DOI: 10.1590/1413-81232017227.25952015

Food risk regulation: the tensions of the Brazilian Health Surveillance System

Ana Virgínia Almeida Figueiredo [1]
Elisabetta Recine [2]
Renata Monteiro [2]

Abstract *This article addresses the dynamics of Brazilian food control practices, highlighting their special risk-related features and the types of intervention, as well as the recently adopted instruments to control risks related to the nutritional composition of food and their institutional repercussions. Food regulation in Brazil dates back to the First Republic. The practice has been remodeled over the years, due to both the increasing complexity of the risks and the introduction of new institutional operational mechanisms. In recent years, with the adoption of instruments such as agreements and terms of commitments established between government and industry and designed to control risks, it has become possible to identify widening gaps in regulatory competence. The adoption of mechanisms without the participation of consumers, with elastic deadlines for compliance by industries and insusceptible to inspection, represents a setback in the democratic process and the practice of health regulation of food currently under way in Brazil.*

Key words *Food control, Food regulation, Food risks*

[1] Diretoria de Vigilância Sanitária, Secretaria de Saúde do Distrito Federal. SGAN Quadra 601 Blocos O/P, Asa Norte. 70830-010 Brasília DF Brasil. anavirginia.figueiredo@gmail.com
[2] Faculdade de Ciências da Saúde, Universidade de Brasília.

Introduction

In the sphere of health surveillance, regulation is a risk management process adopted by State institutions targeting health aspects of potential deficiencies or adversities that may stem from the consumption or use of such products[1,2].

Public health regulation is effectuated through the conjugation of a multi-disciplinary body of technical knowledge and the political context therefore implying the need to conciliate varied, often contradictory, interests, with the expectation that the main result will be to benefit collective health. Regulation goes beyond the mere inspectional aspect, which is the prerogative of the State, and the overriding purpose of its technical and political formulation is to perform as one of the vehicles of public policies directed at risk prevention and health promotion.

Food regulation in Brazil dates back to the First Republic (1889-1930)[3] and was instituted by Decree N°68 of 1889, disciplining the public health police force, with subsequent definition of its incumbencies among which were inspection of food offered to the public and of beverage manufacture and consumption[4]. The basis of those early regulations has remained practically unaltered and is supported on three pillars: regulation, inspection and control. The complexity of the risks arising from the development of production activities has come to require diversification and expansion of the legal and technical-operational instruments involved. These last are prevention and control measures that provide the support needed for the public authority to oversee the conduct of companies in their production and distribution of food products and provision of food services; measures aimed at protecting the health of the populace.

The health regulations governing food have been molded by the influence of social dynamics from which emerge not only technological benefits and innovations but also serious harm and risks to the population's health. The emergent health risks generate a need for the continual improvement of the official apparatus which is the main driver of the regulatory process in the field of health regulation of food. Formerly the main concern was to discipline and control the health standards of food products with an emphasis on biological, physical and chemical aspects. That evolved to embrace risk management in the production process. More recently, however, the scope has broadened even further to include food products' nutritional composition accompanied by other changes associated to the modernization and globalization of economic activities involving food. Those phenomena are expressed in the growing use of a variety of materials such as wide range of additives, in the use of sophisticated technology and the frequent launching of new products on the market many of which are cheap with low nutritional value but highly profitable.

This article addresses the trajectory of the health regulation of food in Brazil, in various social contexts and with an emphasis on more recently adopted strategies such as the Public/Private Partnerships in the field of Health designed to control food product risks associated to their nutritional components.

Health regulation of food: from the dictatorship to democracy

Law-by-Decree Nº 986/1969[5] set out provisions on the health regulation of food in Brazil. It instituted general regulations governing foodstuffs and attributed responsibility for control to the Ministry of Health and similar bodies in the state governments.

At the time it was enacted two antagonistic events occupied the foreground of the social scenario. On the one hand there was a certain euphoria with the revival of economic expansion but on the other there was the severe repression of civil liberties, concentration of wealth and the pauperization of a large part of the population. Prado Júnior[6] states that Brazil's industrial expansion was largely directed at producing consumer goods for the middle and upper classes and the production of raw materials and foodstuffs to meet international market demands.

To facilitate international acceptance of food products it was necessary to demonstrate to the external markets that effective health control existed in Brazil and to establish official regulations governing food production that included product identification and quality standards and covered hygiene aspects among others. Thus the rules had to be with the international regulations in force, disciplining the trading in foodstuffs among countries[7] and controlling risks associated to chemical, physical and especially biological contaminants capable of causing isolated adverse outbreaks or episodes. That fact is expressed in the terms of Law-by-Decree Nº 986/69[5]: *i*) in the term that authorizes the use of international regulations whenever there are no local identity and quality standards established for specific food products; *ii*) when it authorizes production for

Ciência & Saúde Coletiva, 22(7):2353-2366, 2017

exportation subject exclusively to the regulations of the destination country.

That legislation represented an improvement in health control and was one of the preparatory steps in the lead up to Brazil's insertion on the FAO/WHO *Codex Alimentarius* Commission, enabling the country to participate in the international regulation of food and expand trading in such products beyond its boundaries, which duly took place in the 1970s[8].

From then on the technical and legal devices that reorganize health control practices directed at the food production sector were intensified, especially as regards inspecting physical aspects of production and in the exercise of policing authority.

With the advent of greater political liberty and the force of social movements in the 1980s, especially the strategic health reform movement, the banners were taken up in the fight for the right to health and the responsibility of the state and they were duly consecrated at the 8th National Health Conference[9] as a set of ideals and principles that would eventually mold the Chapter dedicated to Health in the current Brazilian Constitution which materialized important social conquests after having overcome considerable pressures and resistance[10].

Thus surveillance and regulation came to occupy an important position in the field of health and as a result the Constitution determined that it is incumbent on the Unified Health System (*Sistema Único de Saúde*–SUS) to *execute health surveillance activities* […] *and check and inspect foodstuffs, understood to mean, control their nutritional content, as well as that of beverages and waters for human consumption*[11].

Comparing the Constitutional text with Law-by-Decree 986/69 currently in force, two facts stand out that expand and enhance the value attributed to public health regulation. The first is that the latter text reinforces surveillance as a health practice and avoids reducing it to a mere exercise of power to police, insofar as it places the terms 'inspect' and 'verify compliance' side by side. Inspection has a more technical meaning of evaluating a product's physical conditions and its production processes to assess risk situations that could jeopardize its quality and harm the health of the individual. Verifying compliance is designed to ensure enforcement of the regulations. The two actions are complementary and in legal and technical terms and effectiveness, they enhance the quality of health surveillance results. The second fact concerns the express obligation to conduct *nutritional control*. This aspect occupied a secondary plane for a long time but has come to the fore in this last decade opening spaces for debate in the field of food health surveillance. The first action was the expansion of mandatory nutritional labeling to cover all packaged foods[12] and more recently attention has focused on the nutritional composition of food products, especially ultra-processed ones[13]. Such products typically have high calorie, salt, sugars and/or fats contents and their nutritional profile is potentially harmful to health, placing them in the category of risks to be controlled. Thus, the expansion of the market for such products has a direct interface with the current pandemic of obesity and other chronic non-communicable diseases (NCDs)[14].

The Organic Law on Health N° 8080/90 which regulates the Unified Health System (*Sistema Único de Saúde*-SUS) established the following definition of health surveillance: *a set of actions capable of eliminating, diminishing or preventing health risks and of intervening in public health problems stemming from the environment, the production and circulation of goods and service provision, in the interests of health* [...][15].

Costa[16] states that the Organic Law on Health underscored the role of public health surveillance as an essentially preventative sphere whose primary objective is to intervene in the presence of health risks of any dimension stemming from economic activities of interest to health. That means joining technical knowledge with legal knowledge in an endeavor to anticipate production process failures, in the sense of avoiding harm or impeding its dissemination, in defense of the populace's health.

With the progress achieved in constructing the regulation of the health surveillance of food which ranges from the Law-by-Decree N° 986/69 to the Organic Law on Health, three substantial changes in concepts and practices of this preventative activity in the field of health have been registered: *i)* establishing rules and verifying their enforcement are insufficient to control risks; *ii)* controlling health risks is fundamentally important and accordingly power of policing must be boosted by allying science and the legal basis for such actions; and *iii)* all types of risks must be addressed whether they are physical, chemical or biological contaminants and that includes any new risks that appear such as certain nutritional components of food.

A period of densification of the legal instruments is in course whereby the "anachronistic"

and the "modern", the "authoritarian" and the "democratic" are being articulated in the configuration of the food sanitation regulatory framework in Brazil. Such instruments are used to assess, address and repress market failures and market ploys in the effort to materialize that which has been transcribed into law ever since the 1960s, namely, the defense and protection of collective health against risks stemming from food production activities.

The late 1990s: a new regulatory autarchy

Towards the end of the 1990s the Brazilian Ministry of Health transferred all health surveillance activities to the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária* - Anvisa) in the context of the regulatory policies engendered in Brazil at the time[17]. That adherence to the international agenda implied that there would be technical and financial stimuli from international bodies that supported privatization and changes in the model of State intervention[18].

Federal Law Nº 9782/99[19] delegates responsibility for the regulation, control and inspection of products and services that involve risks to public health and under that heading come food products and materials, additives, packaging, contaminants and residues, as well as the installations responsible for processing products. In that sense, health surveillance in its aspect as one of the modes of social regulation designed to protect national or supra-national interests[20] has the function of precociously identifying market failures, negative externalities and lack of information for the consumer, to the benefit of the collective interest.

Albeit the official discourse emphasizes that the overall goal of the reconstruction of the State is to enable it to foster economic development, while protecting social and republican rights and strengthening democracy[21], Cruz[18] believes that, regarding the administrative reform carried out in the years 2000, the most important aspects were the delegation of powers to the regulatory agencies and the visible need to increase the degree of public authorities' commitment to maintaining those rules and decisions that directly affect its agents. In that light there was no rejection of the reform on the part of the private sector because the initiatives were intended to produce a tranquilizing institutional climate with stable rules and increased response capacity, all supported by administrative autonomy and the de-bureaucratization of internal processes which would mean greater agility in addressing that sector's plaints.

The counterpoints to that were the social movements and the new legal framework of the Organic Law on Health which demanded institutional health surveillance responses compatible with the interests of the citizens who wanted their health protected against the market's inappropriate practices. According to Souto[3], the failure of that surveillance and regulatory sector to take vigorous action in a manner consistent with its strategic preventive importance in the field of health, notably marked by its sluggishness in responding to market demands, reinforced the arguments of those defending the idea of an overall administrative reform and its swift extension to include that particular field.

The managerial reform brought with it a split between policy formulation and policy execution with the former being centralized in the government's strategic nucleus, that is, the ministries, and the latter decentralized to the agencies. Thus Anvisa became attached to the Ministry of Health and under the aegis of its health policies, albeit retaining its financial and administrative autonomy. Anvisa took on the role of disciplining economic activities of interest to health and of coordinating the set of similar bodies in the governments of states and municipalities that make up the Brazilian Health Regulatory System (*Sistema Nacional de Vigilância Sanitária* - SNVS).

Some of the measures taken by Anvisa in recent years to meet production sector demands have visibly weakened control over potential food risks, such as: *i*) de-bureaucratization which led to the automatic exemption from the obligation to register food products but without the necessary counterpart action of reinforcing inspection in the industries and control over food, to ensure effective surveillance; *ii*) abolition of the rules that instituted identity parameters for food products, leaving the consumer without any reference regarding the products' standards; *iii*) inability to set up an information system accessible to the entire health surveillance network which would allow for simultaneous exchanges of information and fast action on the part of health authorities to confront risks associated to products and services; and *iv*) lack of any mechanisms to control food advertising, especially that directed at children and juveniles.

The public administration reform was innovative in regard to its governance practice making the governing process more participatory and

Ciência & Saúde Coletiva, 22(7):2353-2366, 2017

democratic[22]. That made it possible to include organized civil society in the respective public spaces and bring a plurality of voices to the debate and to the definition of the direction of the decisions to be made.

The functioning of the agencies has been improving in regard to the development of participatory citizen control and those institutions' roles in the Brazilian administrative structure[23]. To that same end, Anvisa has introduced information provision, public hearing and public consultation procedures into its structure. Those communication channels establish a process of participatory management and constitute an ambience for sharing the collective discussion with all the interested parties – citizens, industries and government – in the quest for consensus among the varied interests. It is also a propitious space for exercising citizenship and civil society control which, when technical and ethical parameters are adopted, is capable of demarcating the production-consumption relation to the benefit of collective interests[24].

Anvisa has another sphere of institutionalized participation of society at large known as the Consultative Council[25] and furthemore, to foster visibility, transparency and governance of the participatory regulatory process, it has introduced the Regulatory Agenda (*Agenda Regulatória* –AR)[26].

The first biennial period (2013–2014) of the agenda's four-year cycle included 23 food-related topics. Among them, the theme of N° 19, referring to Advertising of Food with High Quantities of Sugar, Saturated Fats Trans-Fats, and Sodium and of Beverages with Low Nutritional Value, is outstanding insofar as it targets nutritional composition – a highly controversial topic today. The subject has come up for debate again with the support of organized civil society precisely because the increase in NCDs is already affecting the infant and juvenile population.

Technical specialization, flexibility and the ability to adapt to the dynamics of the globalized world, Anvisa's regulatory and executive potential[27], the spaces it is constructing for society's participation and the maturity it is experiencing are capable of moving forward the process of democratizing decision-making processes on how to conduct interventions in the risks associated to those objects that come under the aegis of health regulation. Improving Anvisa depends as much on the active, well-qualified participation of organized civil society, especially users and consumers, as it does on Anvisa's commitment and external articulations to construe itself as a social force comparable to those of the market and government authority.

Nutritional component risks in the regulatory sphere of Anvisa

Given the current epidemiological scenario of deficiency diseases, obesity and other chronic NCDs, concern for the nutritional quality of food in Brazil has come to the attention of two Federal Government administration sectors: the General Coordinating Body for Food and Nutrition (*Coordenação-Geral de Alimentação e Nutrição* - CGAN/DAB/MS) at the Ministry of Health and the General Management Division for Food (*Gerência-Geral de Alimentos*- GGALI/Anvisa) at Anvisa. The former is responsible for implementing the National Policy on Food and Nutrition (*Política Nacional de Alimentação e Nutrição*-PNAN) and the latter for the agenda associated to the Health Control of Food set out in the terms of that same policy.

Anvisa's pioneering experience in its early years and its endeavor to comply with the mandate of the PNAN policy of the day[28] were mainly related to the policy directive "Prevention and control of nutritional disturbances and diseases associated to food and nutrition". As part of the program to combat disorders due to Iodine deficiency in Brazil, the organization established new limits for Iodine content in salt and regulated good practices in salt processing establishments which were subject to monitoring and frequent inspection to ensure compliance[29]. Following that it regulated folic acid and iron content limits for flour and maize meal[30] and those products were subsequently monitored as part of another Ministry of Health program. In 2001, in alignment with the PNAN-1999 policy directive "Ensure the safety and quality of foodstuffs and of food-related services", it became compulsory to provide nutritional information on the labelling of packaged food and beverage containers[12] and the regulations were subsequently harmonized with those of the Southern Cone Common Market (Mercosul).

In addition to the regulations mentioned above, which intervene in the formulation of products by promoting the obligatory addition of nutrients, other rules governing the nutritional information to be displayed in the labelling of industrialized food products were also improved at the time[12]. Those initiatives were the beginning of systematic nutritional control practices

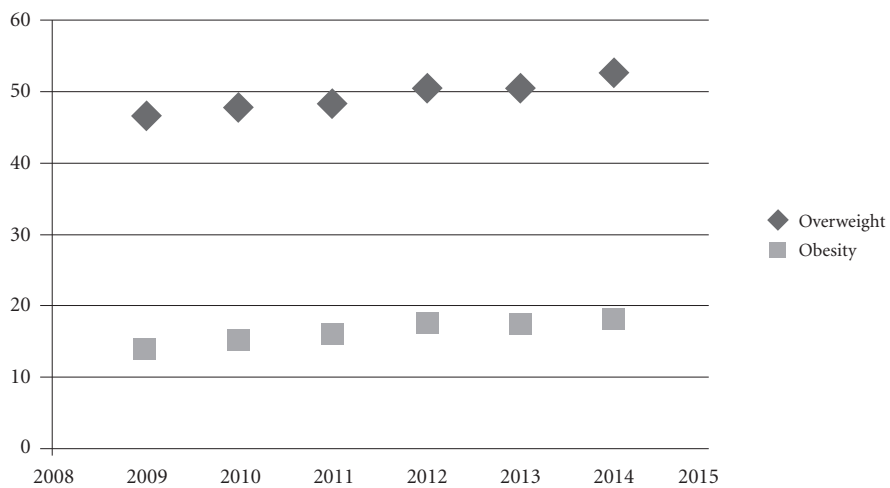
and they had important repercussions in several aspects: *i*) health regulation of food cannot be dissociated from nutritional questions and the respective authority recognizes that protecting the population means controlling any kind of risk stemming from or associated to food; and that understanding has visibly been an integral part of its institutional routine since the organization was created. *ii*) the food products first targeted adjusted their products to meet the nutritional requirements in a context of instituted regulations with accompanying penalties and systematic control measures to ensure product compliance; *iii*) Brazilian industries were obliged to meet the costs of adding nutrients (iron, folic acid and iodine) to those products considered to be of fundamental importance in the government's official nutrition programs; *iv*) the industries became obliged to display detailed nutritional information on the labels of their food products in addition to other information contemplated in previous legislation.

Anvisa and the ministry of health: preferring partnership agreements to regulation

In view of the increasing occurrence of obesity and other NCDs, the increase in health care expenditure and its link to changes in the dietary habits of the Brazilian population due to the increased availability of unhealthy foods, and certain other factors, the government established a series of strategies to address the situation.

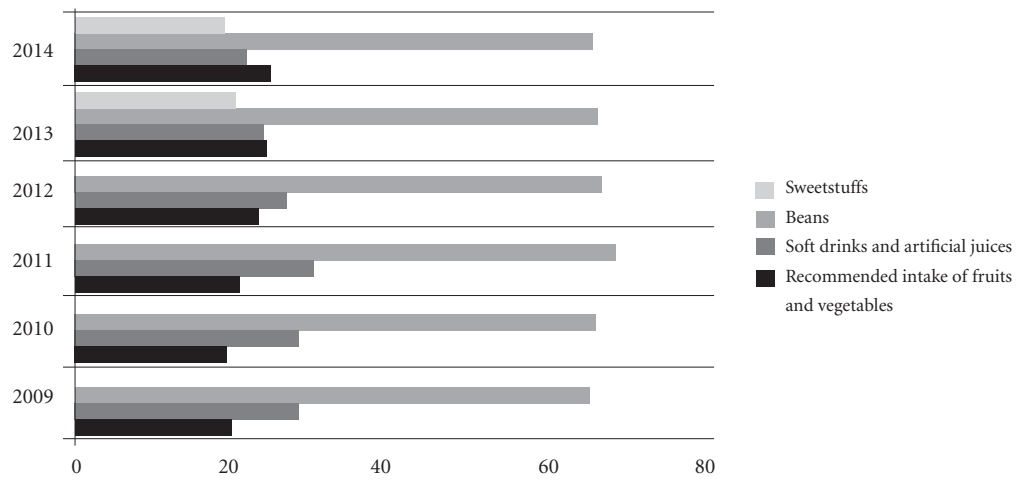
An analysis of the adult urban population in Brazilian capital cities[31-36] (Graph 1) at the end of the last decade showed that the rates of obesity and overweight condition in Brazilian adults were 14.8% and 49.0%[37] respectively and continuing to rise, although there was a certain degree of stabilization detected in the year 2014. The dietary habits of the adult urban population is one of the factors contributing to those nutritional problems because it was found that at least 18% of that population had regularly consumed unhealthy foods such as soft-drinks, artificial juices and sugar-laced food, in the previous six-year period. It was also found that the regular consumption of soft drinks and artificial juices is higher than the recommended daily consumption of fruits and vegetables albeit there was a slight decrease beginning in 2013[31-36] (Graph 2). Those figures indicate the notable presence of ultra-processed industrialized products in Brazilians' daily diets.

In 2007, faced with the increasing prevalence of obesity in the country, the Ministry of Health, in harmony with the international recommenda-



Graph 1. Evolution of overweight condition and obesity in adults aged 18 or over in 27 Brazilian state capitals in the period 2009 to 2014.

Source: Brasil[33-38].



Graph 2. Profile of regular* consumption or recommended** consumption of food*** for the adult populations residing in 27 Brazilian capital cities in the period 2009 to 2014.

Source: Brasil[33-38].

* regular means the consumption of sweet food, beans and/or soft drinks five times per week or more. ** recommended means the daily ingestion of 400g of fruits and vegetables or five portions of this group of food items. *** Sweet food includes ice cream, chocolates, cakes, sweet biscuits and sweet food items in general.

tions, negotiated with the industry to discuss the issue[38]. Following that a Cooperation Agreement was signed between the Ministry and the Brazilian Food Industries Association (*Associação Brasileira das Indústrias da Alimentação*-ABIA) and a Public Call [for Research] was issued to assess the possibility of the production sector's gradually reducing the content of various nutrients in processed foods such as free sugar, trans-fats, saturated fats and salt[39] and that led to some other terms of commitment being signed afterwards.

Those Agreements and Terms of Commitment (A&TC) are a landmark in the discussion on reducing the nutritional parameters of products considered to be unhealthy[40]. However, in 2009 Anvisa coordinated a diagnosis to evaluate the nutritional composition of 24 categories of food products in regard to their sodium, sugar, saturated fats, trans-fats and iron content which revealed considerable variation in the contents of those nutrients inside the categories and from one category to another[41]. If the results are analyzed using the criteria of the United Kingdom[42] regulatory body most of the products would be classified as "High content" for sodium, sugar and fats. Those are disturbing results because children commonly consume such products, which not only have negative effects on their health due to the excess of certain nutrients but also stimulate the formation of consumption habits that adapt the palate to prefer food with precisely that kind of composition.

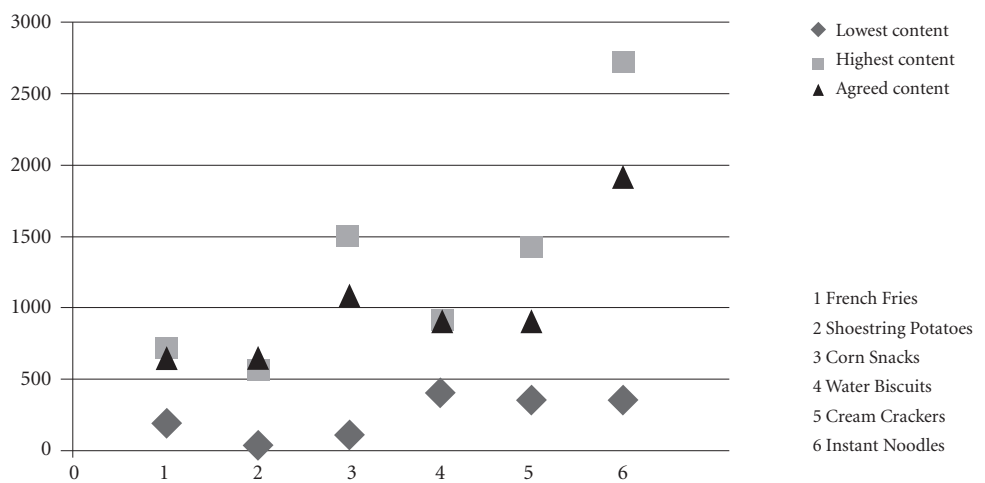
In view of that diagnosis, the health authorities negotiated with the industries to have them, first of all, reduce the levels of sodium in various food categories even though the epidemiological evidence actually showed the urgent need to reduce all of them. Given the absence of an equivalent international reference, the reduction target was set on the basis of three criteria: the lowest sodium limit detected for each type of food that was analyzed; the information displayed on the label; and the information supplied by the industries. Based on the parameters established in the agreement, the Ministry of health hoped to achieve a reduction in the Brazilian population's consumption of sodium to less than 2,000 mg/person/day, by 2020[43].

Government's recognition of the relation between the epidemiological situation and the quality of food was underscored by the approval of the Ministry of Health's Strategic Action Plan to

Confront Chronic Non-communicable Diseases (NCDs) in Brazil for the period 2011–2022[43]; the Inter-sector Plan for the Prevention and Control of Obesity formulated by the Technical Committee of the Inter-ministerial Chamber on Food and Nutritional Security at the Ministry of Social Development[44]; and by the updated version of the PNAN for 2012[45]. There are two outstanding directives in those documents that orientate quality control practices for food: Food regulation and control (*Controle e regulação dos alimentos*) and Promoting healthy, adequate food (*Promoção da alimentação adequada e saudável*). They are initiatives that are harmonious with the measures taken improve the national profile of processed foods, to increase the supply and reduce the prices of healthy foods and to establish regulations to govern food advertising and other aspects.

Between the establishment of the Agreements and Terms of Commitment strategy and that of obligatory regulation the government opted to reinforce the former to interfere in the nutritional profile of food products. The Ministry of Health then expanded that new food health control instrument to focus on reducing sodium content. It should be underscored that the design of those instruments includes some negative aspects: *i*) excessive elasticity – the period of tolerance for sodium reduction, for example, ranged from 3 to 5 years; *ii*) limited coverage – the formality of the Agreements and Terms is restricted to those entities representing industries that chose to ratify them; *iii*) the weakness of compliance possibilities – there are no punitive clauses in the agreements and that fact retards their enforcement.

Thus, to find out about the sodium reductions that were the base of negotiations in the A&TCs we made a comparison of the actual performance of six food products in regard to that nutrient with the reduction targets that had been set in the agreements (Graph 3) and found that the targets of three products had been defined by the maximum value originally identified and those of the other three were also close to the maximum, diverging, therefore from the original proposal. That "flexibility" in the A&TC targets calls for a reflection on the criteria used to arrive at such a decision and suggests that there has been complacency on the part of the agency in its dealings with the market. Among the monitored products, however, there are some already on the market with sodium levels lower than the agreement had specified and, furthermore, produced using viable technology. The standards that were agreed on show that an opportunity to set the standard at the lowest level encountered in the



Graph 3. Comparison of sodium levels diagnosed in six categories of food product and the reduction targets agreed on by government and entities representing food industries. Brazil, 2010-2011.

Source: Brasil; Anvisa. Informe Técnico n. 43/2010; itens 3 and 5 in Chart 2.

monitored products may well have been "wasted" in the construction of the bases for the A&TCs.

Even though obtaining compliance with the A&TCs has been assimilated to the institutional practice of health regulation, disposing of the use of negotiated fixed deadlines and failing to specify sanctions for non-compliance has meant weakening the control measures and undermining the authority of the state in its interventions to limit private sector in ways that ensure that the public interest prevails. It should be noted that the fulfillment of the terms of the A&TCs depends only on the degree of commitment among the parties and is not necessarily binding on other companies or entities in the sector. Given those limitations, the public authority needs to address the risk management of food related to obesity and other NCDs in the same way as it addresses Foodborne Diseases (FD) placing higher value on the use of traditional resources (regulation, product monitoring, inspection of establishments, etc.), in order to achieve effective control over nutritional quality of the food products involved.

However, the interventions to address risks associated to nutritional components of food products in an effort to prevent NCDs runs up against scientific questioning and the production sector's allegations of economic impacts which stimulate strong reaction from the market. One example is how the reaction of big corporations in Denmark forced the Danish government to back down and revoke the measures it had introduced to tax products with high saturated fat content[46]. On the other hand the corporate pressures were not enough to prevent Finnish society from mobilizing and imposing a reformulation of products that would guarantee food with a higher standard of nutritional quality[47].

A&TC experience of government and some industrial entities in the bid to reduce sodium content has been described by Nilson et al.[48] as innovative, legitimate and transparent and based on an intra-institutional articulation with the private sector and the establishment of dialogues and consensual pacts, all of which favor citizen participation and control. Without either praising the vanguard protagonist action alleged by those authors or denying the possible merits of the initiative, some other aspects need to be examined. First the real ideological value of this measure, ostensively revealing the Government's concern for public health, is what stands out given the State's abdication of its prerogative to impose rules on the market and its decision to make the A&TCs malleable and contemplating long timeframes. Second, if civil society participation and control is indeed to be fortified then there must be a series of representations of society involved in the discussions conducted in the public sphere and none of that occurred in the negotiation processes, thereby weakening the legitimacy referred to by the authors above.

Partnership between government and industries: weakness or innovation?

Public-private Partnerships are based on objectives and decision-making being shared by the public and private sectors. In the field of nutrition, that kind of initiative is being adopted in several countries, usually seeking to achieve four objectives: improvement of the nutritional composition of food products; educating the general public; nutritional information in labelling and advertising; and, lastly, research[49]. Those involved in such initiatives declare that they hope to achieve effective results like reductions in resource use and reduction in political-institutional attrition[50], through negotiations among the parties.

In the 1990s, FAO and WHO began to encourage countries to develop joint actions to address obesity and other chronic NCDs by articulating government, industries and consumers[51], alleging that such articulation could transform the food systems, *making them more compatible with nutritional precepts*[52]. They underscored the importance of long-term multi-sector strategies, given that responsibility for prevention of those diseases is shared[53].

In Europe, innumerable partnerships sprang up to face the problem of overweight and obesity in the region, supported by the European Communities Commission and aimed at reducing the unhealthy components of food products[49] and changing consumer behavior. Obesity, however, was treated as being an individual problem in the framework of a liberal-conservative conception and there were no investments in structural changes[54] whatever.

Avoiding the conflicts associated to a direct intervention in the composition of unhealthy products, some countries chose to invest in improving nutritional labelling. For example, they developed Traffic Light Labelling[2] which was adopted by the United Kingdom[55] (voluntary) and Ecuador[56] (compulsory). *Health Star Rating System* is a visual scheme that displays stars on the product label corresponding to an evalua-

tion of the set of nutritional components present in a product. The product rating goes from one to five stars. The Health Star Rating system is used in Australia and New Zeeland but it is not compulsory[57]. Those two visual devices give the consumer a quick demonstration of a product's nutritional profile and worth.

Despite the divergences it is possible that the systematic warnings issued by the international bodies and by local government and media regarding the risks of unhealthy foods, allied to the manufacturers' suspicions of the effects of any eventual compulsory intervention measures – stricter regulation – have persuaded the respective industrial corporations to negotiate with governments and avoid any future instability in trading their products.

The Brazilian government's decision to use instruments like A&TCs to address this issue of the nutritional value of food to the detriment of formal regulation represents a serious regression in comparison with the democratic regulatory process that was in the process of being installed in national agencies, permitting an open debate and the participation of organized sectors of society at large. Furthermore, it shows up government's weakness in food risk management expressed in its by failure to act with necessary agility and the authority vested in it. There are admittedly real political difficulties and the reactions of the market corporations are highly effective but the vacuum allocated to civil society reveals contradictory behavior and the government's clear reluctance to court the support of potential allies – the citizens.

Public Private partnerships are subject to several limitations that could very well jeopardize good governance and the achievement of the desired results because the private-sector partners can interact and endeavor to conduct the government's agenda, avoid their real responsibilities or move the focus of attention to potential solutions that would be contrary to its interests and so on[49]. However, it is worth remembering that according to the logic of the market, their adherence to any sort of partnership cannot culminate in any harm to their profits[58].

Majone[59] states that the formulation of the A&TC fits in perfectly with the "new regulation" that is behind the rationale of government intervention on the part of the regulatory State in its endeavor to adjust itself to the needs of the market. The regulation is flexible instead of rigid and widely applied in the field of social regulation in which health is situated.

In that context it can be seen that the formalized A&TCs' features clearly do not favor the internal realities (obesity epidemic and increased prevalence of other chronic DNCs, growing consumption of high-calorie products with high salt content). In addition to the intrinsic limitations of those A&TCs there is the absence of any effective communication support to inform the public of the benefit of preferring products with the new nutritional attributes in their consumer choices. The decision to adopt A&TC, in a veiled manner, reveals the government's overriding concern to avoid the market's suffering any economic shocks during the period of product adjustment.

Thus the counterweight of implicit vested interests weakened the intervention and led to the decision to avoid any conflicts that might arise from the regulation of sodium. In the earlier regulatory experiences reported above the national industries were formally obliged to enrich their products with nutrients to satisfy the requirements of institutional nutritional programs and, furthermore, obliged to absorb the costs of the procedure. Today the confrontation involves trans-national corporations and the reduction of the unhealthy nutrients has implications in terms not only of costs but also palatability and therefore it is liable to interfere in sales.

The conception of the A&TCs was centralized and they represent a retrocession in food health regulation especially in four aspects: *i)* they nullify Anvisa's risk regulation attributes; *ii*) they create precedents for avoiding or delaying regulation and the disciplining of the reduction in the levels of key nutrients; an essential action to protect health; *iii*) they generate situations of dis-empowerment of the decisions themselves insofar as the A&TC do not foresee ways of inspecting or ensuring compliance with the levels of nutritional components agreed to; and, lastly, *iv*) they reduce the strategic segment of civil society (the consumers) to a nullity insofar as it is kept out of the negotiations of health regulation measures merely in order to reduce the tensions and avoid confrontations with the production sector.

The effects of the A&TCs extend to all the other health regulatory practices because they are responsible for monitoring the products specified in the Agreements. Thus the A&TCs are cause for reflection and concern given that they are devoid of any legal effect in the operational context.

Compared to the practice of formal food health regulation, the A&TCs are symbols of a

treatment designed primarily to protect the markets and they put aside any question of the population's right to health and to healthy adequate food while at the same time setting a precedent for replacing regulation with A&TCs whenever it is necessary to address polemical issues involving health risks. In so doing they are actually expanding the conflicts that are inherent to the regulatory activity.

The fact that certain nutrients in excess (saturated fats, sugars and salt) have harmful effects on health that are quite different (long-term and accumulative) from those caused by most food contaminants (usually short-term and rapidly and extensively propagated when the product has a global circulation) is no excuse for adopting different kinds of intervention on the part of government which hitherto has always applied compulsory rules to regulate that second group of risks.

Although the market has always viewed regulation in a distorted manner seeing it as an unwelcome, authoritarian form of intervention, it is nevertheless both opportune and necessary when the issue is the prevention of health risks. The lack of international parameters in relation to global trade that would give some guidance on how to handle the question of nutrients that represent health risks in food products does not prevent a country from taking bold steps on behalf of the health of its populace nor determine that it should limit itself to slow-acting attenuating measures in that field. The government was right to take the path of reasoning and persuasion but it was wrong to restrict the debate and cut short the dialogue because that resulted in not establishing compulsory rules for reducing sodium and all the other nutrients that pose a health risk.

The glaring absence of any representation of the consumers in the debate on nutrient reductions is contrary to good governance principles[60] and breaks with the practice of creating and strengthening public spaces of intervention and participatory democratic expression in the heart of public institutions. That absence was regrettable insofar as organized consumers could act as differentiated protagonists not only in supporting government in its defense of the public interest and the priority attributed to health issues but also to contribute to the progress of the negotiations to approve the rules and establish adequate reduction targets for the nutrients associated to risk in food products.

Conclusion

In the sphere of public health surveillance, regulatory practice targeting food health risks is a task permeated by tensions and conflict for the public institutions involved. In spite of the prevalence of overweight, obesity and other NCDs and the stimulus of the relevant international bodies for states to intervene in the profiles of unhealthy food products, it has not been possible to override the pressures being applied by the food industry corporations and put regulation into effect. The governance instituted in the ambit of public health institutions has backed down and favored instead the institution of A&TC with negotiation of terms restricted to the participation of government and industries alone. However, in a context as dynamic as food risks, regulation is never finalized; it is always ongoing. Thus in view of the experience of consolidating democratic regulatory process it is still necessary and feasible to hope for a rule that meets the interests of society as a whole, that is to say, one that limits the sugars, fats and salt content of food products thereby reducing the risks associated to their consumption.

Collaborations

This paper idealizes and synthesizes part of the results of a doctoral thesis entitled "Emergent Food Risks: Regulation, conflicts and tensions" defended by AVA Figueiredo at the University of Brasília in November 2014. E Recine and R Monteiro, tutor and co-tutor of the said thesis were responsible for the revision and made additional contributions.

Acknowledgements

Coordination for the Improvement of Higher Level Personnel (*A Coordenação de Aperfeiçoamento de Pessoal de Nível Superior*-CAPES)/ The Ministry of Education, for the support given to the first author which made this study possible.

References

1. Carvalheiro JR. Desafios da Vigilância Sanitária e a Função Regulatória. In: Brasil. Ministério da Saúde (MS). I *Conferência Nacional de Vigilância Sanitária: Cadernos de Textos.* Brasília: Agência Nacional de Vigilância Sanitária; 2001. p. 25-36.
2. Lucchese GA. *Globalização e regulação sanitária: os rumos da vigilância sanitária no Brasil.* Brasília: Anvisa; 2008.
3. Souto AC. *Saúde e Política: A vigilância sanitária no Brasil, 1976-1994.* São Paulo: Sobravime; 2004.
4. Costa EA. *Vigilância sanitária: proteção e defesa da saúde*. São Paulo: Hucitec; 1999.
5. Brasil. Decreto-Lei nº 986, de 21 de outubro de 1969. *Diário Oficial da União* 1969; 22 out.
6. Prado Júnior C. *História econômica do Brasil.* 36ª ed. São Paulo: Editora Brasiliense; 1988.
7. Food and Agriculture Organization of United Nations (FAO), World Health Organization. *Undestanding Codex Alimentarius.* 3th ed. Issued by the Secretariat of the Joint FAO/WHO Food Standards Programme. Rome: FAO; 2006. [acessado 2014 nov 13]. Disponível em: ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf
8. Brasil. Instituto Nacional de Metrologia, Qualidade e Tecnologia. Comitê *Codex Alimentarius* do Brasil – CCAB. *Histórico do Comitê Codex Alimentarius do Brasil – CCAB*. [acessado 2014 abr 16]. Disponível em: http://www.inmetro.gov.br/qualidade/comites/codex_ccab.asp
9. Brasil. Ministério da Saúde (MS). *8ª Conferência Nacional de Saúde.* Brasília-DF, 17 a 21 de março de 1986. [acessado 2014 mar 17]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/8_conferencia_nacional_saude_relatorio_final.pdf
10. Rosas EJ. Os inimigos da reforma sanitária se mobilizam. *Saúde em Debate* 1988; (22):13-18.
11. Brasil. Constituição Federal 1988, Título VIII, Da Ordem Social, Seção II Da Saúde. In: Conselho Nacional de Secretários de Saúde (Conass). *Legislação do SUS*. Brasília: Conass; 2003. p. 20-21.
12. Brasil. Agência Nacional de Vigilância Sanitária (Anvisa). Resolução - RDC Nº 40, de 21 de março de 2001. Aprovar o Regulamento Técnico para Rotulagem Nutricional Obrigatória de Alimentos e Bebidas Embalados, constante do anexo desta Resolução. *Diário Oficial da União* 2001; 22 mar.
13. Monteiro CA.The big issue is ultra-processing. [Commentary]. *World Nutrition* 2010; 1(6):237-259.
14. Monteiro CA, Cannon G. The Impact of Transnational "Big Food" Companies on the South: A View from Brazil. *PLoS Med* 2012: 9(7):e1001252.
15. Brasil. Conselho Nacional de Secretários de Saúde (Conass). Lei nº 8080, de 19 de setembro de 1990. In: Conass. *Legislação do SUS*. Brasília: Conass; 2003. p. 22-37.
16. Costa EA. Regulação e vigilância sanitária para a proteção da saúde. In: Vieira FP, Rediguieri CF, organizadores. *A Regulação de Medicamentos no Brasil*. Porto Alegre: Editora: Artmed; 2013. p. 21-37.
17. Ribeiro JM, Costa NR, Silva PLB. Política de Saúde no Brasil e estratégias regulatórias em ambiente de mudanças tecnológicas. *Interface (Botucatu)* 2000; 4(6):61-84.
18. Cruz V. Estado e regulação: fundamentos teóricos. In: Ramalho PIS, organizador. *Regulação e agências reguladoras: governança e análise do impacto regulatório*. Brasília: Anvisa; 2009. p. 53-86.
19. Brasil. Lei n. 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. *Diário Oficial da União* 1999; 27 jan.
20. Costa NR, Ribeiro JM, Silva PLB, Melo MAC. O desenho institucional da reforma regulatória e as falhas de mercado no setor saúde. *Revista da Administração Pública* 2001; 35(2):193:228.
21. Bresser Pereira LC. Reflexões sobre a reforma gerencial brasileira de 1995. *Revista do Serviço Público* 1999; 50(4):5-29.
22. Bresser Pereira LC. O modelo estrutural de gerência pública. *Revista de Administração Pública* 2008; 42(2):391-410.
23. Brasil. Casa Civil. Câmara de Infra Estrutura – Câmara de Política Econômica. *Relatório do Grupo de Trabalho Interministerial Análise e Avaliação Do Papel das Agências Reguladoras no Atual Arranjo Institucional Brasileiro.* Relatório do Grupo de Trabalho Interministerial. Brasília, setembro de 2003. [acessado 2014 fev 20]. Disponível em: http://www.bresserpereira.org.br/Documents/MARE/Agencias/avaliacao_das_agencias_reguladoras_-_casa_civil.pdf
24. Lucchese GA. *Globalização e regulação sanitária: os rumos da vigilância no Brasil* [tese]. Rio de Janeiro: ENSP/Fiocruz; 2001.
25. Brasil. Agência Nacional de Vigilância Sanitária (Anvisa). *Conselho Consultivo* 2005. Agência/Publicação Agência. Portal da Anvisa. [acessado 2014 abr 28]. Disponível em: http://s.anvisa.gov.br/wps/s/r/9xd
26. Brasil. Agência Nacional de Vigilância Sanitária (Anvisa). Documento orientador. *Agenda regulatória. Ciclo quadrienal 2013-2016.* Brasília: Anvisa; 2012. Programa de Boas Práticas Regulatórias da Anvisa. [acessado 2014 abr 27]. Disponível em: file:///Users/anavirginiafigueiredo/Documents/ATESE/CAPITULOS%20DA%20TESE/REGULACAO/Agenda_Regulatoria_Quadrienal_final_baixa.pdf
27. Peci A. Novo marco regulatório para o Brasil da pós-privatização: o papel das agências reguladoras em questão. Programa de Estudos e Pesquisas em Reforma do Estado e Governança. *Revista de Administração Pública* 1999; 33(4):121-135.
28. Brasil. Ministério da Saúde (MS). *Política nacional de alimentação e nutrição* 2000. 2.ª ed. revista. Brasília: MS; 2003. Série B. Textos Básicos de Saúde. [acessado 2012 mar 25]. Disponível em: *http://189.28.128.100/nutricao/docs/geral/pnan.pdf*
29. Brasil. Agência Nacional de Vigilância Sanitária (Anvisa). Resolução - RDC nº 28, de 28 de março de 2000. Dispõe sobre os procedimentos básicos de Boas Práticas de Fabricação em estabelecimentos beneficiadores de sal destinado ao consumo humano e o roteiro de inspeção sanitária em indústrias beneficiadoras de sal. *Diário Oficial da União* 2000; 29 mar.

30. Brasil. Agência Nacional de Vigilância Sanitária (Anvisa). Resolução - RDC Nº 344, de 13 de dezembro de 2002. Aprovar o Regulamento Técnico para a Fortificação das Farinhas de Trigo e das Farinhas de Milho com Ferro e Ácido Fólico, constante do anexo desta Resolução. *Diário Oficial da União* 2002; 18 dez.
31. Instituto Brasileiro de Geografia e Estatística (IBGE). Pesquisa de Orçamentos Familiares, 2008-2009. Antropometria e estado nutricional de crianças, adolescentes e adultos no Brasil. Rio de Janeiro, 2010. [acessado 2014 mar 11]. Disponível em: http://portal.saude.gov.br/portal/arquivos/pdf/pof_2009_2009_encaa.pdf
32. Instituto Brasileiro de Geografia e Estatística (IBGE). *Vigitel Brasil. Vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico. Estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2009*. [acessado 2014 out 20]. Disponível em: http://189.28.128.100/dab/docs/publicacoes/geral/publicacao_vigitel_2009.pdf
33. Instituto Brasileiro de Geografia e Estatística (IBGE). *Vigitel Brasil. Vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico. Estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2010*. [acessado 2014 out 20]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/vigitel_2010.pdf
34. Instituto Brasileiro de Geografia e Estatística (IBGE). *Vigitel Brasil. Vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico. Estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2011*. [acessado 2014 out 20]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/vigitel_brasil_2011_fatores_risco_doencas_cronicas.pdf
35. Instituto Brasileiro de Geografia e Estatística (IBGE). *Vigitel Brasil. Vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico. Estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2012*. [acessado 2014 out 20]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/vigitel_brasil_2012_vigilancia_risco.pdf
36. Instituto Brasileiro de Geografia e Estatística (IBGE). *Vigitel Brasil. Vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico. Estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2013*. [acessado 2014 out 20]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/vigitel_brasil_2013.pdf
37. Instituto Brasileiro de Geografia e Estatística (IBGE). *Vigitel Brasil. Vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico. Estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2014*. [acessado 2014 out 20]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/vigitel_brasil_2014.pdf
38. Brasil. Ministério da Saúde (MS). Portaria nº 3.092, de 4 de dezembro de 2007. Institui Grupo Técnico com o objetivo de discutir e propor ações conjuntas a serem implementadas para a melhoria da oferta de produtos alimentícios e promoção da alimentação saudável. *Diário Oficial da União* 2007; 5 dez.
39. Brasil. Ministério da Saúde (MS). *Trata sobre o Acordo do Ministério da Saúde com a Associação Brasileira de Indústrias de Alimentos para redução dos teores de sódio, gorduras e açúcares dos alimentos.* Ano estimado 2007. [acessado 2012 mar 15]. Disponível em: http://189.28.128.100/nutricao/docs/geral/acordo_social_reducao_teores_sodio_acucar_gorduras.pdf
40. Brasil. Ministério da Saúde (MS). *Promoção da Saúde e da Alimentação Adequada e Saudável. Redução de sódio, açúcar e gordura trans*. 30 abr. 2012. [acessado 2014 jun 24]. Disponível em: http://dab.saude.gov.br/portaldab/ape_promocao_da_saude.php?conteudo=reducao
41. Brasil. Agência Nacional de Vigilância Sanitária (Anvisa). Perfil nutricional dos alimentos processados. *Informe Técnico nº 43/2010*. [acessado 2013 nov 22]. Disponível em: htpp://www.anvisa.gov.br/wpm/connect/1011330044bbafc3b1f6b10377ff0da5/Perfil+Nutricional.pdf?MOD=AJPERES
42. United Kindown. Food Standards Agency. *Front-of-pack traffic light signpost labeling*. Technicalguidance 2, November, 2007. [acessado 2014 jun 14]. Disponível em: http://multimedia.food.gov.uk/multimedia/pdfs/frontofpackguidance2.pdf
43. Brasil. Ministério da Saúde (MS). *Plano de Ações Estratégicas para o Enfrentamento das Doenças Crônicas Não Transmissíveis (DCNT) no Brasil – 2011-2022*. Brasília: MS; 2011. (Série B. Textos Básicos de Saúde).
44. Brasil. Ministério do Desenvolvimento Social e Combate à Fome. Secretaria-Executiva da Câmara Interministerial de Segurança Alimentar e Nutricional- CAISAN. *Plano Intersetorial de Prevenção e Controle da Obesidade*. Nota para Imprensa. Ano estimado 2012. [acessado 2014 abr 28]. Disponível em: http://www4.planalto.gov.br/consea/noticias/documentos/planalto-intersetorial-de-prevenção-e-controle-da-obesidade
45. Brasil. Ministério da Saúde (MS). *Política nacional de alimentação e nutrição* 2012. [acessado 2012 mar 25]. Disponível em: http://189.28.128.100/nutricao/docs/geral/pnan2011.pdf
46. Petkantchin V. *Nutrition taxes: the costs of Denmark's fat tax. IEM's Economic Note.* may, 2013. [acessado 2014 jun 26]. Disponível em: http://www.institutmolinari.org/IMG/pdf/note0513_en.pdf
47. Puska P. Successful strategies to influence national diets: the Finnish experience. *Zdrav. Varv* 2004; 43:191-196.

48. Nilson EAF, Jaime PC, Resende DO. Iniciativas desenvolvidas no Brasil para a redução do teor de sódio em alimentos processados. *Revista Panamericana de Salud Publica* 2012; 32(4):287-292.
49. Hawkes C. *High Level Group Working Paper on Public Private Partnerships for Health* 2008. [acessado 2014 jul 23]. Disponível em: ec.europa.eu/health/ph_determinants/life_style/nutrition/documents/ev20081028_wp_en.pdf
50. Mitchell M.*An overview of public private partnerships in health* 2008. Boston: Harvard School of Public Health. [acessado 2014 abr 2]. Disponível em: https://www.hsph.harvard.edu/ihsg/publications/pdf/PPP-final-MDM.pdf
51. World Health Organization (WHO). Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (2002: Geneva, Switzerland). *Diet, nutrition and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation*. Geneva: WHO; 2003. (WHO technical report series; 916).
52. Food and Agriculture Organization of United Nations (FAO). *The state of food and agriculture: food systems for better nutrition*. Rome: FAO; 2013.
53. World Health Organization (WHO). Diet, nutrition and the prevention of chronic diseases. *Report of WHO study group*. Geneve: WHO Library Cataloguing in Publication Data; 1990. (World Health Organization technical report series; 797).
54. Borch A, Roos G. Public Private Partnerships fighting obesity in Europe. *Anthropology of food* 2012; 7(Supl.). [acessado 2014 jun 26]. Disponível em: http://aof.revues.org/7286
55. Reino Unido. Food Standards Agency. *Front-of-pack traffic light signspostlabelling*. TechnicalGuidancen. 2, 2007;. [acessado 2014 jun 24]. Disponível em: http://multimedea.food.gov.uk/multimedia/pdfs/frontpackguidance2.pdf
56. Equador. Ministerio de Salud. *Reglamentosanitario de etiquetado de alimentos procesados para el consumo humano* (Acuerdo No. 00004522). [acessado 2015 out 20]. Disponível em: http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2014/08/REGLAMENTO-SANITARIO-DE-ETIQUETADO-DE-ALIMENTOS-PROCESADOS-PARA-EL-CONSUMO-HUMANO-junio-2014.pdf
57. Australia, Nova Zelândia. Australia New Zealand Food Standards Code. *Health star rating system styleguide*. [acessado 2013 nov 20]. Disponível em: http://www.foodsafety.govt.nz/industry/general/labelling-composition/health-star-rating/hsr-style-guide-30-june-2014.pdf
58. Stuckler D, Nestle M. Big food, food systems, and global health. *PLoS Medicine* 2012; 9(6):e1001242. [acessado 2013 set 15]. Disponível em: http://www.plosmedicine.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.1001242&representation=PDF
59. Majone G. Do estado positivo ao estado regulador: causas e consequências da mudança no modo de governance. Regulação Econômica e Democracia: O debate europeu. São Paulo:Editora Singular, 2006. [acessado 2014 mar 10]. Disponível em: http://academico.direito-rio.fgv.br/ccmw/images/0/08/Majone.pdf
60. Hawkes C. Public health sector and food industry interaction: it's time to clarify the term 'patnership'and be honest about underlying interests. *European Journal of Public Health,* v.21, n4, 400-403. 2011. [acessado 2013 nov 11]. Disponível em: http://eurpub.oxfordjournals.org

Article presented 03/10/2015
Approved 08/02/2016
Final version presented 10/02/2016