

## **BRAZILIAN CONSULTANTS' PERCEPTION OF THE FEDERAL TECHNICAL REGULATION OF GOOD PRACTICES FOR FOOD SERVICES<sup>1</sup>**

### *PERCEPÇÃO DE CONSULTORES BRASILEIROS SOBRE O REGULAMENTO TÉCNICO FEDERAL DE BOAS PRÁTICAS PARA SERVIÇOS DE ALIMENTAÇÃO<sup>1</sup>*

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#### **ABSTRACT**

The aim of this study was to evaluate the perception of aspects related to the Technical Regulation of Good Practices (GP) for Food Services by Brazilian consultants. An online questionnaire was distributed to all of the consultants registered in a national program for the implementation of quality management systems. A total of 131 consultants completed the survey. It was confirmed that only the state and the municipality of São Paulo have a Technical Regulation of GP within the ambit of Hospital Nutrition and Dietetics Services. Collegiate Board Resolution RDC No. 216/2004 was cited as the primary reference by the majority of the consultants. The lack of involvement of the employers in GP implementation and the difficulties with the food handlers were the main reported weaknesses. The criteria cited by practitioners included a lack of specifications and the reference to the binomial time/temperature. Given the subjects' experience, another claim that should be considered was that the RDC No. 216/2004 is excessively broad and general. This perception indicates the need for supplementary health legislation by the state and municipal spheres, and also denotes that the federal legislation should be updated.

**Keywords:** Good Manufacturing Practices, Good Food Handling Practices, food hygiene, food legislation, food safety.

#### **RESUMO**

*O objetivo deste estudo foi avaliar a percepção de consultores brasileiros sobre aspectos relacionados ao Regulamento Técnico de Boas Práticas (BP) para Serviços de Alimentação. Um questionário online foi distribuído a todos os consultores registrados em um programa nacional para a implementação de sistemas de gerenciamento de qualidade. Um total de 131 consultores completaram a pesquisa. Confirmou-se que apenas a cidade de São Paulo possui um Regulamento Técnico de BP no âmbito de Serviços de Nutrição e Dietética Hospitalar. A Resolução da Diretoria Colegiada RDC No. 216/2004 foi citada como referência primária pela*

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maioria dos consultores. A falta de envolvimento dos empregadores na implementação das BP e as dificuldades enfrentadas com os manipuladores de alimento foram as principais fragilidades reportadas. Os critérios reportados pelos consultores incluíram a falta de especificações e a referência ao binômio tempo/temperatura. De acordo com a experiência dos consultores, outra consideração feita pelos mesmos e que deve ser apreciada com atenção refere-se à RDC No. 216/2004 ser ampla e geral. Esta percepção indica a necessidade de as esferas estaduais e municipais instituírem legislações de saúde complementares, além de indicar que a legislação federal deve ser atualizada.

**Palavras-chave:** Boas Práticas de Fabricação, Boas Práticas de Manipulação, higiene alimentar, legislação alimentar, segurança alimentar.

## INTRODUCTION

According to the latest data from the Brazilian Household Budget Survey (IBGE, 2004, 2010), the share of expenditures for food outside the household by Brazilian families went from 24.1% to 31.1% in 6 years. Both studies indicate that the population from the southeastern area of the country had the greatest monthly food expenditure away from home. The number of food services in BR has augmented because people are increasingly dining out due to lifestyle changes. As said by SANCHES & SALAY (2011), the relevance of out-of-home food consumption indicates the need for dietary and nutritional interventions. Therefore, factors related to hygiene and sanitary conditions should be considered in addition to the nutritional and sensory aspects of meals. In that context, Foodborne Diseases (FBD) are a serious public health issue that severely impacts the actors involved, particularly those who get sick (OLIVEIRA *et al.*, 2010).

The Secretariat of Health Surveillance of the Brazilian Ministry of Health (MS) disclosed that from 2003 to 2018 10.898 outbreaks of FBD were reported. An annual average of 681 outbreaks and 13,015 patients. There are records of FBD throughout the national territory. The Southeast (39.0%) and South (29.7%) regions reported a higher number of outbreaks (BRASIL, 2019).

In 2004, the Collegiate Board of Director of the Brazilian National Health Surveillance Agency (ANVISA) published the Technical Regulation of Good Practices (GP) for Food Services, which is associated with the Collegiate Board Resolution - RDC No. 216, to protect the health of the population. In Article 3 of that law, establishments had a period of 180 d from the date of publication to adapt (BRASIL, 2004).

The RDC No. 216 was published in 2004. The legislation precursor of GP in the country, Ordinance of the Department of Health No. 1428, which approved the Guidelines for the Establishment of Good Manufacturing Practices (GMP) for Food Industry, was passed in 1993. In spite of that, there is a continued low level of adequacy of GP in food services in BR (VALENTE & PASSOS, 2004; AKUTSU *et al.*, 2005; BALTAZAR *et al.*, 2006; SACCOL *et al.*, 2009; RODRIGUES & SALAY, 2012). It has been shown that the documents required by RDC No. 216/2004, including the Handbook of GP and the

Standard Operating Procedures (SOPs), which contain instructions for handlers and the monitoring of records, are among the greatest challenges (YAMAMOTO *et al.*, 2004; WHITE *et al.*, 2005).

Managers tend to execute quality programs only after inspections or due to customer demand. Implementation of GP does not require large investments; it only takes time, goodwill, teamwork and decisive operations. It is fundamental that a professional in the food realm, such as a nutritionist, is employed to perform the task. The work of consultants should also be mentioned; they possess diverse backgrounds in the area of food service, directing and guiding actions objectively. After a successful consultancy, an organization should be able to operate independently and improve its quality management system. Thus, consultants as skilled professionals who can critically reflect on existing regulations, since only practical applications enable the detection of the fragilities and obstacles. In view of the above, this study was aimed at evaluating aspects related to the Brazilian Technical Regulation of GP for Food Services by means of the expertise of consultants.

## **MATERIALS AND METHODS**

The study was conducted from Feb to Nov 2012, and included all of the consultants registered in the Safe Foods Program, which is linked to the S System. The latter comprehends the National Service for Industrial Training, the Brazilian Micro and Small Business Support Service, the National Service for Commercial Training and the Social Service of Commerce and promotes the implementation of GP in food handling and food services. An invitation was made to the program coordinator over the phone and, upon acceptance, an authorization to conduct the survey was sent online to all 2,784 registered consultants. Those with less than one year of experience and who did not use RDC No. 216/2004 were excluded.

An online questionnaire containing 12 questions was developed (VOLPATO, 2007; GIL, 2010). Personal information was required in order to build a profile of the consultant: education; experience; operating location; and time spent on the implementation of GP in food service. Issues related to the Technical Regulation of GP for Food Services - RDC No. 216/2004 were addressed: use of the regulation; identification of the site with additional or supplemental legislation; identification of the legislation applied to hospital kitchens; assessment of locations with positive experiences in the implementation of federal legislations; challenges in implementing the regulation; lack of specifications for any item; and suggestions and opinions. This data collection tool was previously tested in a pilot study and the necessary adjustments were performed. The data analysis was applied to the open questions through transcription of the obtained data on the forms, which were subsequently classified into the items most frequently mentioned by the subjects (RICHARDSON, 1999). The online form was sent via e-mail to all of the consultants for data collection. A maximum of four e-mails was sent to those who failed to respond to the first contact, and a follow-up e-mail was sent 10 d later.

The experimental design was approved by the Research Ethics Committee at Universidade Federal de Santa Maria (Process N° 23081.007898/2010-70) and the Certificate of Presentation for Ethical Consideration was obtained (serial N° 0108.0.243.000-10) (CNS, 2012). All of the professionals involved in the study received feedback on the results via e-mail. The data were tabulated in a spreadsheet using the statistical software Statistical Package for the Social Sciences (SPSS) version 18.0. The results are displayed as absolute and relative frequencies.

## RESULTS AND DISCUSSION

A total of 128 consultants comprised the final list of participants. The profiles of the majority of the participants revealed that they had received undergraduate degrees in Nutrition and worked as consultants in quality management programs in the food sector (Table 1). As in Resolution No. 600/2018 of the Federal Council of Nutrition, nutrition consultancy is a covers the examination and issue of opinion on a matter related to the area of food and human nutrition, with a fixed term, without assuming the Technical Responsibility (CFN, 2018). A consultant should be confident, conscientious, and possess the practical and theoretical domain to give their input in the area of food quality, assets which were observed in the profiles (Table 1).

The lack of knowledge about operating and/or sanitary quality systems was indicated by 51.1% of the managers of the meal production units in a study conducted in Campinas, SP (EBONE *et al.*, 2011). Thus, the consultant may be taken as an indispensable figure for the improvement of these systems. An investigation analyzed the profile of nutritionists in the National School Nutrition Program (PNAE) in the northeast region of BR; 32.1% of the subjects worked as consultants associated with the PNAE (MELLO *et al.*, 2012).

Another positive aspect of the sample was the participation of consultants from the 26 states and the federal district. The states with the lowest participation, RR, TO and MA, contributed with four questionnaires each. SP had the highest amount of participants with 19 completed questionnaires. The know-how of the majority also called attention (Table 1).

**Table 1** - Profile of the consultants taking part in the current study.

Education	n (%)
	<b>n=128</b>
Nutrition	65 (50.8)
Food Engineering	17 (13.3)
Veterinary Medicine	11 (8.6)
Pharmacy	4 (3.1)
Food Technology	3 (2.3)
Biology	2 (1.6)
Others (chemical engineering, industrial chemistry, agronomy and physics)	14 (10.9)
No response	12 (9.4)

<b>Experience in Good Practices in Food Services</b>	
More than 10 years	51 (39.8)
6 to 10 years	53 (41.4)
2 to 5 years	22 (17.2)
No response	2 (1.6)
<b>Areas of Practice</b>	
Consulting	93 (72.7)
Lecturer of courses/seminars - Educator	77 (60.2)
Teaching	66 (51.6)
Technical authority	48 (37.5)
Auditor	30 (23.4)
Other activities (public worker, entrepreneur, clinician and researcher)	19 (14.8)
<b>Operating sites</b>	
South	39 (30.5)
Northeast	36 (28.1)
Southeast	34 (26.6)
Midwest	20 (15.6)
North	16 (12.5)
No response	3 (2.3)

Respondents were allowed to select more than one option for each issue.

Ninety-seven of the respondents apply other laws in addition to RDC No. 216/2004, thus showing that the heterogeneous performance of the consultants is not exclusive to food services. This result derives from the finding that more than 50% apply RDC No. 275/2002, which was published by ANVISA. The latter normalizes the Technical Regulation of SOPs that applies to Food Producing/Industrializing Establishments and the GMP Checklist (BRASIL, 2002).

More than 50 laws and norms, in addition to RDC No. 275/2002, were reported to be used by consultants. The following laws are distinct: Ordinance No. 326/1997 - MS (33.7%); Ordinance No. 1428/1993 - MS (18.0%); Ordinance No. 6/1999 - Health Surveillance Center of SP State (16.9%); Ordinance No. 2619/2011 - Municipal Health Secretariat of São Paulo, 10.1%); Ordinance No. 78/2009 - Health Secretariat of RS State and Ordinance No. 368/1997 - Ministry of Agriculture, Livestock and Food Supply, both of which presenting 7.9%; and the Brazilian Standards, published by the Brazilian Association of Technical Standards No. 15635 of 2008 (4.5%) (BRASIL, 1993, 1997a,b; SÃO PAULO, 1999, 2011; ABNT, 2008; RIO GRANDE DO SUL, 2009).

Respondents were asked if they knew of any municipality and/or state with specific sanitary legislation for hospital kitchens. Six did not answer and only four answered yes but did not specify. Two of those who answered yes cited the state of MG and only one respondent cited the municipality of Belo Horizonte/MG; both failed to disclose the specific legislation. One respondent reported the state and municipality of São Paulo and the Ordinance No. 2619/2011, which pertains to hospital kitchens.

According to STANGARLIN *et al.* (2012), the Hospital Nutrition and Dietetics Service (SNDH) is a flawed sector with regard to specific legal information on hygiene and sanitary conditions. The main laws in the SNDH cited by the consultants were: RDC No. 216/2004 (91.5%), RDC

No. 275/2002 (50%), Ordinance No. 326/1997 (45.1%) and Ordinance No. 1428/1993 (40.2%). Even though RDC No. 216/2004 was the most cited, hospital kitchens are beyond its scope.

In 2014, the RDC No. 52 was enacted, which changes the scope of the RDC No. 216/2004, including the food and nutrition units of health services. However, breastfeeding, Enteral Nutrition Therapy Units (TNE) and human milk banks are not included in this legislation (BRASIL, 2014; BRASIL, 2004).

With regard to challenges in implementing the Technical Regulation of GP in food services, 70 consultants responded yes, but four of them failed to specify. As expected, the consultants reported the lack of commitment by managers as the primary obstacle (Table 2). This finding is in agreement with KARAMAN *et al.*, (2012), who indicated that managers failed to consider food safety as a business priority and assumed that costs outweigh the benefits.

A primary challenge for consultants is the task of raising awareness of entrepreneurs to the importance of GP implementation and the continuous attempt to modify the poor habits of handlers. Therefore, the professional must be prepared to reason. A similar result was found by WILCOCK *et al.* (2011); factors identified as essential to the successful implementation of a quality program were related to the company, its employees, the program and external support. Nonetheless, the most important factor was managers' commitment. A study conducted in Europe pointed to that managers' opinion that a transparent food hygiene rating could lead to improved business (DJEIK *et al.*, 2014). EGAN *et al.* (2007) emphasized that the training of managers may be effective in reducing food safety problems because capacitation is a required precursor for the implementation of realistic and safe food practices. In addition, there is a negative association between knowledge and attitudes in the practices of food handlers, suggesting that training may produce greater knowledge but may not always result in behavioral changes (ANSARI-LARI *et al.*, 2010). In this context, the hygiene of the employees and that of the place, as well as the hygienic-sanitary quality seals in the establishments, are among the factors that affect consumers' choice of where to enjoy a meal (SANCHES & SALAY, 2011). Other difficulties described by consultants included financial aspects and aspects associated with facilities (Table 2). Many establishments have structural problems but limited resources for renovations.

**Table 2** - Main difficulties for implementation of the Technical Regulation of Good Practices in Food Services (RDC No. 216/2004) reported by the consultants taking part in the current study.

Difficulties	n (%)
	n=66
Commitment of the entrepreneur	33 (50.0)
Handlers	23 (34.8)
Financial	13 (19.7)
Facilities	12 (18.2)
Surveillance	9 (13.6)

Excessively general legislation	7 (10.6)
Cooling	4 (6.1)
Documentation	4 (6.1)
Cold/hot storage	4 (6.1)

Respondents were allowed to report more than one difficulty for each question.

Problems related to health surveillance and legislation were reported as concerning issues. Nearly 14% of the consultants reported aspects regarding surveillance, which, in the open questions, encompassed the lack of knowledge of the legislation by the surveillance organizations as well as the lack of surveillance and its punitive aspect. Approximately 11% of the consultants indicated that, in general, RDC No. 216/2004 is too broad. This finding was confirmed because four consultants indicated difficulties in implementing the requisites for cooling and the hot and cold storage of foods.

Four of the consultants indicated difficulties in aspects related to documentation, which is a low number, since the professionals are responsible for facilitating the description and implementation of Handbooks and SOPs. Nevertheless, such result denotes a weakness, since consultants are unsuccessful in achieving 100% compliance in this requisite when the company lacks a GP coordinator and offers minimal technical training to prepare the documents.

The following issues were also indicated by the consultants: maintenance of the ongoing improvement process; compliance with the thawing criteria; lack of a technical manager; high turnover of employees; low quality of suppliers; lack of periodicity and routines; lack of legislation for SNDH; procedures for the collection of samples; fruits and vegetables sanitization; and the liability and expiration date of food. The present findings corroborate those of BAS *et al.* (2006), who reported the low level of training, high turnover of workers, lack of motivation, lack of financial resources, inadequate equipment, physical conditions of installations and governmental failures as the main problems in the implementation of quality programs in food companies.

Although 56 consultants answered yes, three failed to identify when evaluating the lack of specification of any item or requisite in RDC No. 216/2004. The majority of the professionals indicated the lack of specifications related to food maintenance and exposure to hot and cold, that is, the need to establish a binomial time/temperature for these requirements (Table 3). The only specifications of temperature in the RDC No. 216/2004 are listed in item 4.8 - preparation, item 4.8.15 - temperatures  $> 60^{\circ}\text{C}$  for a max of six h for hot conservation, and item 4.8.17 - max expiration date of 5 d for food prepared and stored under refrigeration at  $\leq 4^{\circ}\text{C}$ . The max expiration date for temperatures  $> 4^{\circ}\text{C}$  and  $< 5^{\circ}\text{C}$  should be reduced to ensure the sanitary conditions of prepared food (BRASIL, 2004). Preferably, specifications for the conservation of hot and cold prepared food should not be limited to preparation areas. In this case, both stages would be covered by standby or maintenance, and could be cited in the item referring to preparation, and the distribution in the item

related to exposure of the prepared food. Another example of the lack of specification of temperature relates to item 4.8.5, which specifies that perishables should be exposed to room temperature for a min length of time (BRASIL, 2004). This specification complicates arguments among food handlers when the time and room temperature are not specified, considering the diversity and heterogeneity found in BR. Handlers frequently believe they can leave food exposed to room temperature for as long as necessary if the execution of their tasks in the production area is not impaired.

**Table 3** - Items and requirements indicated as not being specified in the Technical Regulation of Good Practices for Food Services by the consultants taking part in the current study.

Items or Requisites	n (%) n =53
Hot/cold storage and exposure	10 (18.9)
Excessively broad	9 (17.0)
Time/temperature	9 (17.0)
Handler	8 (15.1)
Documentation	6 (11.3)
Expiration date	6 (11.3)
Refrigeration/freezing	4 (7.5)
Hygiene of fruits and vegetables	3 (5.7)
Water	3 (5.7)
Training	3 (5.7)

The respondents were allowed to indicate more than one item or requirement for each question.

The WHO (2006) identifies two key contributors to FBD, both related to temperature: inappropriate storage and insufficient temperature during cooking. To corroborate the previous items, the participants of the current survey raised the need for additional details and indicated that RDC No. 216/2004 is excessively broad. They also indicated the need for complementary or additional specific laws. Note that SP and its capital have complemented the general aspects of the federal legislation for many years by fulfilling its role as legislator to guide and educate.

As regards the handlers, the participants indicated aspects as the lack of details about their conduct, the establishment of microbiological standards, and the permission to use adornments, enamels and makeup by indirect handlers. On the topic of training, it was emphasized that detailed specifications referring to workload and schedule are absent. Effective training in safe and hygienic food handling imparted during training is a key element in the control of FBD (PHILLIP, 2010). The efficacy of the training is highly dependent on the management of the company and the willingness to provide the resources and systems for food handlers to implement GP (EGAN *et al.*, 2007). In addition to improving knowledge and empowering food handlers, training can increase self-efficacy and reduce anxiety and stress levels of food handlers (DA CUNHA *et al.*, 2015).

Ordinance No. 78/2009 includes complete and specific regulations on the training course in GP for food services, which details the workload (16 h), the content, the institutions that may facilitate

the training and the necessary procedures. Its supplement also includes the regulation of procedures for the managers responsible for the food handling activities (Rio Grande do Sul, 2009).

In the opinions and suggestions section (Table 4), 14 consultants suggested the need for supplementation and stated that RDC No. 216/04 is too broad and general. Compared with other international regulations, including the North American Food Code (FDA, 2009), the Brazilian legislation is generally not specific. Indeed a gap in sanitary surveillance services exists, which was caused by the lack of location-specific food service regulations (SACCOOL *et al.*, 2015).

**Table 4** - Opinions and suggestions about the Technical Regulation of Good Practices for Food Services given by the consultants taking part in the current study.

Opinions/Suggestions	n (%) n=33
Need for complementation, general/broad	14 (42.4)
Greater surveillance	7 (21.2)
Lack of specific criteria for the cold chain	5 (15.2)
Need for subdivision of the scope	5 (15.2)
Lack of commitment by the company and the employees	4 (12.1)
Partnerships between educational institutions and the public sector	3 (9.1)
Greater coverage in relation to Standard Operating Procedures	2 (6.1)
Standardization of the evaluation criteria in the inspection	2 (6.1)
Display checklist	2 (6.1)
Specification of the room temperature	1 (3.0)
Report on the managers' profile	1 (3.0)
Disagreement with state and municipal legislation	1 (3.0)

Respondents were allowed to indicate more than one opinion or suggestion for each issue.

The opinion about subdividing the scope relates to the range in food services with regard to aspects such as size, which are not addressed by the federal legislation. This specification is satisfied by the supplementary legislation of São Paulo, especially Ordinance No. 2619/2011 (São Paulo, 2011). Moreover, the need for a checklist is a critical issue, and other states should follow the examples of RS and SC (Rio Grande do Sul, 2009; Santa Catarina, 2010). These tools are important to enable the self-assessment in the establishments. The opinions and suggestions are related to the findings shown in Tables 2 and 3.

## CONCLUSIONS

In view of the findings attained by means of the survey conducted with qualified consultants, the achieved conclusions constitute important suggestions in order to enhance food safety in Brazil. For instance, employers and food handlers must recurrently undergo special trainings and receive substantial instructions from qualified personnel in order to show a better capacitation to perform their tasks. That may come from the Public, Private and Academic realms, through food safety programs, thus involving the society as a whole. Moreover, the federal legislation must be updated so that

the Brazilian population receives a stronger protection regarding food safety. Foodborne diseases are not efficiently avoided around the country, thus constituting a Public Health threat.

## DECLARATION OF CONFLICTING INTERESTS

The authors declared no potential conflicts of interest.

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