


Secretaría de Agricultura, Ganadería Pesca y Alimentos Subsecretaría de Política Agropecuaria y Alimentos Dirección Nacional de Alimentos	QUALITY PROTOCOL	
Code: SAA012	Version: 06	26.09.2006

At the head note the version in English is: Secretariat of Agriculture, Livestock, Fishing and Food. Undersecretariat of Agricultural Policy and Food. National Food Administration. -----


There is a logotype: "Argentine Food – A Natural Choice".-----

## QUALITY PROTOCOL FOR DULCE DE LECHE (MILK CARAMEL ARGENTINIAN TYPE) -----

Date of making it official: November 22th, 2006 – SAGPyA Resolution N° 798/2006.-----

Institutions and companies participating in the drawing up and evaluation of this protocol.-----

- **Dirección Nacional de Alimentos** (according to its version in English= Food National Board = SAGPyA) -----
- **Andyson S.A.** -----
- **Instituto Nacional de Tecnología Industrial - INTI Lácteos** (according to its version in English= National Institute of Industrial Technology - Dairy products) -----

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## INTRODUCTION -----

The *Dulce de Leche* is a product that belongs to the gastronomic and cultural heritage of our country, and it is very well known and related to Argentina. -----

Besides, various market trends towards the increased differentiated product consumption of raw material and/or ingredients that belong to it, together with the information about its manufacturing process and geographical origin, highlight the importance of being identified as a typically Argentinian product. -----

### 1. Scope -----

This protocol defines and describes the quality attributes that the *Dulce de Leche* must fulfill in order to aspire to use the Seal “Argentine food – A Natural Choice” and its English version. -----

The manufacturing companies must fulfill the regulations in force on Good Manufacturing Practice, conditions for the *Dulce de Leche* and for packages, that were mentioned in the Argentinian Food Code- [according to its initials in Spanish = C.A.A.] (Chapter I “General Provisions”- GMC resolution N° 080/96 included in the Code through Resolution MsyAS N° 587/97; Chapter VIII “Diary Products”- Sections 592 and 595; Chapter IV “Elements, vessels, packages, wrapping, apparatus and devices).

Likewise, it should be stated that in this protocol the required analyses must be performed using the accepted official methods and by the laboratories officially authorized for the above mentioned studies. -----

The C.A.A. defines as *Dulce de Leche*: the product obtained by concentration and heating at a normal or reduced pressure of milk or reconstituted milk, with or without the addition of solids from diary origin and/or cream, and adding saccharose (partially substituted or not by monosaccharides and /or disaccharides), with or without the addition of other food substances (Joint Resolution 33/2006 and 563/2006 from SAGPyA and SPRRS modifies several sections from the Diary Food Chapter from C.A.A. – B.O. 22/09/06). -----


Although this has been stated in C.A.A., a *dulce de leche* shall be considered of “Premium” quality as regards this protocol if it fulfills the differentiating and additional attributes mentioned in it, related to the product, the process and occasionally the package. -----

The differentiating attributes to be considered in this protocol are the following: -----

- Method of obtaining <sup>1</sup> milk. -----
- Milk characteristics. -----
- Used sweeteners. -----
- Manufacturing process. -----
- Final product (description and organoleptic characteristics). -----

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<sup>1</sup> The method of obtention combines both a mechanical procedure and a manual procedure. -----

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## 1. Foundations of differentiating attributes -----

### **Product attributes** -----

We have worked on physical, chemical and biological attributes, overcoming the requirements of the Argentinian Food Code. -----

It should be stated that the unique and compulsory ingredients according to the protocol for the manufacturing of the *Dulce de Leche* are raw bovine milk, ordinary sugar cane type A (section 768bis pursuant to CAA) and / or higher qualities (included in section 768 pursuant to CAA), glucose, sodium bicarbonate and occasionally vanillin. -----

Taking into account that one of the main ingredients of the product is milk obtained by the milking of cows, its obtention and quality are a differential factor. In this document parameters are established for raw bovine milk thus allowing to fix differential factors that assure a high quality final product. -----

As regards additives: -----

- No conservative agents should be present and used, i.e. although during the manufacturing of this product Natamicine and/or sorbic acid or its equivalent in sodium, potassium or calcium sorbate or other salts from the same acid may be added, they shall not be accepted in this protocol. -----
- No other additives should be present and used exception made sodium bicarbonate, and/or potassium bicarbonate and vanillin (in case of using it). -----

### **Process attributes** -----

The protocol includes conditions related to the primary production so that the quality of the raw material should be guaranteed, as the application of Cattle Good Practice (CGP). The application of *Dangers and Control Critical Points Analysis* system [according to its initials in Spanish APPCC or] has been chosen in each step of the process of manufacturing the *Dulce de Leche*. -----


With reference to the manufacturing of the product the usage of a methodology to avoid crystallization has been underlined, thus obtaining the *Dulce de Leche* without granules. -

On the other hand, transport and storage conditions and parameters should be observed pursuant to the inocuity and quality assurance system applied. -----

### **Package attributes** -----

Pursuant to rules in force for packages in general, the criterion of the preference package has been taken in the destiny markets. For this protocol the usage of glass packages and metallic packages (tinplate) shall be admitted. -----

However, the usage of transparent glass packages allows a better observation of the product quality and this is related to the environment protection as it can be recycled. -----

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Furthermore, other innovative materials approved by the legally competent health authority shall be considered and evaluated. -----

**PRODUCT DIFFERENTIATING ATTRIBUTES** -----

**Raw Material** -----

***Method of obtention and milk conservation conditions*** -----

The *Dulce de Leche* is manufactured with raw milk product obtained from the milking of cows, whose feeding system is mainly based on the direct consumption or depending on the type of fodders. -----

The geographical region of production should guarantee that milk cows are mainly fed with fodders. -----

It is very important to highlight that the period between the milking and the manufacturing should be inferior to 72\* hours and the storage temperature during the total period should be lower than 6°C; during the transportation the cold chain should be kept and they should get to a maximum temperature of 9°C. -----

\* Note: periods not longer than 48 h. are recommended. -----

The dairy farm supplying milk used for the manufacturing of *Dulce de Leche* that is protected by the seal shall fulfill Cattle Good Practice (CGP). It is recommended as reference the Technological notebook N° 4 of INTI Dairy products and the Sanitation Good Practice Code for milk and dairy products, manufactured by the committee of the Codex for food sanitation. -----

***Milk characteristics*** -----


The raw milk used for the manufacturing of *Dulce de Leche* should fulfill the following requirements: -----

- a) To come from dairy farms free of brucellosis and tuberculosis, being officially certified by SENASA<sup>2</sup> (according to its initials in Spanish = Servicio Nacional de Sanidad = Sanitary National Service).-----
- b) Quantity of milk fat matter not inferior than 3.2% p/p. -----
- c) Quantity of total proteins not inferior than 3.0% p/p. -----
- d) Somatic cells count: not higher than 400,000 cel/ml. -----

Value corresponding to the geometrical mean of the results of the samples tested during a period of three months, with at least a sample a month, of the raw milk at the moment they are received at the establishment. -----

- e) Mesofiles aerobe bacteria count not superior than 100,000 CFU/ml. -----

<sup>2</sup> The dairy farms supplying those institutions that are registered in official programmes to control and eradicate Brucellosis y Tuberculosis.

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Value corresponding to the geometrical media of the results of the samples tested during a period of two months, with at least a sample a month, of the raw milk at the moment of the reception in the establishment. -----

f) Absence of addition in milk. This parameter will be reached if the freezing point is equal or lower than -0.518 °C. -----

g) Absence of antibiotic residues. This parameter will be reached when a “Negative” result appears at the microbiological inhibition tests. -----

h) Acidity: 14 to 17 °Dornic. -----

i) pH: 6.55 to 6.75. -----

**Used sweeteners** -----

The sweetener used is cane sugar and in a 30% of its formulation. It can be partially replaced by glucose syrup [solids (° Brix: minimum 78%, pH 4.5-5.2; dextrose equivalent to 36-40%] up to reach 40% of total sugar. -----

**Flavoring agent** -----

In case of using flavoring agents the only one that is allowed in this protocol is vainillin - (chemical formula C<sub>8</sub>H<sub>8</sub>O<sub>3</sub>, MW 152.14, crystalline white powder, melting point 81-83 °C): maximum 0.00075 % p/p of the formulation. -----

**Technological and manufacturing/adjuvants** -----

Sodium and/or potassium: 0.04 to 0.06 % of the formulation. -----

Betagalactosidase is recommended (lactase). -----


<sup>2</sup> The dairy farms are excluded from those institutions that are registered in the official programmes to control and eradicate brucellosis and tuberculosis. -----

**Final product** -----

*Dulce de Leche* shall respond to the following characteristics<sup>3</sup>: -----

- Humidity: maximum 30% p/p. (Rule Recommendation FIL 15B: 1988) -----
- Milk total solids: minimum 24% p/p. -----
- Ashes (500-550 °C): maximum 2.0% p/p. -----  
(Rule Recommendation AOAC15° Ed. 1990.930.30) -----
- Milk fat: 6.0% minimum p/p. (Rule Recommendation FIL 13C: 1987) -----

<sup>3</sup> Some of the parameters mentioned are equal to the ones established by CAA, but it is considered appropriate to specify them: humidity, milk total solids, ashes, milk fat, positive *Staphylococcus aureus* coagulase. -----

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- Proteins: minimum 5.0 % p/p. (Rule Recommendation FIL 20B: 1993) -----
- Natamicine nor Sorbic Acid or its equivalent in sodium, potassium or calcium sorbate or other salts resulting from the same acid as preserving agents. -----
- The presence of serum in powder of any origin nor fats of non dairy origin is not admitted.-----
- Vainillin (optional).-----
- Yeasts and moulds: inferior to 5 cfu/g. (Rule recommendation FIL 94B: 1990), -----  
Ref.: section 592 of CAA. Two sample plates should be used in order to control the environment. -----
- Positive coagulase Staphylococcus aureus: Absence in 0.1g. -----
- Salmonella spp: Absence in 25 grams -----
- Listeria monocitogenes: Absence in 25 grams -----
- Sodium and / or potassium bicarbonate -----
- Appearance: creamy, caramel-like brown and without granules. -----

**PROCESS DIFFERENTIATING ATTRIBUTES** -----

**1. Inocuity assurance system** -----


The manufacturing shall be carried out in lab sites by the national health authorities under strict rules of sanitation and security.-----

The manufacturing company of *Dulce de Leche* that aspires to use the Seal “*Argentine Food – A Natural Choice*” should fulfill the Dangers Analysis and Critical Points Control from the moment the raw material is received to the moment it is marketed. It is recommended to have as a reference the SENASA resolution 718/1999 that accepts the “Manual for the Application of Danger analysis and Control critical points (HACCP)”-----

**2. Manufacturing process** -----

***Raw milk therapy.*** -----

- Filtration: Before entering the reservoir or process, milk should be filtered.-----
- Neutralization: Milk should be neutralized using high quality food grade sodium bicarbonate. -----

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- Lactose hydrolysis<sup>4</sup>: Include a method\* during determined process stage that protects against the non crystallization of the *Dulce de Leche*, so that the appearance of the product is not altered as regards the presence of granules.-----

- **Note:** The method that is recommended for lactose hydrolysis, consists of the use of beta galactosidase (lactase) previous to cooking. The hydrolysis grade to be achieved ranges from 15 to 50 %. -----

**Cooking and cooling** -----

The endpoint of the product concentration is determined by refractrometry and is between 69-74 grades Brix (the sample should be at the same temperature the determination is performed). -----

**3. Packaging** -----

The packaging of *Dulce de Leche* should be performed under the strict sanitation and security rules automatically and semiautomatically in specially conditioned rooms; i.e. the filling chambers should be separated from the manufacturing chamber and jam temperature should be guaranteed at the moment of packaging at not less than 60°C.-----

**Packages control** -----

Recommended methods for the elimination of contaminants: -----

- Visual observation and package inversion. -----
- Treatment with filtered air(sterilizing filter) under pressure. -----
- Use of UV Light. -----
- Metal detector. -----
- Chlorine water washing: minimum 0.4 ppm. -----
- Treatment with drinking water at a temperature higher than 80 °C. -----

**4. Storage and transportation characteristics** -----


Product storage site should be cool, dry, close and free of pollutants. -----

The company should guarantee the carrier that the finished product fulfills the sanitation conditions of the means of transport, that it is authorized and be used for food transport.-

It is recommended that the storage and transport of the product should be done at a temperature not superior than 30°C and the inferior relative humidity at 80%, protected from sunlight. -----

**IMPORTANT.** The product that is considered in this protocol shall be separated and the

<sup>4</sup> Lactose hydrolysis may be carried out at another stage of the process. -----

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SAGPyA N° 392/05 resolution and identify correctly the lots and the loads, in order to guarantee the handling of the rest of the products without the protection of the Seal.-----  
 With this purpose, the company shall need the documents and records that protect the goods have the trademark on its label. -----


**PACKAGE DIFFERENTIATING ATTRIBUTES** -----

To give luster to the product and its packaging, transparent glass primary packages shall only be admitted with a cap containing a safety button besides an outer plastic cover or strip to protect it from violation; tinfoil or any other innovating material approved by the competent authority and acceptable in the market, being the variable the shape and size of them. -----

Packages made of PET (polyethylenreftalate) and cardboard shall not be admitted. -----

*Alicia R. López López*  
*Traductora Pública*  
*Inglés*  
*Mat. To. X Fo. 001 Capital Federal*  
*Inscrip. C.T.B.A. Nro. 2647*



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**Audit date:**

**Auditing company:**

**Audited company:**

Location site:

Headquarters:


Locality:

Telephones:

***Name of the responsible for the quality at the company / title***


**Product: DULCE DE LECHE (MILK CARAMEL Argentinian type)**

**Reference code protocol: SAA012**


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## RESULTS

Attributes	Compliance		Remarks
	YES	NO	
<b>1. Of Raw Material</b>			
<b>Raw milk</b>			
a. SENASA certificate supporting that it comes from diary farms free of brucellosis and tuberculosis.			
b. Quantity of Milk fat matter: not inferior at 3.2% p/p.			Check record/s and write down the date and result of each analysis.
c. Quantity of total proteins: not inferior at 3.0% p/p.			Check record/s and write down the date and result of each analysis
d. pH: 6.55 to 6.75			Check record/s and write down the date and result of each analysis.

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Attributes	Compliance		Remarks
	YES	NO	
e. Acidity 14 to 17 °Dornic			Check record/s and write down the date and result of each analysis.
f. Somatic cell count: not superior to 400,000 cel/ml (geometric mean of the results of the analyzed samples during a period of three months, with at least a sample a month)			Check record/s and write down the date and result of each analysis
g. Mesofile aerobes bacteria count: not superior to 100,000 CFU/ml (geometric mean of the results of the analyzed samples during a period of two months, with at least a sample a month)			Check record/s and write down the date and result of each analysis
h. Freezing point: equal or inferior to -0.518 °C.			
i. Antibiotic residue: negative to microbiological inhibition test.			Check record/s and write down the date and result of each analysis


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Attributes	Compliance		Remarks
	YES	NO	


For the items a, b, c, d, e, h and i (included) the result of at least 2 analyses (with a minimum difference of 30 consecutive days) performed in authorized laboratories, before each audit.

For the items f and g what is described in this audit approval should be respected.

<b>2. Flavoring agent</b>			
a. Vainillin: In case of using it, check quality certificate of supplier			
<b>3. <u>Sweeteners</u></b>			
Cane sugar: check the records that support the allowed proportion of use (maximum limit up to 30% in the formulation, being possible to replace partially it by glucose up to a 40% of the total sugar).			
a1. Quality certificate of the supplier			


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Attributes		Compliance		Remarks
		YES	NO	
A2. Check in storage the allowed quality				
a. Glucose syrup (cane sugar substitution) :	1 Solids: minimum 78 %			Check record/s and write down the date and result of each analysis
	2 pH: 4.5 to 5.2			Check record/s and write down the date and result of each analysis
	3 Supplier quality certificate			
<b>4. Manufacturing /technology adjuvant</b>				
a. Sodium, potassium and/or calcium bicarbonate: check records supporting the allowed proportion of use				


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Attributes	Compliance		Remarks
	YES	NO	
b. Supplier quality certificate			
<b>5. Final product</b>			
a. Humidity: maximum 30 % p/p. (Recommendation FIL 15 B: 1988)			Check record/s and write down the date and result of each analysis
b. Ashes (500-550 °C): Maximum 2.0 % p/p. (Recommendation AOAC15° Ed.1990.930.30)			Check record/s and write down the date and result of each analysis
c. Proteins: minimum 5.0 % p/p (Recommendation FIL 20B: 1993)			Check record/s and write down the date and result of each analysis
Milk fat: minimum 6.0 % p/p. (Recommendation FIL 13C: 1987)			Check record/s and write down the date and result of each analysis
d. Natamycin and sorbic acid or its equivalent in sodium, potassium or calcium sorbate and other resulting salts			Check record/s and write down the date and result of each analysis

For the items 3 b1 and 3 b2 the result at least 2 analyses (with a minimum difference of 30 consecutive days) done in laboratories authorized for that purpose, before each audit.


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Attributes	Compliance		Remarks
	YES	NO	
of the same acid: Lack of it. (determined by HPLC)			
<p>g. Yeasts and moulds: Inferior to 5 CFU/g. (Recommendation FIL 94B: 1990) Ref.: Section 592 of CAA. Two sample plates should be used pararellaly to control the environment</p> <ul style="list-style-type: none"> <li>• Homogenate 10g / 90 ml (<math>10^{-1}</math> dilution)</li> <li>• Spot: divide 10 ml of homogenate in 3 plates. Test in depth.</li> <li>• Medium: Agar YGC.</li> <li>• The result is obtained (CFU / g) with all the counts of each plate</li> </ul>			Check record/s and write down the date and result of each analysis
h. Positive coagulase Staphylococcus: Absence in 0.1g			Check record/s and write down the date and result of each analysis


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Attributes	Compliance		Remarks
	YES	NO	
i. Salmonella spp: Absence in 25 gramos			Check record/s and write down the date and result of each analysis
j. Listeria monocitogenes: Absence in 25 gramos			Check record/s and write down the date and result of each analysis.
k. Appearance: without granules, creamy and caramel brown color.  (Visual examination)			Check record/s and write down the date and result of the each analysis
<b>6. Process</b>			
a. Perform the lactose hydrolisis. (Indicate the method in examinations)			
Product Endpoint : 69 to 74 °Brix (The sample should be at the same temperature the determination is done)			Check record/s and write down the date and result of the each analysis
b. Packaging temperature:			Check record/s and write down the date and result of the each




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Attributes	Compliance		Remarks
	YES	NO	
Not inferior to 60 °C			analysis.
c. Check the cleaning schedule and match with the records applied in the manufacturing plant			
d. Check the corrective actions records related to POES applied in the plant.			
e. Clothes and general conditions appropriate for the personnel.			
f. Records control associated to the standards calibration of patterns and measurement instruments			
g. Record of substitution of parameters to be controlled defined by each PCC Control Critical Point).			
<b>7. Of the Package</b>			

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Attributes	Compliance		Remarks
	YES	NO	
Check at the warehouse the declared packages associated to this protocol			

***Note: All analyses should be carried out using well known official methods, performed by officially authorized laboratories for special studies, and fitted with the equipment and instruments calibrated with its corresponding certificates.***

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**Conclusions**

People interviewed by the audited firm: -----  
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**On behalf of the auditing company**

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**Upon approval of the audited company**

Signature, name and seal

Signature and name