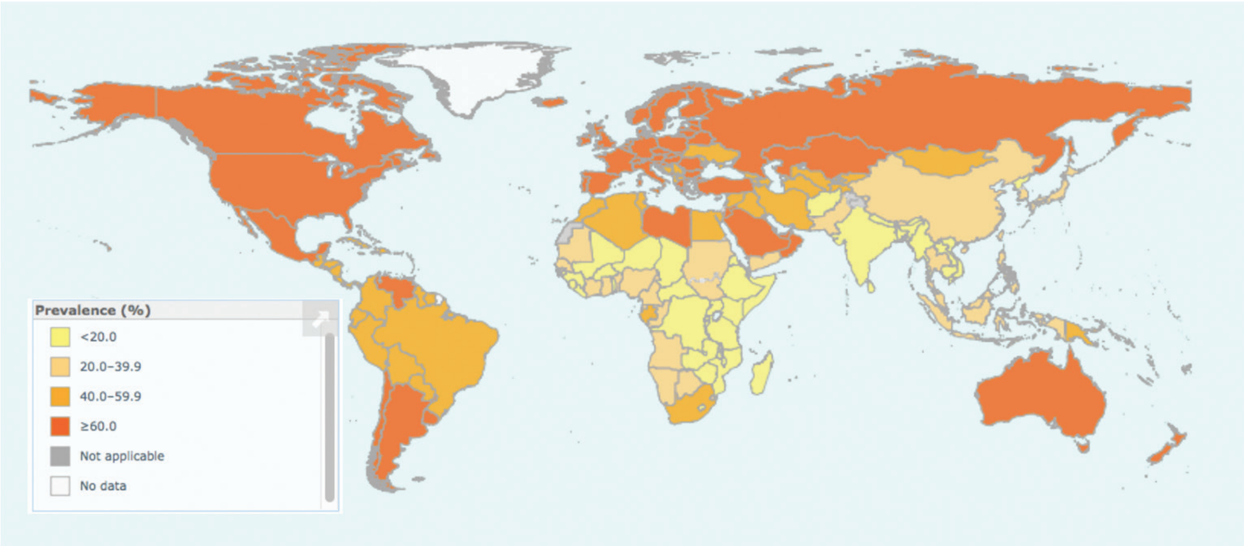

Figure 1. World Health Organization Global Health Observatory (GHO) data. Global overweight and obesity prevalence. *Source*: World Health Organization http://www.who.int/gho/ncd/risk_factors/overweight/en/.

Approach	Category	Effectiveness for obesity treatment—long term (>1 year)	Side and adverse effects
Pharmacological	Prescription drug	5% total body weight (Khera 2016)	Significant and serious, with some drugs having received FDA approval, then subsequently withdrawn from the market
Bariatric surgery	Medical device	30% of total body weight in the morbidly obese (Chow 2016)	High risks associated with surgery and postsurgery complications, including nutrient inadequacy or deficiency
Meal replacements	Conventional food and medical food	7–8% total body weight (Heymsfield 2003)	Only nonserious (nuisance) effects reported

Table 1. Relative comparison between pharmacological, surgical and meal replacement approaches to obesity treatment and prevention.

More recent studies have demonstrated MR effectiveness at maintaining weight loss up to several years. Intervention studies involving MR use with a year or more of follow-up have shown a range of sustained weight loss from 2% up to 11% of baseline body weight (**Figure 2**) [6–21].

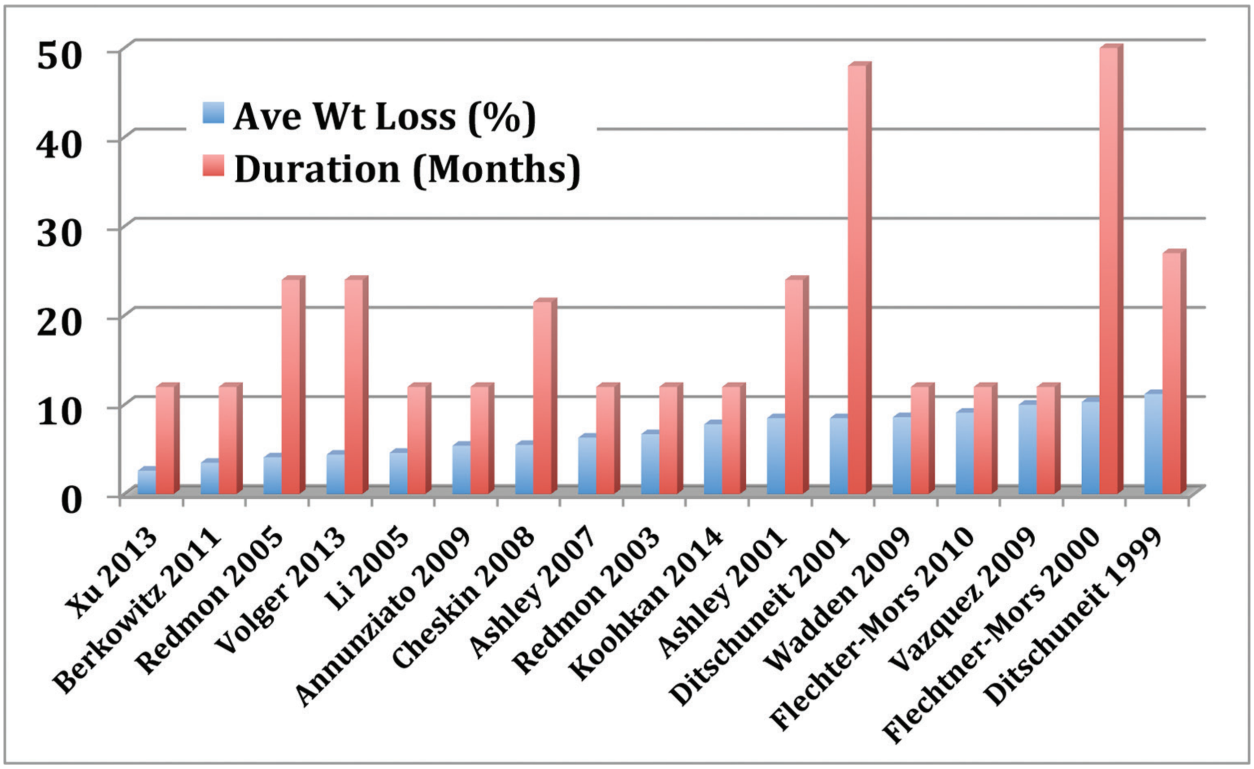

Figure 2. Weight loss and maintenance from randomized controlled trials ≥1 year in duration involving meal replacement.

Portion size is a key factor in determining energy intake and may be closely linked to obesity. Research indicates that portion size is directly correlated with energy intake, suggesting that controlling portion size is an effective approach to reduce energy intake and combat obesity [22]. Among the few portion control tools researched to date, liquid MR are considered among the most effective and consistent, particularly if combined with other efforts to encourage consumption of high-nutrient-dense, low-energy-dense foods [22]. Furthermore, MR promote adherence to a restricted calorie diet due to simple preparation and convenience compared to preparing and cooking low-calorie foods at home. MR generally contain a tight range of total calories, macro- and micronutrients (**Figure 3**), and are a nutrient-dense tool, especially useful for supporting adherence to a calorie-restricted diet through portion control.

Satiety and appetite are known to impact total energy intake, as well as food choices and eating behavior. Both are regulated by a combination of mechanical and endocrine effects ranging from the gut to the brain. With respect to diet, protein has been identified as an important contributor to satiety, defined as the absence of hunger between meals. Dietary protein can induce satiety through several mechanisms including thermic effects and induction of gut hormones such as cholecystokinin (CCK) and glucagon-like peptide 1 (GLP-1) and ghrelin [23]. Intervention studies show that increased protein intake, using protein-enriched MR, is effective at increasing satiety, reducing hunger sensations, decreasing energy intake and facilitating weight loss in obese subjects [24, 25].

Many authoritative bodies around the world have sanctioned the use of MR for weight loss and control. As far back as the mid-1980s, Codex Alimentarius recognized the use of MRs for weight control [26]. In 2010, the European Food Safety Authority (EFSA) concluded that MR are effective for both weight loss and weight maintenance [27]. Most recently, the Academy of Nutrition & Dietetics (AND) rated strongly the use of MR as part of a comprehensive weight management program [28].

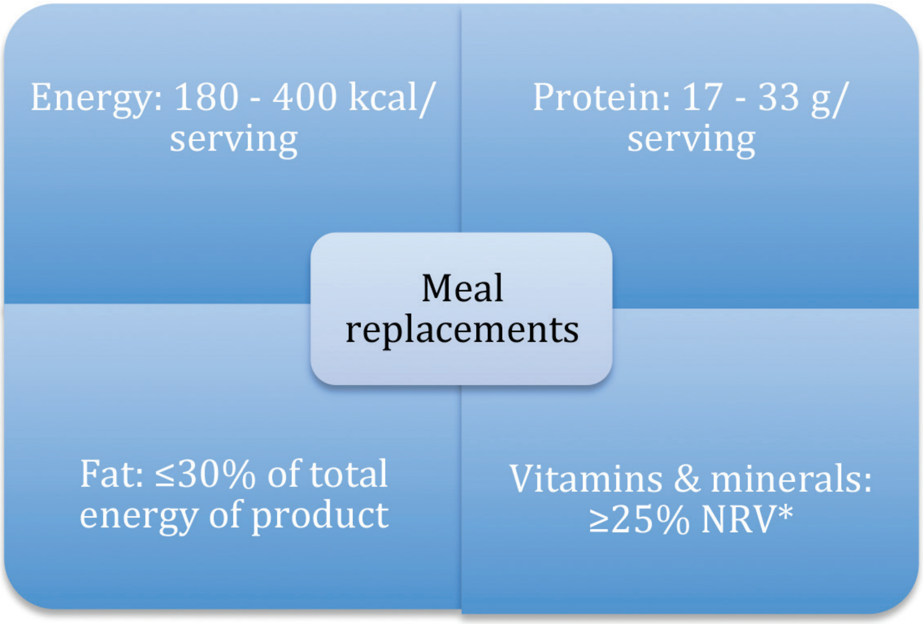

Figure 3. General macro- and micronutrient composition of meal replacement products.

3. Metabolic benefits of meal replacement

Weight loss in obese subjects during an intervention is comprised of water, fat and lean (muscle) mass. The amount and extent of fat and muscle loss depend on the specific weight loss intervention. As lean mass determines the basal metabolic rate (BMR), the goal for any weight loss program is to lose fat mass, while preserving muscle mass. This helps to maintain a higher BMR, which in turn helps to maintain energy expenditure, which can often decline with weight loss. Use of protein-enriched MR products has been shown to effectively maintain lean body mass during weight loss [24, 29], particularly when combined with resistance exercise [30].

Glycemic index (GI) represents a measure of the ability or rapidity of a given food to raise an individual's postprandial blood glucose level. GI is determined for a given food in reference to a standard food, usually white bread, and reflects the blood glucose-raising ability of digestible carbohydrates in a given food [31]. Examples of relative GI values of different foods can be found in **Table 2**.

A growing body of evidence suggests that the GI and glycemic load (GL, a measure of how much a given food will raise an individual's blood glucose level following consumption) of the diet play an important role in human metabolic functions and health. High GI foods and a high GL stimulate a rapid rise in insulin levels, which on a chronic basis can result in insulin resistance [32, 33]. The GL of a food is calculated by multiplying its GI by the amount of carbohydrate it contains per serving, and then dividing by 100. GL is a function of the amount of carbohydrate intake and the GI of the food. In contrast, GI is an inherent property of a food, independent of the amount of carbohydrate ingested. The GI value of a diet can impact insulin sensitivity and glucose metabolism [34]. Blood sugar levels have also been implicated in appetite control, suggesting that. Furthermore, MR promote adherence to a restricted calorie diet due to simple preparation and convenience compared to preparing and cooking low-calorie foods at home. The GI of a diet may impact overall food and energy intake [35]. Accordingly, low-GI diets have been shown to be an effective approach for managing diabetes [36, 37] and obesity [38, 39]. The combination of a high-protein, low-GI diet in obese subjects is effective at inducing weight loss and maintenance of lean body mass [25, 36, 40]. Although it varies by formulation, MR tend to be high in protein and have a low GI (<55), making them ideal for incorporation into an overall low-GI diet plan.

High GI (≥ 70)	• Foods digested rapidly by the body and cause quick elevation in blood sugar levels • White bread, pretzels, and candy
Medium (56 - 69)	• Foods digested at a slower rate than high GI foods, causing moderate elevations in blood sugar levels • Apricot, oat bran, and popcorn
Low GI (≤ 55)	• Foods digested at a slower rate causing slower increases in blood sugar levels • Cheese, yogurt, and nuts • Meal replacements

Table 2. Glycemic index (GI) values of select foods.

As with insulin sensitivity, the degree of intrabdominal and visceral fat is tightly linked to metabolic syndrome. Surrounding the body's critical organs, such as the heart and liver, visceral fat stimulates systemic inflammation and is known as an increasingly serious risk factor for chronic diseases, including cardiovascular disease and diabetes [41]. In simple terms, "sarcopenic obesity" can be defined as low skeletal muscle mass and strength combined with excess body fat, much of which is visceral fat [42, 43]. The concept has also been described as "thin outside, fat inside" or "TOFI" [44]. Related to obesity, individuals can have the same body mass index (BMI), but vastly different inflammatory states and risk levels due to

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differences in distribution and degree of visceral fat [45]. As there is as yet no medical cure, resistance and strength exercise, combined with a high-protein diet, is recommended as one of the only effective means of addressing sarcopenic obesity and complications of excess visceral fat [30, 46]. When used in conjunction with reduced total calorie intake and resistance exercise, MR can also be effective at reducing visceral fat [19, 30, 47].

With respect to safety, use of MR for weight control and other metabolic benefits is among the safest approaches studied. Many individual intervention studies [48–50] as well as systematic reviews [51] have confirmed that MR safely facilitate weight loss and maintenance.

4. Meal replacements and nutritional adequace

According to the *2015 Dietary Guidelines for Americans*, individuals should consume more nutrient-dense foods to better balance meeting nutritional needs while avoiding excess calories or energy [52]. A position paper from the Academy of Nutrition & Dietetics concluded that there is a positive association between dietary energy density and increased adiposity [53]. Nutrient density is a term referring to the amount of essential nutrients in a food relative to the amount of energy (calories) that food delivers. High-nutrient-dense foods provide a high level of nutrients with relatively low caloric value, and low-nutrient-dense foods provide a high level of calories with relatively low nutrient content [54, 55]. Examples of nutrient-dense foods include fruits, vegetables, whole grains, lean meats and dairy.

In the United States, more than half of the population fails to achieve the recommended intakes for key nutrients, including vitamins A, C, D and E, fiber, magnesium and potassium [56], all of which have been deemed “nutrients of concern” or “shortfall nutrients” by the 2015 Dietary Guidelines Advisory Committee [57]. Incorporation of more nutrient-dense foods into the diet is an effective approach to achieve proper nutrient adequacy without adding excess calories.

Overweight and obese individuals are at even higher risk than the general population of experiencing nutrient deficiency, particularly vitamin D [58]. This is believed to be due, in part, to overconsumption of a high-energy-dense and low-nutrient-dense diet [59], a phenomenon described as “overfed but undernourished” [60]. Furthermore, weight loss regimens, particularly those involving rapid weight loss, can lead to compromised nutritional status [61].

With a modest amount of calories, added essential vitamins, minerals and fiber, MR are considered to be a nutrient-dense food. Indeed, a variety of studies demonstrates that use of MR during a weight control regimen helps to ensure adequate intake of essential nutrients [12, 62–64].

5. Meal replacement definitions and standards

In some markets around the world, regulations exist to define MR, both in function and in composition. The definition, specific authorized claims for weight loss or management and composition standards (for both macro- and micronutrients) vary by country (**Table 3**). The *Codex Alimentarius* composition standards for MR were established back in 1991 and have served as the basis for the definition in a number of other markets [65]. Establishing regulations and composition standards has served as the basis for sanctioning weight loss benefit claims for MR and has facilitated harmonization in multi-country regions (e.g., EU). Together with the plethora of data supporting the safety and efficacy of MR, these standards have also led to increased use, research and acceptance of MR by the healthcare professional community [66].

	Codex	Australia	Brazil	Canada	Chile	EU	Indonesia	Korea	US & China
Energy	200–400 kcal	≥200 kcal	≥200–400 kcal	≥225 kcal	≥200–400 kcal	200–250 kcal	≥200 kcal	≥200–400 kcal	None
Protein	25–50% of total energy; ≤125 g/day	≥12 g	25–50% energy of product and <125 g	20–40% energy of product	25–50% energy of product and <125 g	25–50% energy of product	≥12 g	≥10% NRV	None
Fat	≤30% of total energy	None	≤30% energy of product	≤35% energy of product	≤30% energy of product	≤30% energy of product	≤13 g	None	None
Fat from linoleic acid	≥3% of total energy of linoleic acid (glycderide form)	None	≥3% energy of product	≥3% energy of product	≥3% energy of product	≥1 g	None	None	None
Linoleic acid & linolenic acid ratio	None	None	None	4:1–10:1	None	None	None	None	None
Vitamin	33–25% of specified amount in Codex 181-1991 (depend on # of servings/ day)	Specific minimum indicated	Specific minimum indicated	Specific minimum indicated	Specific minimum indicated	≥30% NRV	≥25% RDA	≥25% NRV	None
Mineral	33–25% of specified amount in Codex 181-1991 (depend on # of servings/ day)	Specific minimum indicated	Specific minimum indicated	Specific minimum indicated	Specific minimum indicated	≥30% NRV w/ specific limit on Na & K No min limit: F, Cr, Cl, Mo	≥25% RDA	≥25% NRV	None
Essential amino acids	None	None	None	None	None	Yes—profile WHO 1985	None	None	None

Table 3. Comparison of standards and regulations for meal replacements in various markets around the world.

However, in other markets with high obesity prevalence, including the United States, Mexico, China and Russia, no such standards have been established. The reasons for the lack of MR regulations and standards in these countries vary, but are tied closely to the existing food and/or dietary supplement policy and regulatory framework. For example, in the United States, composition or identity standards are not expressly required in order for products to bear health benefit claims. For MR, as with conventional foods and dietary supplements, the ability to bear a weight loss claim is predicated on the availability, quality and quantity of scientific substantiation, not a formal definition for MR or composition standards [67]. In contrast, in the case of Mexico, MR are regulated under the category of food supplements. By regulation, food supplements are not permitted to bear claims of any kind [68], thus eliminating the ability to communicate a weight loss benefit for the category and reducing the need to establish a definition. Finally, in China, MR are regulated under the health or functional food category [69]. Products in this category are required to go through animal and/or human testing (depending on the desired claim) as part of a premarket registration process. This testing requirement to validate the health food product prior to market has precluded the need for a specific MR definition or standard.

Establishing full recognition of the health benefits of MR in these markets may ultimately require a formal definition and composition standards. Indeed, the absence of a formal regulation for MR has allowed the category to be inappropriately targeted with antiobesity policies aimed at, for example, curbing the public's consumption of sugars. In Mexico, MR are subject to the same tax aimed at reducing intake of sodas and other sugar-sweetened beverages as part of a broader public health initiative [70]. In the United States, similar policy has been proposed at both the Federal [71, 72] and state levels [73] and has passed at the local level [72, 74]. In some cases, MR have been exempted (Berkley, CA), and in others, this exemption has not been expressly granted (Philadelphia). Imposing such policy on MR seems incongruent with the state of the evidence, which clearly demonstrates that MR are part of the obesity solution, not the problem.

The absence of a formal definition for MR may negatively impact the consumer, as products claiming to be a MR may not meet basic compositional expectations. Consumers conceivably stand to benefit from a standard or regulation by receiving properly formulated and consistent products. The absence of a formal definition has also prevented the category from being included in potentially beneficial public policy aimed at obesity and disease prevention. Without a clear standard of identity and recognition of its health benefits, MR cannot be included in government-sponsored programs such as Flexible Savings Accounts or Health Savings Accounts.

6. Summary and conclusions

Rates of obesity and comorbidities continue to rise worldwide. MR are among the safest most effective tools available demonstrating significant and long-term weight loss. MR use provides benefits well beyond weight loss, including body composition and metabolic benefits from its low glycemic index. As a nutrient-dense food, MR are also effective at achieving and maintaining nutrient adequacy without delivering excess calories. Although well defined in some markets, MR still lack a formal definition and regulation in several key markets around the world. The absence of this formal recognition and composition standards has left the category vulnerable to onerous public policy while being excluded from potentially beneficial policy. Efforts to establish formal regulations in these key markets should be considered in order for the category to provide its full impact on obesity and public health.

Conflict of interest statement

Dr. Shao is a full-time employee of Herbalife International of America, Inc, a global nutrition company that manufactures and markets nutritional products (functional foods and dietary supplements), including meal replacement products.

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