1
Argentina

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1.1
Legal Framework

1.1.1
Introduction

Argentina is a federal country, so her legal framework has national and provincial levels. National laws approved by both Chambers of the National Congress, must be promulgated by Decrees issued by the National Executive Power, which establishes their publication in the *Official Bulletin* and the period for the law's entry in force. Each province used to have its own food regulation, until 1969, when a national food law was passed. This law created the Argentine Food Code (CAA),[1)] which is the Annex to National Law 18284/69 and its Regulatory Decree 2126/71. Provinces can pass provincial laws, as long as they do not contradict national laws.

In addition to complying with the CAA, some food groups have a specific set of regulations. For example, for meats and its derivatives, a Regulation on Inspection of Animal Origin Food established by Decree 4238/68 is in force; it has been applied nationwide since 1968 and is updated regularly. The fact that both Decree 4238/68 and the CAA were approved in less than 1 year indicated at that time the need to establish a regulatory framework with defined physical, chemical, and microbiological requisites (among others) for all types of foods. This regulatory framework has been designed to ensure the safety and authenticity of food products, and to avoid their possible adulteration and undesirable modification.

Law 14878/59 on oenological products, approved in 1959, regulates the manufacture and marketing of wines and other oenological products, and is one of the oldest Argentine food laws.

Other mandatory national laws that apply to food commerce are the Consumer Defense Law 24240/93 and the Commercial Loyalty Law 22802/83, which establish, among other topics, net weights and their tolerances for different products.

1) In Spanish, *Código Alimentario Argentino*.

Global Food Legislation: An Overview, First Edition. Edited by Evelyn Kirchsteiger-Meier and Tobias Baumgartner.

Geographic Indications and Denominations of Origin for agriculture products and processed foods must comply with Law 25163/99, except in the case of wines, which are covered by Law 25966/04.

The enforcement and fulfillment of these laws require the Ministries to approve specific ''Resolutions'' that can be applied in particular topics. Decisions issued by bodies dependent on the Ministries are called ''Dispositions'', and serve as references for the whole country's jurisdiction; for example:

- Dispositions on medical food and energy drinks issued by the Drug, Food and Medical Technology National Administration[2] (ANMAT; dependent on the Ministry of Health).
- Dispositions on specific animal and vegetal food issued by the National Service of Agrarian and Food Health and Quality[3] (SENASA; dependent on the Ministry of Agriculture, Livestock and Fisheries).

Finally, in a descending hierarchy, ''Ordinances'' are issued by Municipalities and apply at the district level.

The sanction of the CAA implied a great update effort in general food aspects and in the specific main food groups. It is recognized as a regulatory improvement at the national level due to the comprehensiveness and depth with which different subjects are treated. At the Latin American level, the CAA also represented a pioneering legal framework and a referent in food legislation for several countries since the 1970s.

The Argentine food scientist Dr. Carlos Grau, a pioneer in advocating harmonization of food regulations, was the main author of the Latin American Food Code (1960), that reproduces the Argentine Federal Food Regulation (1953), the regulation on which the CAA was based.[4] The Latin American Food Code was also the basis for several regulations in Latin American countries during the 1960s. A revised version was published in 1964.

The text of Law 18284/69 is relatively short, but its Annex, the CAA, comprises 22 chapters (Table 1.1). The first five chapters can be considered as horizontal, dealing with the following topics: general (Chapter I), processing plant requirements (Chapter II), contaminants and allowed preservation treatments (Chapter III), food packaging and other food contact materials (FCMs) (Chapter IV), and food labeling (Chapter V). Chapter XVIII is also horizontal because it deals with general food additives requirements.

Another chapter that can be considered as horizontal is the one on dietary foods (Chapter XVII). By definition, dietary foods are packaged products modified in their composition by the addition, removal, or replacement of certain components. Due to the ubiquity of products with added vitamins, minerals, in all the text etc.,

2) In Spanish, *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*.
3) In Spanish, *Servicio Nacional de Sanidad y Calidad Agroalimentaria*.
4) Ariosti, A. (2012) The advancement of the MERCOSUR food contact materials regulations and a panorama of the situation in Latin America, in *Proceedings of the Global Food Contact Conference 2012, Baltimore, MD*. Smithers Pira, Leatherhead.

Table 1.1 Structure of the CAA.

Subject	Description	Chapter
General	General definitions	I
	Standards for factories and other facilities	II
	Contaminants limits (inorganic, organic, and microbiological); catering and ready meals; preservation methods	III
	Food packaging and FCMs	IV
	Labeling	V
Specific	Meat products, poultry, fish, and eggs	VI
	Oils and fats	VII
	Dairy foods	VIII
	Farinaceous foods	IX
	Confectionery products (including honey and specialties)	X
	Vegetal foods	XI
	Waters, non-alcoholic beverages, ice creams and powders for their preparation, juices, etc.	XII
	Fermented beverages (beer, cider, and wine)	XIII
	Alcoholic beverages (distilled spirits, liquors, and aromatic herbs for alcoholic beverages)	XIV
	Stimulant products (cocoa, tea, coffee, and "yerba mate")	XV
General	Auxiliary components (spices, sauces, color additives, essences, etc.)	XVI
	Dietary foods	XVII
	Food additives	XVIII
Specific	Protein flours, concentrates, and isolates	XIX
General	Analytical methods	XX
	Product recall procedures	XXI
Specific	Miscellaneous	XXII

a high proportion of foods on the market are classified within this group, as well as new products developed according to novel guidelines for healthy eating.

The rest of the chapters correspond to specific food groups, and establish their physical, chemical, and microbiological parameters. When an item is modified, the last update date appears in the heading.

1.1.2 Argentina in the MERCOSUR

The establishment of the "Common Market of the South" (MERCOSUR, in Spanish, *Mercado Común del Sur*; MERCOSUL, in Portuguese, *Mercado Comum do Sul*) had, as a consequence, the improvement of the Member States' food legislations. Since foods traditionally occupied a relevant role in the markets of the Member States (Argentina, Brazil, Paraguay, and Uruguay) at the moment of its constitution (Treaty of Asunción del Paraguay, 1991), the need to harmonize criteria and regulations was of extreme importance. The Protocol of Ouro Preto

(Brazil, 1994) established the present institutional structure of the block. The executive body of the MERCOSUR, which sanctions the harmonized Resolutions on food and food packaging, is the Common Market Group (GMC is its acronym in Spanish and Portuguese).[5] On 31 July 2012, Venezuela joined the MERCOSUR (to which she applied as candidate country in July 2006).[6]

All decisions in the MERCOSUR must be approved by consensus and afterwards they are incorporated into the national regulatory frame, in a process known as transposition. The GMC Resolutions have a systematized structure and are referenced by the designation XX/YY, where XX is the GMC Resolution consecutive number and YY are the two last digits of the year of sanction; for example, GMC Resolution 10/91 (the first Packaged Food Labeling Resolution). In the case of Argentina, the MERCOSUR GMC Resolutions related to foods are transposed into the CAA Chapters at the specific Article, or by creation of a new Article in the corresponding Chapter, or by incorporation as an Annex to the corresponding Chapter.

In the case that new measures approved by the MERCOSUR imply important changes either from the technological or economical point of view, the deadline for entry in force varies depending on the case (e.g., 1 year for the prohibition of potassium bromate as a flour enhancer;[7] 3 years for mandatory nutritional labeling,[8] because it involved a change of all food package labeling).

In the food area, GMC Resolution 59/99 establishes that the MERCOSUR competent bodies must consider as references the standards, principles, and guidelines of the *Codex Alimentarius*. Other main sources used as references are international guidelines (e.g., recommendations of the Council of Europe or the German Federal Institute for Risk Assessment[9] (BfR)) or regulations issued by international institutions (EU Commission, US Food and Drug Administration (FDA), US Department of Agriculture (USDA)).

Since the creation of the MERCOSUR, priority has been given to harmonization of horizontal subjects (labeling, food packaging and other FCMs, additives) and of specific topics for food groups of major commercial importance for the block trade (e.g., dairy products). In some areas, due to their complexity and the possible impact level, each Member State has its own regulations, and at present no criteria harmonization has been possible. As an example, foods in which vitamins and minerals have been added in a voluntary or mandatory way are classified as dietary foods according to the CAA (Chapter XVII), while in other Member States they are not classified as such.

Once sanctioned, the MERCOSUR GMC Resolutions are legally binding for the Member States on harmonized issues, as any technical barrier to trade must be avoided. At the national level, differences may arise on administrative

5) Kopper, G. and Ariosti, A. (2010) Food Packaging Legislation: Sanitary aspects in *Ensuring Global Food Safety. Exploring Global Harmonization*, 1st edn (eds. Ch. Boisrobert, A. Stjepanovic, S. Oh, and H. Lelieveld), Academic Press/Elsevier, New York, pp. 227–261.
6) *Supra* note 4.
7) MERCOSUR GMC Resolution 73/93.
8) MERCOSUR GMC Resolutions 44/03, 46/03, and 47/03.
9) In German, *Bundesinstitut für Risikobewertung*.

procedures or national authorities in charge of the enforcement, but not on technical issues. In some cases, the national safety authorities of the Member States have complemented, but not altered, some technical aspects of the MERCOSUR GMC Resolutions. For instance, the Argentine Ministry of Health has adopted all the MERCOSUR GMC Resolutions on food additives and has resolved that some of them must be declared with their whole name in the labeling, due to possible adverse effects on specific groups of consumers. These national Resolutions have been incorporated into the CAA (See section 1.4.4). Another example is that in Argentina, the percentage of non-nutritive sweeteners must be declared when used (this specific issue has not yet been discussed in the MERCOSUR).

1.2
Food Safety Authorities and Enforcement Procedures

1.2.1
Introduction

Currently, the Ministries dealing with food health policy, primary production, industrialization, and marketing are the Ministry of Health, Ministry of Agriculture, Livestock and Fisheries, Ministry of Economy and Public Finances, and Ministry of Industry (Figure 1.1). The Ministry of Agriculture, Livestock and Fisheries was created in 2009 by Decree 1366/09 on the basis of the former Secretariat of Agriculture, Livestock, Fisheries and Food (that depended on the Ministry of Economy).

Food control all over the country is performed by the provincial food control bodies (or Food Control Offices[10]), under the surveillance of the National Ministry of Health), and the SENASA and its delegations. The National System for Food Control was created in 1999 by Decree 815/99 to consolidate and make food safety surveillance more efficient, enforcing the CAA all over the country (Article 1). In addition, this Decree created the National Food Commission[11] (CONAL) (Article 5), and established the responsibilities of the different bodies, as described below.

The Ministry of Health, and the Ministry of Agriculture, Livestock and Fisheries have representatives at the CONAL, the body responsible for the evaluation of proposals for the review and update of the CAA, and of any new relevant application in the food area. The Presidency of the CONAL alternates between the two Ministries.[12] The CONAL Meetings Acts are public and can be accessed through the web.

Originally, the SENASA was responsible for the control only of animal-origin food production. Nowadays, this body depends on the Ministry of Agriculture, Livestock and Fisheries, and it deals with the control of bulk production of all types of food of animal and vegetal origin (with certain exceptions) and their packaging materials,

10) In Spanish, *Oficinas de Bromatología*.
11) In Spanish, *Comisión Nacional de Alimentos*.
12) Decree 815/99, Article 7.

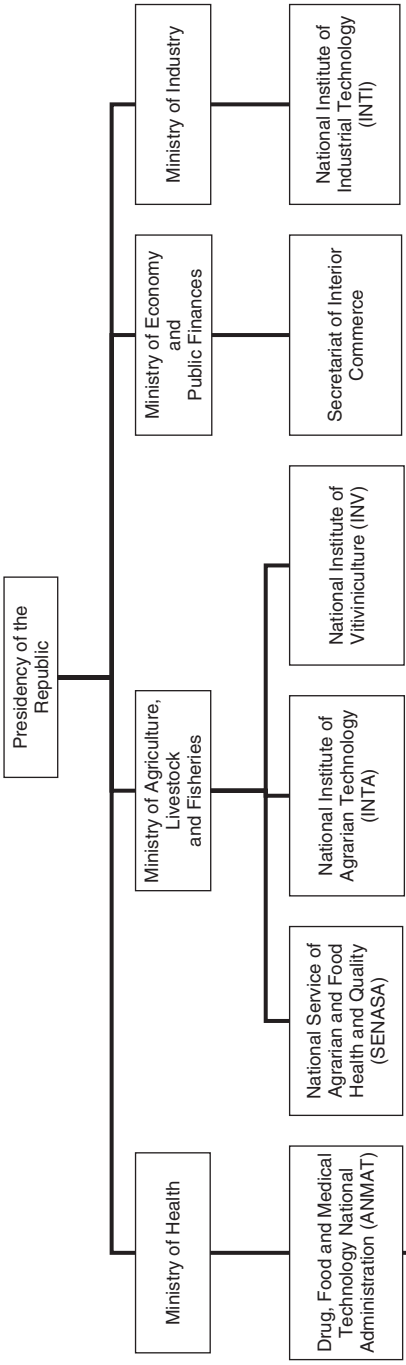

Figure 1.1 Structure of national institutions related to food safety.

for domestic commerce between provinces and for import/export, implementing food safety policies in its area.[13]

The National Food Institute (INAL),[14] dependent on the ANMAT, is responsible for the control of foods and packaging materials intended for internal commerce and for import/export, not covered by other bodies, with special emphasis on food conditioned and labeled for direct sale, implementing food safety policies in its area.[15]

Another body dependent on the Ministry of Agriculture, Livestock and Fisheries, with responsibility in food control, is the National Institute of Vitiviniculture (INV).[16] It deals with vine cultivation, grape harvest, wine (and other oenological products) production, packaging, trade, etc., implementing food safety policies in its area.

The Ministry of Economy and Public Finances is also involved in food control, through the Secretariat of Interior Commerce, which is responsible for the enforcement of the Commercial Loyalty and Consumer Defense Laws. These laws establish, according to the nature of the products, the weight tolerances, food labeling requirements, food packaging metrology (certain allowed volumes and weights), etc.

Some national institutions, such as the National Institute of Industrial Technology (INTI),[17] dependent on the Ministry of Industry, and the National Institute of Agrarian Technology (INTA),[18] dependent on the Ministry of Agriculture, Livestock and Fisheries, perform research and development activities in different areas of the food value chain, and help to update and adopt new products and technologies in a safe way.

INTI's technical representatives from its different Centers,[19] along with technical representatives from the Ministries, ANMAT, INAL, INTA, SENASA, etc., participate in the MERCOSUR Technical Working Groups and Committees since 1991 (e.g., the MERCOSUR Food Commission).

1.2.2 Food Processing Plants

In Argentina, food processing plants and processed products must be approved by the responsible official body. The clearance of food processing plants is performed in two stages: (i) the municipalities approve the facilities, according to the building codes that apply in the jurisdictions, and (ii) the provincial food control bodies (or Food Control Office) approve the operation of the factories, according to a consistent flow diagram of the processes involved in food manufacture (e.g., to avoid cross-contamination). Food plants must also have an environmental assessment report

13) Decree 815/99, Articles 12 and 13.
14) In Spanish, *Instituto Nacional de Alimentos*.
15) Decree 815/99, Articles 14 and 15.
16) In Spanish, *Instituto Nacional de Vitivinicultura*.
17) In Spanish, *Instituto Nacional de Tecnología Industrial*.
18) In Spanish, *Instituto Nacional de Tecnología Agropecuaria*.
19) For example, the Plastics Centre, the Cellulose and Paper Centre, the Foods Centre, the Dairy Centre, the Meats Centre, etc.

approved by the environmental authority. Official inspectors perform visits to the plants and audit all the aspects considered necessary, helped by check lists provided by the safety authorities. Non-conformities may arise in this process; when they are minor, a provisional approval can be granted; when the situation is regularized, the final approval is issued.

After these requirements are met, a national identification number is granted: the National Factory Register (RNE)[20] number, which consists of eight digits; the first two digits identify the Province and the other six, the consecutive order of approval. Not only food processing plants, but also distribution centers, import/export warehouses, etc., must be identified by the RNE number.

The SENASA is the body responsible for the clearance of animal-origin products processing plants, such as cattle slaughterhouses, milk processing plants, honey extraction plants, vehicles for certain food transportation, etc. In these cases, the SENASA grants a specific code for the authorized food processing plant, but the RNE number issued by the provincial Food Control Office is always needed.

Industrial plants that process food by irradiation must be approved by the national food safety authority, with previous assessment by the National Commission of Atomic Energy (CNEA),[21] which must also control the radiological safety of the plant operation.[22] The CNEA, created in 1950 by Decree 10936/50, depends on the Ministry of Federal Planning, Public Investment and Services.

Some food processing plants (e.g., water bottling, dairy products, meat products, food additives, and food products classified as dietary foods according to the CAA, Chapter XVII) must have a Technical Director who must be a professional with a University degree.[23]

1.2.3 Food Products

All foods must be approved by the Food Control Offices prior to their release in the market (pre-market approval system). The manufacturer must submit a dossier describing briefly the manufacturing process, the percentage composition of the product, its shelf-life and the way it was determined, and a draft of the package labeling. The manufacturer proposes the sale denomination of the product, but in the end, it is the food safety authority that establishes it, according to the food classification or composition. As an example, a breakfast cereal can be a normal product; however, if vitamins or minerals are added to it, the product becomes a ''fortified'' product and it is classified as a ''dietary food'' – accordingly, the sale denomination of the product is ''breakfast fortified cereal'' (thus, as seen previously, the processing plant must have a Technical Director).

According to the pre-market approval system of FCMs in force in Argentina,[24] the food packaging manufacturer must submit technical reports on the safety

20) In Spanish, *Registro Nacional de Establecimiento*.
21) In Spanish, *Comisión Nacional de Energía Atómica*.
22) CAA, Article 174.
23) CAA, Articles 16 and 17.
24) MERCOSUR GMC Resolution 03/92.

assessment of the food packaging to the national or provincial authority for its clearance. The food manufacturer is obliged to keep a copy of the food packaging clearance in its files.

When a food product is approved, a national identification number is granted: the National Food Product Register (RNPA)[25] number, which also consists of eight consecutive digits for each facility. It must be noted that whilst there is only one RNE number for each facility of each company in the country, the RNPA number may be repeated, as the numbering will be consecutive for all products manufactured at each plant.

The RNPA number must be granted before marketing the product in the country. Once it is granted, in general it does not expire, although some jurisdictions require its renewal every 5 years. In the case of some specific products such as dietary supplements, the RNPA number must be always renewed every 5 years. Once the manufacturer submits the information to obtain the RNPA number, the food safety authority has 30 days to grant it. If after this period the food safety authority does not take a decision, the company can begin to market the product using the submission number, until the final official decision.

Both the RNE and RNPA numbers must be printed on the package labeling of all products. With this information on the labeling, it is possible to know if the product is legally marketed by an authorized company.

In the case of products approved by the SENASA (e.g., dairy products, products with more than 80% meat (hamburgers, processed meat derivatives)), the specific codes granted by this food safety authority must also be printed in the package labeling. These codes have the format X/Y/Z, where X corresponds to the facility, Y to the product, and Z to its presentation in different weights or number of units (e.g., sausages, hamburgers).

1.3 Basic Principles of Food Law

1.3.1 Positive Regulation

The CAA is a regulation based on the positive principle. This means that only processes and additives expressly mentioned in it are allowed.[26] Originally, the CAA contemplated the great majority of the products in the market. Nevertheless, Article 3 states that all kinds of food can be manufactured, as long as only those processes and additives allowed for products of a similar nature are applied. This Article has been very useful, due to the wide range of foods developed in the last decades.

25) In Spanish, *Registro Nacional de Producto Alimenticio*.

26) CAA, Article 2.

1.3.2 Traceability

Traceability systems are in different stages of development, depending on the different food groups. All raw materials stored in a facility must be adequate, labeled as intended for processing foods, of known origin, and provided by an authorized manufacturer.

In 2011, the food safety authorities approved a national integrated system for processing plants and manufactured products, called the Federal Program of Food Control. The main feature is a database of public consultation that can be used to determine, by means of the RNE and RNPA numbers printed in the package labeling, if the processing plant and the food product are approved. Since its creation all the Argentine Provinces have been incorporated into this Program.

Furthermore, the lot number must be printed on each product package. This allows identifying the product record, according to the criteria established by the manufacturer (e.g., manufacturing date, packaging line, elaboration tank).

Due to sporadic foot-and-mouth disease (FMD) cases and the key role of cattle health in the Argentine economy, it is extremely controlled and traceability can be established for each animal.

Another example where traceability is of great importance is the case of post-consumer polyethylene terephthalate (PET) packages recycling. MERCOSUR GMC Resolution 30/07 was transposed into the CAA as an Annex to Chapter IV. It establishes that traceability must be maintained along the value chain of the recollection, decontamination, and use of post-consumer recycled PET (PCR-PET). The stakeholders in this value chain are: (i) the manufacturer of PCR-PET (through recollection, washing, and decontamination of post-consumer PET bottles, in approved facilities operating with licensed technologies that must have ''No Objection Letters'' (NOLs) to their use from the US FDA or favorable Decisions on their use by the European Food Safety Authority (EFSA); (ii) the converters that use mixtures of PCR-PET and virgin PET to manufacture parisons or preforms; (iii) the food manufacturer that blows the parisons into PET bottles and fills them with the foodstuff (e.g., soft drinks); and (iv) the consumer. These bottles can be found today in the Argentine market and are indelibly marked with the (Spanish) acronym ''PET-PCR,'' and thus can be easily identified by the consumer or the safety inspector.

1.3.3 Precautionary Principle

For a number of years, the precautionary principle has been used in some product labeling, where warnings on the presence of allergens have been incorporated by food companies (e.g., ''This product is manufactured in plants where peanuts, soy, etc., are processed''). The food safety authorities have banned this kind of warning, demanding to declare unambiguously if the specific allergen is present or not in the product. The capability of available methods used to accurately establish the

levels of different allergens, according to the elaboration process, is still a matter of study. The use of these warnings is in suspense, as analytical work in this area is proceeding.

Another example is the case of the prohibition of the manufacture of feeding bottles and other drinking devices for infants with bisphenol A (BPA)-based polymers.[27] In this sense, the MERCOSUR and the Member States followed the policy of the EU Commission, which applied the precautionary principle, among other considerations, to forbid the use of BPA for the manufacture of polycarbonate infant feeding bottles,[28] although at present (February 2014) the technical opinion of the EFSA is that no risk is associated with the normal use of BPA-based baby feeding bottles.[29]

1.3.4
Responsibility Principle

Food processing plant approval is granted by the food safety authorities to the company owners. In cases where a Technical Director is needed, the responsibility for the product is shared between him/her and the owners.[30] As long as products are approved by the food safety authorities, the responsibility is also shared by the State. The company employees are responsible for infractions, and the company owners, managers, and technical directors also share this responsibility.[31]

In the case of food packaging, the responsibility is also shared between the food safety authority (that approves the package), the packaging manufacturer (who must sell only approved packages), and the food manufacturer (who must buy and use only approved packages).

1.4
Overview of Selected Regulation Areas

1.4.1
Mandatory Nutritional Labeling

One of the most important changes in Argentine food legislation is the new mandatory nutritional food labeling applied since August 2006 for packaged food,

27) ANMAT Dispositions 1207/2012 and 2269/2012.
28) European Union Commission Implementing Regulation (EU) No. 321/2011 of 1 April 2011 amending regulation (EU) No. 10/2011 as regards the restriction of use of bisphenol A in plastic infant feeding bottles. *OJ*, 2.4.2011, 87/1–87/2.
29) EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) (2010) Scientific opinion on bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A. *EFSA Journal*, **8** (9), 1829; EFSA Panel on Food Contact Materials, Enzymes and Flavourings and Processing Aids (CEF) (2011) Statement on the ANSES reports on bisphenol A. *EFSA Journal*, **9** (12), 2475.
30) CAA, Article 17.
31) CAA, Article 19.

with specific exceptions (alcoholic beverages, mineral water, spices, vinegars, infusions).

The new framework of GMC Resolutions was adopted by the MERCOSUR Member States in 2003. A 3-year transitional period was established so that industry could assimilate the new concepts and adapt to the proper labeling rules. In 2006, another complementary regulation was approved.[32] The main changes introduced were: (i) nutritional information per serving was made compulsory for all types of foods, while previously it was mandatory only for dietary foods and voluntary for all other types of foods, and had to be expressed per 100 g or 100 ml; (ii) information on Energetic Value (EV) and certain nutrients (carbohydrates, proteins, total fats, saturated fats, trans fats, dietary fiber, and sodium), is now required; (iii) the percent coverage of Daily Values (%DV) according to Food and Agriculture Organization/World Health Organization (FAO/WHO) recommendations, must also be given; (iv) in the case of trans fats, there is no recommended value; (v) for sodium, the daily value established is 2400 mg; (vi) non-significant values per serving were established for every attribute;[33] and (vii) tolerances allowed for the declared value of the contents for all nutrients and EV are ±20%.

In Argentina, the CONAL has established that the information of the nutritional labeling may be based on food chemical analysis or may be taken from centesimal composition tables. For some components, like saturated and trans fatty acids, laboratories have updated their analytical capability and a better use of compositional tables is in process.

The addition of some optional nutrients is contemplated, like specific carbohydrates (sugars, polyalcohols, starch) and other fat components (cholesterol, mono-, and polyunsaturated fatty acids). Vitamins and minerals may be included only if their amount per serving is higher than 5% of the Dietary Reference Intakes (DRIs) established by the FAO/WHO.

Information must be presented in the way the food is bought. Servings must be expressed in g or ml and home measurement. EV, nutrients, and %DV must be presented in a pre-established order in a table format (Table 1.2).

A serving is defined as the amount of food eaten on a normal occasion by people and infants older than 36 months. The reference size of servings in g or ml and home measurements were set for each food type, classifying all the products in seven different groups (bakery products, meat products, dairy products, fats, vegetables, fruit juices, and products of eventual consumption based on carbohydrates and fats). In Argentina, for certain foods, nutritional information must be presented without specifying servings (e.g., infant food, dietary supplements, medical foods, and salt).[34]

Nowadays, there is a high fulfillment of the labeling requirements in all packaged foods, even in those which are exempted, such as frozen foods.

32) MERCOSUR GMC Resolution 31/06.

33) For example, less than 0.2 g is the non-significant value for the attribute "saturated fat content" and can be informed as "0" in the nutritional table.

34) CONAL, Meeting Act 68/2006.

Table 1.2 Example of nutritional information labeling.

Nutritional Information Serving … g or … ml (home measurement)		
	Amount per serving	**%DV[a]**
Energetic value	kcal and kJ	—
Carbohydrates	… g	—
Proteins	… g	—
Total fats	… g	—
Saturated fats	… g	—
Trans fats	… g	(Not established)
Dietary fiber	… g	—
Sodium	… mg	—

[a]% Daily Values are based on a 2000 kcal diet. Your daily values may vary according to your energetic needs.

1.4.2 Complementary Nutritional Labeling

Nutritional content claims were approved in the MERCOSUR in 2012 (GMC Resolution 01/12) to harmonize the block present regulations on the subject and to avoid technical barriers to trade (TBT). This Resolution also establishes the need to regulate written and oral product advertisement.

If a nutrient claim is made, it is mandatory to declare its content in the nutritional table and also the %DV (if the later is established, e.g., for vitamins and minerals).

The allowed nutrient content claims are: ''Lite, Low'' for EV and the following nutrients: carbohydrates, total fats, saturated fats, cholesterol, and sodium; ''Free, No … , Without … , Zero'' for the same attributes and trans fats; ''Very Low'' for sodium; ''No … added'' for sugars and salt. It is allowed to highlight, by mean of the claims ''Source'' and ''High … , Rich … ,'' the presence of the following nutrients: proteins, fiber, vitamins, minerals, and ω-3, ω-6, and ω-9 fatty acids. In each case the values are established per product servings.

Comparative claims for nutrients and/or EV were also approved. The comparative claim is valid if a 25% minimum change is achieved, either for reduction (''Light … , Lite … , Reduced … , Less than … '') or for increment (''Increased … , More than … '').

In Argentina, there is as yet no general legal framework regulating health claims. Thus, prior to their use in the products, the food safety authority must approve them for each specific food manufactured by each company, in a case-by-case procedure.

In 2011, the ANMAT issued Disposition 7730/2011 on the criteria to assess the relationship between food intake and health prevention. Even though this regulation applies only to advertisements, it constitutes the initial step for a future

Table 1.3 MERCOSUR GMC Resolutions on food labeling.

Subject	Description	GMC Resolution No.
General	Food labeling	26/03
Nutritional labeling	Framework Resolutions	44/03; 48/06
	General principles	46/03
	Servings portions	47/03; 31/06
	Nutrient claims	01/12

regulatory framework on health claims labeling. The established criteria follow the *Codex* principles in general terms.

In summary, nutritional labeling has been subject to major changes in the last few years, both at the Member State and MERCOSUR levels. Not only has a mandatory regulatory framework been adopted, but a new conceptual approach has been followed, where information must be expressed per serving, new components have been incorporated, and EV and nutrient contents must be presented in a pre-established order. Changes will doubtlessly continue, anticipating major modifications in health claims – an area that is starting to be discussed by the MERCOSUR Member States.

At present, all the MERCOSUR GMC Resolutions on food labeling (Table 1.3) have been transposed into the CAA (Chapter V).

1.4.3 Food Hygiene and Safety

Food hygiene in the country has advanced due to the collaborative work mainly of State and food companies. In 1996, the MERCOSUR issued GMC Resolution 80/96 ''Technical Regulation on safety conditions and good manufacturing practices for processing plants/industrialized foods.'' As a consequence, Good Manufacturing Practices (GMPs) are mandatory and have gradually been implemented since that year in all food processing plants. Since 2008, manufacturing plants for certain specific products must implement the Hazard Analysis and Critical Control Points (HACCP) system,[35] for example, in the case of processed foods for infants and children,[36] where severe safety standards are required due to the vulnerable target population. The implementation of GMPs, the HACCP system, and other quality assurance systems by companies has been growing in recent years. The need to put safe products on the market has also resulted in an improvement in food quality along the whole value chain, as food companies require that all their suppliers must implement quality assurance systems. In 2001, a measure was passed in the country with a strong impact on the implementation of GMPs. Food companies are required to train employees in food handling and manufacturing processes taking into account GMPs.[37] Employees must also obtain a Sanitary Card certifying their

35) CAA, Article 18.
36) CAA, Chapter XVII.
37) CAA, Article 21(d).

health status,[38] and must take and approve various courses, recognized by the food safety authorities, in charge of specialized trainers.

Food microbiological requirements have also been updated and adjusted according to the type of product. In 1993, the general criteria were established by the MERCOSUR, taking as references, in addition to the *Codex Alimentarius*, the International Commission on Microbiological Specifications for Foods (ICMSF) recommendations.[39] Microorganisms and/or toxins must be identified in food groups according to their epidemiological risk. Analytical methods, sampling plans, and microbiological levels must be established. Foods on which microbiological tests must be performed were defined: dairy products, meat products for consumption without heat treatment (cured sausages, salami, ham, etc.), refrigerated products (poultry, vegetables, fish and seafood, etc.), frozen products, fresh pasta (stuffed and non-stuffed), beverages (water, fruit juices), sauces, peanuts, canned preserves, etc. In 2012, microbiological criteria for ready meals were established. These products are classified according to their composition and processing methods (with and without heat treatment, etc.). The absence of *Salmonella* spp. and *Listeria monocytogenes* in 25 g, and *Escherichia coli* O157:H7/NM in 65 g, is mandatory.[40]

The country has not suffered any severe or massive food-borne crises related to food safety.

Several MERCOSUR GMC Resolutions already transposed into Chapter IV of the CAA mention in a general way that food packaging and FCMs must be manufactured according to GMPs. There is as yet no specific MERCOSUR GMC Resolution on food packaging GMPs, like EU Regulation (EC) 2023/2006. Nevertheless, food packaging manufacturers that supply the medium and big food manufacturers apply GMPs in their companies, voluntarily or by agreement with the customers.

HACCP system implementation is required in the case of meat for export. Every slaughterhouse must have a responsible veterinarian to control the sanitary status of the animals. In this aspect, although in the present international context the volume of meat exported by Argentina is small, the country has a history as a meat exporter and applies an active protection policy of her livestock. In the 1990s, with the bovine spongiform encephalopathy (BSE) crisis, Argentina completely closed her borders to all foods that could act as prion vehicles and thus there were no cases of this disease. Argentina, classified as a country free of FMD with vaccination, is on constant alert to prevent the passage of unvaccinated animals through the country's extensive northern border and makes efforts to improve sanitary controls on her cattle.

An important aspect to consider is the product recall system in the case of a sanitary emergency. Since 2008, companies have been required to have a system that ensures an effective recall of products that may pose a risk to public health and/or that may not comply with the regulations.[41] According to their risk, foods are classified in three levels, and detailed product recall and risk communication procedures are mandatory.[42]

38) CAA, Article 21(a).
39) MERCOSUR GMC Resolution 59/93.
40) CAA, Article 156 tris.
41) CAA, Article 18 tris.
42) CAA, Chapter XXI.

All sanitary events must be reported to the Food Surveillance Service, depending on the ANMAT.

With respect to acceptable levels of contaminants, general or specific maximum values have been established, depending on the food matrix and contaminant type. In 2011, the maximum limits for inorganic contaminants in the edible portion of food products were updated in the MERCOSUR,[43] except for food products for babies and infants, which are regulated by specific Resolutions. Limits were established for arsenic and cadmium in foodstuffs of vegetal and animal origin and salt, mercury in seafood, and tin in tinplate canned products.

In 2002, the maximum acceptable limits, sampling plans, analytical methods, and lot acceptance criteria for aflatoxins were updated in the MERCOSUR.[44] For instance, the limits for aflatoxin M1 in fluid milk and powdered milk are 0.5 and 5.0 $\mu g\ kg^{-1}$, respectively; the maximum limit for the sum of aflatoxins B1+B2+G1+G2 in peanuts, peanut paste, maize grains, maize flour, and maize semolina is 20 $\mu g\ kg^{-1}$.

For pesticides, the CAA only establishes as mandatory for all the agricultural products, the requisites of the Law of Pesticides and its updates.[45] This law, besides banning the use of organochlorine pesticides (dieldrin, endrin, heptachloro, hexachlorocyclohexane) for vegetal and animal treatment, established detailed lists of authorized pesticides and their Maximum Residue Limits (MRLs)[46] in fresh vegetables and fruits, cereals, legumes, etc., and meats of different species and their derivatives. After 40 years since the sanction of this Law and the several SENASA updates, in 2010 all the forbidden pesticides and the pesticides with restrictions were consolidated into SENASA Resolution 934/2010, where tolerances were updated, new MRLs for pesticides not included in the Law of Pesticides were established, new criteria were incorporated, and a list of products exempted from tolerances was published. EMRLs (Extraneous Maximum Residue Limits) for forbidden pesticides, but that can be present in food due to their persistence in the environment, were established according to the *Codex Alimentarius*.

Foreign agrarian products and derivatives not produced in the country can be imported if they comply with the *Codex* MRLs requirements for specific residues. In some cases, the general criteria are being adapted, as when taking into account plagues and seasons. Thus, SENASA Resolution 608/2012 established MRLs for specific vegetal products not considered previously.

All the phytosanitary products put into the Argentine market and used in the country must be included in the National Register of Vegetal Therapeutics.[47] In 2001, limits for veterinary drugs residues in food of animal origin were established by MERCOSUR GMC Resolution 58/01. Nevertheless, this Resolution listed only a few MRLs, so SENASA Resolution 559/2011 enlarged the number of substances listed, establishing acceptable MRLs for different veterinary drugs in foods of animal origin in different types of tissues and organs (muscles, adipose tissue,

43) MERCOSUR GMC Resolution 12/11.
44) MERCOSUR GMC Resolution 25/02.
45) CAA, Article 1406; National Law 18073/1969.
46) In Spanish, *límites máximos de residuos* (LMR).
47) In Spanish, *Registro Nacional de Terapéutica Vegetal*; Resolution 350/1999 of the former Secretariat of Agriculture, Livestock and Fisheries.

skin, kidneys, liver), and in different animal species. Tolerances vary according to the type of veterinary drug and in some cases no MRLs are needed (e.g., in the case of organic acids and tranquilizers).

Law 20466/1973 on fertilizers established a list of approved products for use in the improvement of crops. SENASA Resolution 264/2011, in which the regulation on fertilizers and substitutes is at present consolidated, has updated this list. The approved products are classified as: (i) fertilizers (whose components can be chemical, organic-chemical, organic, biological, amino acids based, based on blood, bones, and/or hooves flour, and mechanical mixtures); (ii) emendations (chemical, organic, or biological products that improve soil condition without nutrients contribution); (iii) substrates; (iv) protectors; (v) chemical or biological conditioners; (vi) pre-inoculants; and (vii) pre-inoculated products. All the fertilizer manufacturers must be approved and have a register number issued by the safety authority (SENASA).

In 2005, non-detectable levels for nitrofuranes and their metabolites were established in foods of animal origin (meats and derivatives, milk, eggs, and honey).[48] The reference method established for the analytical assessment is high-performance liquid chromatography/double mass spectrometry (HPLC/MS-MS).

1.4.4
Food Additives, Flavors, Enzymes, and Vitamins

Since the foundation of the MERCOSUR, an intensive harmonization process on food additives has been being performed (Table 1.4). By definition, a food additive is any ingredient intentionally added to food (without a nutritional purpose) in order to modify its physical, chemical, biological, or sensory characteristics, during any stage of its manufacture.[49] Contaminants, vitamins, minerals, or other nutrients are not included in the definition.

The following issues must be taken into account when selecting a food additive: its safety under normal use; its inclusion in the positive list; its allowed use for specific foods; and its compliance with established composition, identification, and purity specifications.[50] Additives must be commercialized in their original closed packages, labeled as ''For Industrial Use'' under their trademarks, and always kept in their original packages. In Argentina, during 2007, it was established that factories that manufacture, fraction, or mix additives must have a Technical Director (professional with a University degree) who is responsible along with the owner for the additives quality.[51]

GMC Resolution 17/93 establishes that for the review of the MERCOSUR food additives positive list, the *Codex Alimentarius* recommendations, and the EU and the US FDA regulations must be considered as international references. Other recognized organizations are: the IARC (International Agency for Research on Cancer), JECFA (Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives), RIVM (Netherlands National Institute

48) CAA, Article 155 bis.
49) MERCOSUR GMC Resolution 31/92; CAA, Article 6.
50) MERCOSUR GMC Resolution 31/92; CAA Article 1391.
51) CAA, Article 1395 bis.

Table 1.4 MERCOSUR GMC Resolutions on food additives.

Subject	Description	GMC Resolution No.
General	General requisites	31/92
	Auxiliary components: definition and functions	18/93; 84/93
	Criteria to update general list	17/93
	Food additives transference principle	105/94
	Criteria for maximum concentrations in food	52/98
	Restrictions of use of some additives	15/05
	Use exclusion	34/07
	Flavorings/seasonings	10/06
	Positive list of additives and functions (including colorants)	11/06
	GMPs additives list	34/10
Specific food	Bakery products	50/97
	Meat products	73/97
	Confectionery	53/98
	Desserts	54/98
	Soups	16/00
	Catering	51/00
	Ice creams	07/06
	Sauces	08/06
	Beverages	09/06
	Cereal products	09/07
	Snacks	02/08

for Public Health and the Environment[52]), and ITIC (International Toxicology Information Centre).

Recognized technological functions for additives were established (colorants, chelating agents, antioxidants, etc.) and the acronym that identifies each one (COL, SEC, ANTIOX, etc.).

The last review of the food additives positive list (including colorants) was sanctioned in 2006. This list is ordered by the international identification number (International Number Systems (INS)) and by its recognized technological functions.[53]

By applying GMPs, the food manufacturer can use a certain number of additives, in such quantities as necessary to fulfill the technological objectives, if their use is allowed in the product. These additives are considered safe as they do not have an acceptable daily intake (ADI). The last GMPs additives positive list update was performed in 2010.[54]

For specific food groups, certain additives and their concentrations of use were established by the MERCOSUR (Table 1.4). In the food groups where the MERCOSUR has not yet harmonized the use of allowed additives, those listed in the CAA can be used (the national regulations apply in the absence of block harmonized legislation). For instance, in fats and oils, only the use of antioxidants

52) In Dutch, *Rijksinstituut voor Volksgezondheid en Milieu*.
53) MERCOSUR GMC Resolution 11/06.
54) MERCOSUR GMC Resolution 34/10.

is allowed; some of them have a maximum concentration of use and some of them can be used applying GMPs. In several food groups, additives are almost forbidden (e.g., in the case of milk, water).

According to the general food packaging labeling regulations, additives must be declared in the list of ingredients with their INS number or their full name and function.[55] Additionally, some additives must be declared with their full chemical name in Argentina: tartrazine, benzoic acid (and its calcium, potassium, or sodium salts), sulfur dioxide and its sulfites derivatives,[56] and some non-nutritive sweeteners.[57]

Flavorings are classified according to their manufacturing process and have no INS number, as these additives are generally complex mixtures of substances.[58] They must be declared in the food product list of ingredients with their recognized function acronyms: ARO (aroma enhancer) and/or SAB (flavor enhancer). In the flavorings manufacturing process, many additives from the food additives positive list are allowed, such as thickeners, antioxidants, preservatives, etc. Therefore, the ''food additives transference principle'' must be taken into account here, which states that if a food additive is used as an ingredient of another food additive formulation, in such concentration that a technological function is accomplished in the final food product, it must be declared in its ingredients list.[59]

With regard to enzymes, just a few are approved as additives in the positive list:[60] amylases (INS 1100) as flour enhancers (function acronym FLO); proteases (INS 1101(i)) and ficin (INS 1101(iv)), both used as flour enhancers, flavor enhancers, and glazing agents (function acronyms FLO/EXA/GLA); glucose oxidases (INS 1102) as antioxidants, preservatives, or stabilizers (function acronyms ANT/CONS/EST); invertases (INS 1103) as stabilizers and thickeners (function acronyms EST/ESP); and lipases (INS 1104) as flavor enhancers (function acronym EXA). Amylases, proteases, glucose oxidases, and lipases can also be used applying GMPs.[61]

The rest of the enzymes are considered as auxiliary components[62] and are defined as ''substances of animal, vegetal, or microbial source that act promoting desirable chemical reactions.''[63] The auxiliary components are added during the food manufacturing process for certain technological purposes and are eliminated or inactivated during it, being practically absent in the final food product (as in the case of fermentation agents, clarifying agents, etc.). Therefore, they must not be declared in the list of ingredients in the food packaging labeling.

The CAA establishes the possible source of each type of enzymes (fungi, bacteria, fruits, plants, animals, etc.), as well as other permitted uses (in beer, juices, wines, vegetable oils), and allows the use of other enzymes (lactase, pectinases, and phospholipase C (incorporated in 2009)).[64]

As mentioned previously, vitamins and minerals are not considered additives, and the food products in which these nutrients can be added are classified in two types:

55) MERCOSUR GMC Resolution 26/03.
56) CAA, Article 1396.
57) CAA, Article 1345.
58) MERCOSUR GMC Resolution 10/06.
59) MERCOSUR GMC Resolution 105/94; CAA, Article 1396.
60) MERCOSUR GMC Resolution 11/06.
61) MERCOSUR GMC Resolution 34/10.
62) In Spanish, *coadyuvantes de tecnología*; MERCOSUR GMC Resolution 84/93.
63) MERCOSUR GMC Resolution 18/93.
64) CAA, Article 1263.

1) *Fortified food*. This definition is applied when the nutrient addition is not compulsory. The fortification level in the portion varies according to the nutrient: (i) liposoluble vitamins and minerals, 20–50% DRI, and (ii) hydrosoluble vitamins, 20–100% DRI. The reference levels are established by the FAO/WHO. It is not allowed to fortify certain food groups such as meats, candies, etc. At present, almost all milks in the Argentine market are fortified.
2) *Enriched food*. This definition is applied when the nutrient addition is compulsory, due to potential nutritional deficiencies in the population. These decisions are issued by the Ministry of Health and are approved by national laws. At present, these products are: table salt enriched with iodine;[65] milk under the scope of the "Argentine Mother–Infant Plan"[66] enriched with iron, zinc, and vitamin C;[67] and wheat flour enriched with iron, vitamins B1 and B2, niacin, and folic acid.[68]

Both fortified and enriched foods belong to the group "dietary foods,"[69] as will be seen in Section 1.6.

1.4.5 Food Packaging

Food packaging and other FCMs and its components are not considered as indirect food additives, as in the US FDA regulations.

The requirements for plastics, ceramic, and regenerated cellulose packaging in the MERCOSUR are, in general, similar to the those established by the EU legislation (overall migration limits, specific migration limits, components concentration limits, fat reduction factor for the migration test with fatty stimulant, in the case of plastics; specific migration of cadmium and lead, in the case of ceramics). The European Committee for Standardization (CEN)[70] standards on plastics migration methods have been adopted.[71]

Furthermore, the MERCOSUR regulation incorporates from the US FDA an important concept in the case of PCR-PET packages, such as the US FDA threshold of regulation (TOR),[72] and certain positive lists of substances and their restrictions for plastics, polymeric coatings (used as varnishes for metallic cans), silicones, rubbers, and paper and board. Certain substances covered by Food Contact Notifications (FCNs) recognized by the US FDA, and not included in the US Code of Federal Regulations (CFR)[73] positive lists, can also be included in the MERCOSUR positive lists.[74]

MERCOSUR GMC Resolution 15/10 on colorants and pigments for plastic materials, is based on the Council of Europe "Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food (dated 13.09.1989)."

Detailed references for the MERCOSUR Resolutions in force can be found in Table 1.5.

65) National Law 24786/97.
66) In Spanish, *Plan leche materno-infantil*.
67) National Law 25459/01.
68) National Law 25630/02.
69) CAA, Chapter XVII.
70) In French, *Comité Européen de Normalisation*.
71) MERCOSUR GMC Resolution 32/10.
72) US CFR: 21 CFR 170.39.
73) US CFR: Title 21.
74) *Supra* note 5.

Table 1.5 MERCOSUR GMC Resolutions on FCMs.

Subject	Description	GMC Resolutions No.
General	Framework resolution: general requisites for FCMs	03/92
	Reference analytical methodology for the control of FCMs	32/99
Plastic FCMs	General requisites	56/92
	Positive list of resins and polymers	02/12
	Positive list of additives	32/07
	Migration methods	32/10
	Colorants and pigments	15/10
	Fluorinated polyethylene	56/98
	Polymeric and resinous coatings for foods	55/99
	Refillable PET packages for carbonated non-alcoholic beverages	16/93
	Multilayer PET packages, with central layer containing recycled material, for carbonated non-alcoholic beverages	25/99
	Recycled PET for food packages (multilayer and monolayer packages)	30/07
Metallic FCMs	General requisites	46/06
Glass and ceramic FCMs	General requisites	55/92
Cellulose-based FCMs (paper and board)	General requisites	19/94; 35/97; 20/00
	Positive list of components	56/97
	Overall migration method	12/95
	Papers for filtration and hot cooking	47/98
	Recycled cellulose fibers	52/99
Regenerated cellulose FCMs	Films	55/97
	Casings	68/00
Elastomeric FCMs	General requisites	54/97
	Positive list of components	28/99
Adhesives	General requisites	27/99
Paraffins for food contact	General requisites	67/00

1.4.6 Genetically Modified and Novel Food

In Argentina, the production of genetically modified organisms (GMOs) obtained by genetic engineering is restricted to three crops: soy, sunflower, and cotton. Due to the international background, the country is one of the major producers and exporters of soy bean, and almost all of it is a GMO. Thus, Argentina is aligned with

other countries in the use of this technology, and has maintained a strong position against the declaration of GMOs in food labeling at the international level and at the *Codex* Committees. The proportion of GMO sunflower seed is not important and even less in the case of cotton, which has no food application in the country.

The approval of a new GMO is issued by the Ministry of Agriculture, Livestock and Fisheries, through the National Advisory Commission on Agricultural Biotechnology (CONABIA).[75] Companies performing research and development activities in the GMOs field submit new petitions for approvals to the food safety authority and the official assessment usually takes approximately 2 years.

In recent years, two new sunflower seed varieties have been approved. They are obtained by conventional hybridization and are used in the manufacture of sunflower oils that have a modified fatty acid composition. The new products are called ''high oleic sunflower oil'' (oleic acid content ≥75% of total fatty acids) and ''high stearic-high oleic sunflower oil'' (stearic acid content ≥15% and oleic acid content ≥60% of total fatty acids).[76] Both sunflower oils are used for partial substitution of saturated or hydrogenated fats in food formulations, as palm oil is not produced in the country.

In the Argentine regulation, there is no definition of novel foods, as in other jurisdictions.[77] However, these types of products have had a strong presence in the market for years (e.g., spreads, and milk with phytosterols and phytostanols). Nevertheless, these products are commercialized within the regulatory framework, either because the companies use the submission number (as previously seen, when the food safety authority does not grant the RNPA number after the 30-day assessment period, manufacturers can temporarily use the corresponding submission number) or because these novel foods were approved according to Article 3 of the CAA.

In other areas, and by special request from the food safety authorities, multidisciplinary expert working groups were formed to study cases of interest, such as probiotics and prebiotics. In this case, the existence of a recognized scientific institution such as the CERELA – CONICET (Reference Centre for Lactobacilli – National Council of Scientific and Technical Research),[78] in the Province of Tucumán, was extremely helpful. As a consequence, in 2001, the FAO/WHO organized the First Joint Expert Consultation about Health and Nutritional Properties of Probiotics in Argentina.[79] The characteristics that microorganisms must have to be recognized

75) In Spanish, *Comisión Nacional Asesora de Biotecnología Agropecuaria*.
76) CAA, Article 528.
77) Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1) amended by Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 (OJ L 268, 18.10.2003, p. 1), Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and Regulation (EC) No. 1332/2008 of the European Parliament and of the Council of 16 December 2008 (OJ L 354, 31.12.2008, p. 7).
78) In Spanish, *Centro de Referencia para Lactobacilos – Consejo Nacional de Investigaciones Científicas y Técnicas*.
79) Joint FAO/WHO Expert Committee on Food Additives (2001) Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food Including Powder Milk with Live Lactic Acid Bacteria. Córdoba, Argentina.

as probiotics were defined in 2011.[80] Since then in Argentina ''foods with probiotics'' are classified as dietary foods[81], and they have not been yet harmonized by MERCOSUR. Taking into account the need to cover new ingredients and food products, Chapter XXII ''Miscellaneous'' of the CAA was created in 2013.[82] This chapter, at present, contains only Article 1417, which cleared the use of trehalose.

In Argentina, there is as yet no legal framework that covers functional foods. The perspective is to follow the international trend of allowing the use of health claims for those products for which a consistent cause–effect relationship between the bioactive component intake and the physiological effect on human health can be proved on a scientific basis.

1.4.7 Import/Export Regulations

Argentina has been traditionally a major producer and exporter of food commodities, but at present a national objective is to export products with more added value. The SENASA controls the hygiene aspects of vegetal and animal food primary production, and the trade of these products in bulk. In the case of processed packaged products for direct sale, control is performed by the INAL; in the case of oenological products the control is performed by the INV.

Products intended only for export can comply with the requirements of the CAA or those of the destination country, but in the last case they cannot be put on the Argentine market. In 2012, ANMAT Disposition 2999/12 approved the mandatory Electronic Management System (SGE).[83] In the SGE, the export petition and its monitoring must be done through the ANMAT web page. RNE and RNPA certificates must be presented. If the export is performed by a third party, a certified communication to the manufacturer must be submitted.

Imported products must comply with the CAA. It is also mandatory to submit the authorization for their consumption in the internal market of the origin country, issued by the food safety authorities (certificate of free circulation), in order to avoid differences in quality. A brief description of the type of packaging used must also be presented, along with the rest of the documentation required for the food product. In the case of products coming from countries affected by BSE, certificates stating that they cannot transmit this disease must be submitted. These certificates must be issued by the food safety authorities of the origin country. On arriving in Argentina, the products are withheld by Customs, until the Argentine food safety authority issues their free circulation in the internal market.

In 1991, Decree 2092/91 established that products imported from countries with which there exist treaties of economic integration or mutual recognition agreements, or where there exist similar control systems as in Argentina, or that take as reference the *Codex Alimentarius* recommendations, are recognized as complying with the CAA requirements.[84] This Decree was aimed at facilitating

80) CAA, Article 1389.
81) CAA, Chapter XVII.
82) CONAL, Meeting Act 95/13.
83) In Spanish, *Sistema de Gestión Electrónica*.
84) CAA, Article 2.

food import and overcoming delays in the CAA update on issues such as products, ingredients, additives, labeling, etc. However, as a consequence, taking into account this equivalence principle and fair competition rules,[85] claims used abroad began to be adopted also in Argentina by local manufacturers; nevertheless, they were not allowed by the CAA. Nowadays, instead, the labeling of products strictly according to the CAA requirements and in the Spanish language is mandatory.

A mutual recognition agreement was signed in the MERCOSUR,[86] according to which different control systems applied by the Member States are accepted, on the basis that they can achieve the same results and thus can be considered as equivalent. The objective was to simplify trade between the Member States, and to avoid border checks and control duplication. For block trade, the MERCOSUR Resolutions on harmonized issues are recognized. In the case of non-harmonized issues, national regulations on imported products are applied. An agreement was formally signed with Brazil – a country with which Argentina has implemented a simplified system for the trade of certain products since 2000.[87]

In the case of imported FCMs not yet in contact with foodstuffs, they must comply with the requirements established in Chapter IV of the CAA. The importer must present also a notification stating that the FCM complies with the regulations of the country of origin and that it is legally commercialized in that jurisdiction. This notification can be a free circulation certificate issued by an official body or a declaration by the manufacturer, certified by an official body or by a commerce or industry chamber.

1.5 Accountability Regulations

The owners of the food companies are responsible for all the products they put into the market.[88] In the case of sanctions, penalties are shared between all the stakeholders of the distribution chain (food manufacturer, warehouse, supermarket, etc.). The Technical Director of the factory is responsible, along with its owners, for the manufacturing process, the raw materials quality, and the finished products.[89] The Technical Director must be a qualified professional recognized by the food safety authority (e.g., food engineer, food chemist, chemist, biochemist, veterinarian, agronomist). In certain cases, a specific degree is required for the Technical Director (e.g., a pharmacist responsible for dietary supplements manufacture).

The food safety authorities (in particular, the Ministry of Health) implement technical update programs and improvements in food control. When a non-conformity is detected, the administrative penalties are proportional to the associated risk to health and sometimes the food safety authority can pass the case to the specific court that applies penal law (Figure 1.2). The ANMAT has classified non-conformities and sanctions according to the proportionality principle: very grave (very high risk, with

85) Decree 2092/91, Article 2.
86) MERCOSUR GMC Resolution 59/99.
87) ANMAT Disposition 789/00.
88) CAA, Article 18, item 10.
89) CAA, Articles 16 and 17.

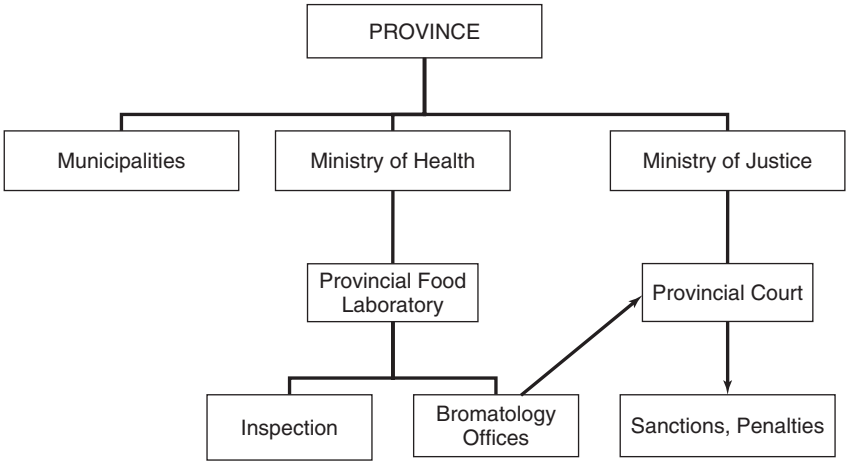

Figure 1.2 Provincial structure and relationship with the Ministry of Justice.

health compromise), grave (high risk), moderate (probable future risk or danger of food quality loss), and slight (low risk). Fine amounts, independently from other administrative measures, are established by ANMAT Disposition 1710/08.

The major causes of non-conformities are related to non-compliance with the Consumer Defense Law. The authority responsible for applying this law is the Secretariat of Interior Commerce – Ministry of Economy and Public Finances, instead of the food safety authorities. Examples of these non-conformities are:

1) Exceeding the tolerances for differences between quantities declared in the labeling and the real ones.
2) Using additives not allowed in certain products in order to improve their yield (starch in ham, soy protein in hamburgers, pork meat in products declared as of bovine origin, etc.).

Although these non-conformities are in general not very frequent, they do not pose a risk to consumer health. When their causes are economic (better yield or use of cheaper meats), they constitute a violation of consumer rights and unfair competition between manufacturers.

1.6
Current Topics – Special Topics and Challenges

1.6.1
General Situation

The constant development of new products by leading companies requires an updated reference regulatory framework. One of the most important decisions adopted at the national level in 2010 emphasizes the requirement to restrict the use

of hydrogenated fats because of the deleterious known effect of trans fatty acids. Maximum contents for trans fats were established:[90] (i) 2% in direct consumption fats (vegetal oils and margarine) and (ii) 5% of the total fats fraction for the rest of the processed foods. The implementation deadlines are: 2 years and up to 4 years, respectively.

Moreover, the modification of food composition according to any health-related pattern (decrease in EV or sodium, added vitamins, minerals, etc.), has been generalized in such a way that a high proportion of the products in the market have some characteristic that enables them to be classified as ''dietary food.''[91]

Dietary foods must be sold only packaged in defined units and not in bulk, and the labeling must not mention diseases. They are divided into different groups according to the target population group (healthy people, people with particular physiological states, and people with nutritional deficiencies), or food characteristics (dietary supplements, sweeteners), or miscellaneous (chia oil, colostrum, modified fiber foods, foods with propolis, probiotics, prebiotics).

The main products for healthy people are foods for infants and young children. In 2007, Argentina adhered to the WHO ''International Code of Marketing of Breast-milk Substitutes,'' which was fully transposed into the CAA. The nutritional information on the labeling must be expressed as percentage and not per serving, so the physician can recommend the adequate intake according to the age and weight of the infant or young child.

Another important group that is evolving is the one corresponding to fortified foods. The allowed nutrients are proteins, amino acids, minerals, and essential fatty acids, in a higher proportion than in the normal food. As seen in Section 1.4, fortification is usually optional in Argentina, while enrichment of some foods with vitamins and minerals is mandatory.

Examples of products for people with particular physiological states are foods modified in terms of EV, carbohydrates, proteins, lipids, and minerals. The allowed non-nutritive sweeteners for modification of EV and carbohydrates are saccharin, cyclamate, aspartame, acesulfame-K, sucralose, stevioside, neohesperidin dihydrochalcone, glycyrrhizin, neotame, and thaumatin.

Gluten-free foods occupy a place of particular interest, taking into account health concerns that promoted the active participation of the Celiac People Associations. In 2011, the gluten-free mandatory logos (Figure 1.3) that these products must show in the labeling were established.[92] There are also two recognized voluntary logos (Figure 1.4). The logos contain the phrase ''Sin T.A.C.C.''[93] The INAL is the food safety authority that performs analytical determinations to certify that products are gluten free and every 2 months updates the online list of public consultation, where celiac individuals can check the status of gluten-free products in the Argentine market via the Internet.

Dietary supplements were incorporated in the CAA and the last update was performed in 2008.[94] By definition, in their formulation a wide variety of listed

90) CAA, Article 155 tris.
91) See Section 1.1.1; CAA, Chapter XVII.
92) CAA, Article 1383 bis.
93) In Spanish, meaning ''Without wheat, oats, barley, rye.''
94) CAA, Article 1381.

Figure 1.3 Mandatory gluten-free logos. (Reducciòn Màxima; translation: 11 mm maximum reduction.)

Figure 1.4 Voluntary gluten-free logos.

ingredients (amino acids, peptides, proteins, lipids, marine lipids, carbohydrates, vitamins, minerals, dietary fiber) alone or combined can be used. Herbs are allowed in the list and the country integrates an international working group for its update.[95] As in the case of all foods, herbs as ingredients must be declared in the labeling in descending percentage order, mentioning their common and botanical denomination, and the somatic parts used. Vitamins and minerals must be present in a concentration no less than 20% of the DRI per unit or portion and must not exceed the ''No Observed Adverse Effect Level'' (NOAEL). In the case of liposoluble vitamins and iron, if their concentrations exceed the DRI, a warning phrase in the labeling must express ''Potential accumulative toxic effects, consult a physician.'' Therapeutic indications are not allowed in labeling or in advertisement. Import products must have evidence (free circulation certificate) of being legally marketed in the country of origin, and present the labeling in Spanish. The approval is granted for 5 years.

For some products that are not contemplated by the CAA, the ANMAT has issued Dispositions that serve as references for provincial food safety authorities.

95) CONAL, Meeting Act 98/2013.

For instance, in the case of medical foods, the ANMAT issued Disposition 7333/99 that defines these products as especially formulated to be administered by enteral route (gastrointestinal absorption) for the specific dietary management of a disease or an especial condition established through medical assessment. Therapeutic indications in labeling, brochures or advertisement are also forbidden. Another example is the case of the energy drinks, which were questioned due to its usual consumption along with alcoholic beverages. The ANMAT originally classified them as dietary foods, and in 2013 they were incorporated into the CAA as such, under the denomination of ''non-alcoholic beverages with taurine and caffeine''[96]. In their formulation the following substances can be used: glucuronolactone, inositol, carbohydrates, vitamins and/or minerals and/or other authorized ingredients.

A field where clear guidelines are difficult to establish and also to control is the advertisement of the beneficial effects of foods on health. The ANMAT has established certain requisites that companies intending to use health claims must comply with.[97] This regulation has diminished the excess advertising on food health claims. The next stage will be the adoption of guidelines on health claims in food labeling.

It is interesting to mention that, at present, there are voluntary agreements between the food safety authorities and food companies to reduce the level of sodium in food. These measures have not yet been incorporated into the CAA, but nevertheless they are very important examples of collaborative work in the food area.

Allergens are a topic in which hard work is being done. In 2010, it was decided that the presence of eight main allergens (wheat, fish, crustaceans, eggs, milk, soy beans, peanuts, and tree nuts) must be clearly declared in all food labeling[98] and unclear warning phrases were forbidden. However, this measure was suspended due to uncertainties about the detection levels of the available analytical techniques and their feasibility. Nowadays, researchers and professionals from different food safety authorities, academia, official institutions, and food companies are working on these issues, through the creation of an Allergen Platform, in order to develop criteria, analytical methods, and legislation proposals.[99]

With respect to food packaging, the MERCOSUR GMC Resolutions on cellulosic materials in contact with foods (Table 1.5) are being reviewed since 2011, taking into account Recommendation XXXVI of the German BfR and the US FDA positive lists. In the review project, they have been condensed in two documents that were submitted to a public consultation process (a project on the requisites for cellulosic FCMs of general use, and a project on the requisites for cellulosic materials for cooking and hot filtration). During 2013, the MERCOSUR Packaging Group evaluated the results of the above-mentioned public consultation, began the study of a new Brazilian proposal on the requisites for cellulosic materials for cooking in oven, and began the review of Resolution GMC 32/07 on the positive list of additives for plastic materials submitted by Brazil.

96) CAA, Article 1388 and 1388 bis.
97) ANMAT Disposition 7730/11.
98) CAA, Article 235 seventh.
99) CONAL, Meeting Act 98/2013.

1.6.2 Developments and Perspectives

The need for updated and clear regulation is a basic aspect of food safety. Thus, food safety authorities started and continue to update the regulatory framework in a very active way from different areas: ANMAT, CONAL, INAL, INV, SENASA, etc. The public availability of and the virtual access to the whole documentation related to food safety is a key area in which food safety authorities have invested a great effort. The upgrading and modernization of the bodies involved in the management of the safety food system is under way.

While there have been great advances in the last decades, following international trends, many subjects are still pending. At the MERCOSUR level, further harmonization of other food groups should continue, especially in complex areas such as dietary foods. Other countries, such as Brazil, have adopted a more restrictive list of dietary supplements (only the addition of vitamins and minerals is allowed). However, other Member States may adopt regulations on non-harmonized topics that in our country may seem difficult to adapt to the CAA structure (e.g., foods for athletes, definitions of bioactive compounds). It also would be important to transpose the MERCOSUR GMC Resolutions in the different Member States, avoiding excessive delays that may give rise to differences in public health protection or technical barriers to trade between them.

Appendix 1.A: Internet Sources

Food Regulations and Registers

- The Argentine Food Code update is available in Spanish at: *www.anmat.gov.ar/alimentos/normativas_alimentos_caa.asp*
- The Argentine regulations and other documents can be found at the InfoLEG web site (in Spanish, *Información Legislativa y Documental*), dependent on the Ministry of Economy and Public Finances; the full texts of all regulations with number and hierarchy (Laws, Decrees, Ministerial Resolutions, and Organisms Dispositions) are available at: *www.infoleg.mecon.gov.ar*
- All the MERCOSUR GMC Resolutions and complementary information can be found at:
  - ''MERCOSUR'' web page: *www.mercosur.int* (in Spanish and Portuguese)
  - ''PUNTO FOCAL (Focal Point) – Food Area'' web page: *www.puntofocal.gov.ar/mercosur_sgt_alim.htm* (in Spanish)
- The Electronic Management System (SGE) can be accessed at: *www.anmat.gov.ar/Despapelizacion/principal.asp*
- CONAL Meetings Acts are available at: *www.conal.gov.ar*
- The lists of food manufacturing plants and processed foods approved by the INAL for import/export, and those registered by the provinces, is available at: *www.anmat.gov.ar/Alimentos/consulta_alimentos_establecimientos.asp*

- The official lists of gluten-free foods in Argentina are available at:
  - General list and information on each Province: *www.anmat.gov.ar/Alimentos/libres_gluten/Alimentos_Libres_de_Gluten.asp*
  - General list, last version (updated 18 January 2014): *www.anmat.gov.ar/listados/Listado_de_Alimentos_Libres_de_Gluten_18_01_2014.pdf*
- The Law of Pesticides (Law 18073/1969) is available at: *http://infoleg.mecon.gov.ar/infolegInternet/verNorma.do?id=19949*

Food Safety Authorities and Technical Official Institutions

- ANMAT (Drug, Food and Medical Technology National Administration), *www.anmat.gov.ar*
- CNEA (National Commission of Atomic Energy), *www.cnea.gov.ar*
- CONAL (National Food Commission), *www.conal.gov.ar*
- CONABIA (National Advisory Commission on Agricultural Biotechnology), *http://64.76.123.202/site/agregado_de_valor/biotecnologia/20-CONABIA/index.php*
- INAL (National Food Institute), *www.anmat.gov.ar/Alimentos/Alimentos.asp*
- INTA (National Institute of Agrarian Technology), *www.inta.gob.ar*
- INTI (National Institute of Industrial Technology), *www.inti.gob.ar*
- INV (National Institute of Vitiviniculture), *www.inv.gov.ar*
- MERCOSUR (Common Market of the South), *www.mercosur.int*
- Ministry of Agriculture, Livestock and Fisheries, *www.minagri.gob.ar*
- Ministry of Economy and Public Finances, *www.mecon.gov.ar*
- Ministry of Health, *www.msal.gov.ar*
- Ministry of Industry, *www.industria.gob.ar*
- SENASA (National Service of Agrarian and Food Health and Quality), *www.senasa.gov.ar*

Appendix 1.B: Abbreviations

ADI	Acceptable Daily Intake
ANMAT	Drug, Food and Medical Technology National Administration
BfR	German Federal Institute for Risk Assessment
BSE	Bovine spongiform encephalopathy
CAA	Argentine Food Code
CEN	European Committee for Standardization
CERELA	Reference Centre for Lactobacilli
CFR	Code of Federal Regulations (US)
CNEA	National Commission of Atomic Energy
CONABIA	National Advisory Commission on Agricultural Biotechnology
CONAL	National Food Commission
CONICET	National Council of Scientific and Technical Research
DRI	Dietary Reference Intake
EFSA	European Food Safety Authority

EMRL	Extraneous Maximum Residue Limit
EV	Energetic Value
FAO/WHO	Food and Agriculture Organization/World Health Organization
FCM	Food Contact Material
FCN	Food Contact Notifications
FDA	Food and Drug Administration (US)
FMD	Foot-and-mouth disease
GMC	Common Market Group
GMO	Genetically modified organism
GMP	Good Manufacture Practice
HACCP	Hazard Analysis and Critical Control Points
HPLC/MS-MS	High-Performance Liquid Chromatography/Double Mass Spectrometry
IARC	International Agency for Research on Cancer
ICMSF	International Commission on Microbiological Specifications for Foods
INAL	National Food Institute
INS	International Number Systems (Additives)
INTA	National Institute of Agrarian Technology
INTI	National Institute of Industrial Technology
INV	National Institute of Vitiviniculture
ITIC	International Toxicology Information Centre
JECFA	Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives
MERCOSUR/ MERCOSUL	Common Market of the South
MRL	Maximum Residue Limit
NOAEL	No Observed Adverse Effect Level
NOL	No Objection Letters
PCR-PET	Post-consumer recycled polyethylene terephthalate
RIVM	Netherlands National Institute for Public Health and the Environment
RNE	National Factory Register
RNPA	National Food Product Register
SENASA	National Service of Agrarian and Food Health and Quality
SGE	Electronic Management System
TBT	Technical Barriers Trade
TOR	Threshold of Regulation
USDA	US Department of Agriculture