FACULTY OF LEGAL SCIENCES

"SCHOOL OF INTERNATIONAL STUDIES"

TOPIC:

"Analysis of the feasibility of the International Standard ISO / IEC 17025: 2005 for UDALAB"

Work prior to obtaining a Bachelor of International Studies with a major in bilingual foreign trade

AUTHOR:

Geovana Pamela Romero Vintimilla

DIRECTOR:

Juan Manuel Maldonado

Cuenca, Ecuador

2015

DEDICATION

I dedicate this graduation work to the full support of Oswaldo and Caty, my parents, who gave me life, support, and education. From this achievement I would only give back a little of what they have given me; thanks to their effort and sacrifice I am the person I proudly am today.

To Santiago, my brother, who has shown me that his happiness is my well-being, his great example of a man and brother, as well as his reprimands and unconditional support, have been instrumental in the development of this work.

Bertha and Luisa Palacios Guerrero (+), my grandmothers, who despite their earthly absence, have inspired me every day to fulfill my goals without fail. Their infinite and incomprehensible love has filled my life and encouraged me to pursue my dreams.

Finally, I dedicate this work to Luis Martinez, my boyfriend, who with his love and patience has understood every situation, has believed in me, and has been proud of me for everything I have achieved, and will continue to achieve.

ACKNOWLEDGEMENTS

First I thank God, for allowing me to get where I am today.

I appreciate the pressure and continued questions of my uncles, cousins, boss, co-workers, and friends who have motivated me to finish this work.

And a special thanks to Juan Manuel Maldonado, my supervisor, who, with his wisdom and experience, has managed to guide me and help me with the problems presented throughout the course of this work; without his patience and motivation, I would not have been able to complete this thesis successfully.

TABLE OF CONTENTS

INDEX OF TABLES AND ILLUSTRATIONS

TABLES

ILLUSTRATIONS

ABSTRACT

Thanks to Resolution 116 of the COMEX (Foreign Trade Committee) many food products have been restricted from entering Ecuador. Consequently, food testing laboratories will be operated under the requirements of ISO / IEC 17025, to provide services to importers who need tests required by said regulations, who will then be able to introduce their foods into the country.

Today, in Ecuador, there are not even 30 food testing laboratories under the operation of the international standard ISO / IEC 17025. Because of this situation, this thesis shows the gap between ISO 9001, which is UDALAB compliant, and ISO / IEC 17025. This is done in order for UDALAB to receive accreditation and therefore run the necessary tests required by the INEN on restricted foods.

INTRODUCTION

Any company that wants to succeed long term should offer good quality products. Today quality is not only a requirement but it is also seen as a business strategy that is growing nationally and internationally.

In this context, during the sixties and seventies, in several countries, standards for quality systems were developed. The two most important standards of that time began in the United States (MIL-Q-9858[a]) and the UK (BS 5750). In 1987 the series of ISO 9000 standards that govern quality processes was developed.

The first version of the requirements and specifications for the competence of testing laboratories began with the implementation of ISO / IEC Guide 25, which was replaced years later by the ISO / IEC 17025.

The first version of the ISO / IEC 17025 referred to the ISO 9001 and 9002, which was later amended by the ISO 9001: 2000. In 2005, the second version of the standard was made which incorporated and amended certain provisions of the contents of the ISO 9001: 2000. This amendment required that laboratories comply with ISO / IEC 17025, as well as ISO 9001.

On the other hand, thanks to the growing use of quality management systems, and Resolution 116 of COMEX (Foreign Trade Committee) which restricts the entry of some goods imported into Ecuador, the need for laboratories to test functionality grew. Under the guidance of an international quality standard like ISO / IEC 17025, importers could ensure reliable and technically valid results in the test reports, which in turn permit the entry of certain restricted products into the country.

CHAPTER 1: PRODUCT IDENTIFICATION AND TYPE OF TEST

Introduction

With the entry into force of Resolution 116 of the Committee of Foreign Trade (COMEX) from December 3, 2013, a total of 293 products are required to submit a certificate of recognition, as a preliminary document, on the customs declaration to enter the country. These certificates are issued by the Ecuadorian Standards Institute (INEN).

For those products where there is no certification body accredited to issue INEN certificates, according to Resolution 002 of the Interministerial Committee for Quality (CIMC), the option of submitting test reports issued by private laboratories is accepted; provided they are accredited by the Ecuadorian Accreditation Organization (OAE). This body is responsible for compliance with the international standard ISO / IEC 17025 which regulates the competence of laboratories.

In this chapter, it is important to identify the product, type, and test method the UDALAB uses, based on the implementation of the International Standard; it is also important to mention that this law regulates laboratory activities based on the product being tested.

The research will be based on the analysis of foodstuffs restricted by Resolution 116 from 2010 until 2014, followed by a statistical study of monthly imports by sub-heading tariff during the five years mentioned. In addition, an analysis of importers, laboratories accredited by the OAE, and an exploration of the INEN rules will be performed; this will be done in order to determine the test method used within the scope of the project.

1.1 Legal regulations for food imports to Ecuador

Beginning in 2013, with the aim of changing the productive matrix of the country, many foreign trade policies of Ecuador were altered, especially those related to imports.

Today, new regulations and resolutions need to be considered when importing certain products.

1.1.1 Resolution 116 of the COMEX

The Organic Code of Production, Trade, and Investment (COPCI) created the Committee for Foreign Trade (COMEX) as the body responsible for the adoption of national policies on trade; so that, according to Article 72, paragraph (f) the COPCI is the power of COMEX to "issue rules on records, authorizations, documents, licenses, and import and export procedures, other than customs, general and sectoral, including the requirements that must be met, apart from customs formalities"[1]

In Resolution 116 of the COMEX, 155 products with different tariff sub-headings under food groups are subject to documents control, in addition to the necessity for a certificate of recognition by the INEN. (See Annex I).

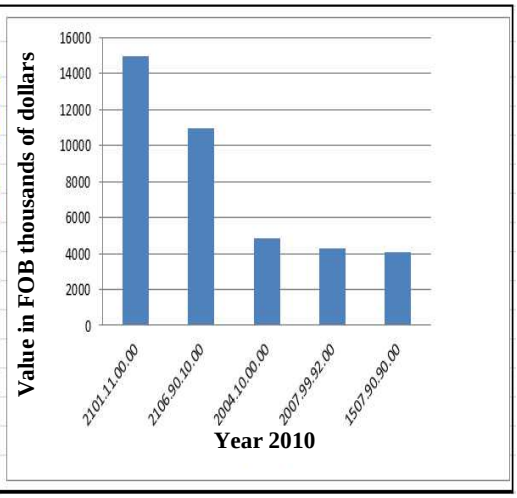
1.2 Industries of interest and importation statistics

The extensive list of foodstuffs restricted by Resolution 116 of the Comex shows the 13 most represented items from 2010 to 2014. Below is a table showing the FOB import values by tariff sub-heading for each year.

[1] Resolution 116 COMEX, 2013, Pg. 2

Illustration 1: Behavior of imports by tariff sub-heading in 2010

	Tariff Sub-heading	Value in FOB thousands of dollars
1	2101.11.00.00	14970,47
2	2106.90.10.00	10947,21
3	2004.10.00.00	4862,71
4	2007.99.92.00	4303,46
5	1507.90.90.00	4047,24
6	1901.90.90.00	3671,14
7	2103.90.20.00	3439,49
8	2101.20.00.00	2358,84
9	1602.50.00.00	2217,46
10	2103.90.90.00	1739,07
11	2104.10.10.00	1734,96
12	1509.10.00.00	1727,62
13	2101.12.00.00	1641,01
	TOTAL	57660,68



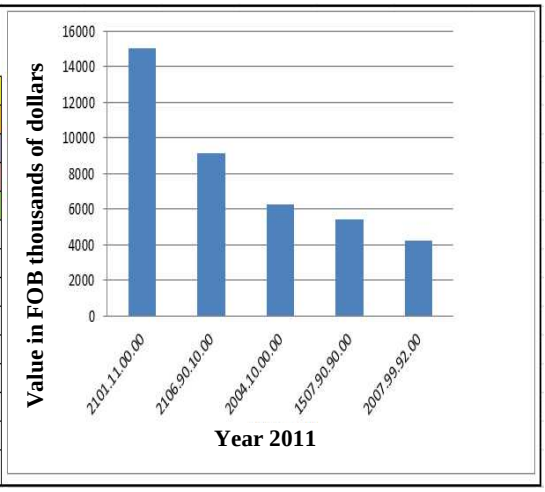
Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In illustration No. 1, according to data from the Central Bank of Ecuador, we can see the top 13 tariff sub-heading FOB values for imports in 2010; the total sum was $57.6 million. The following paragraph details the imports of the top 5 sub-headings.

The tariff sub-heading 2101.10.00.00 had the highest level of imports, reaching a total of $14.9 million, followed by 2106.90.10.00 with $10.9 million; the second highest sub-heading is 36.75% less than the first sub-heading. Third is the sub-heading 2004.10.00.00 at $4.8 million, which is 125% less than the second highest sub-heading. Finally, the fourth and fifth subheadings, 2007.99.92.00 and 1507.90.90.00, totaled $4.3 and $4 million, respectively. There was a decrease in imports of 12.99% between the third and fourth highest sub-headings and 6.33% between the fourth and fifth.

Illustration 2: Behavior of imports by tariff sub-heading for 2011

	Tarrif Sub-heading	Value in FOB thousands of dollars
1	2101.11.00.00	15029,42
2	2106.90.10.00	9165,48
3	2004.10.00.00	6234,11
4	1507.90.90.00	5439,29
5	2007.99.92.00	4229,85
6	1901.90.90.00	3901,8
7	2103.90.20.00	3869,58
8	1602.50.00.00	3082,36
9	2101.20.00.00	2284,85
10	2103.90.90.00	1836,38
11	1509.10.00.00	1834,07
12	2104.10.10.00	1643,32
13	2101.12.00.00	1596,08
	TOTAL	60146,59



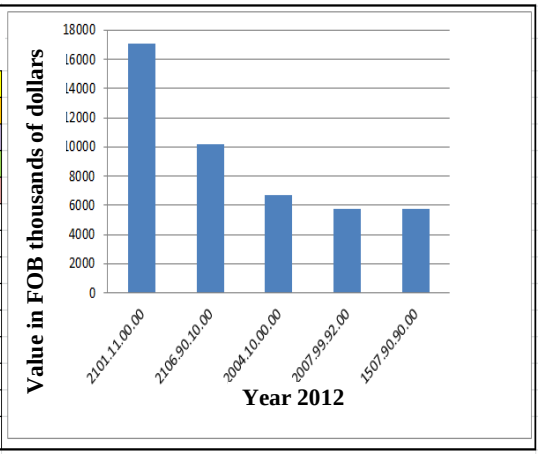
Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In illustration No. 2, according to data from the Central Bank of Ecuador, we can see the top 13 tariff sub-heading FOB values for imports in 2011; the total amount was $60 million. The following paragraph details the imports of the top 5 sub-headings.

The tariff sub-heading 2101.10.00.00 had the highest level of imports, reaching a total of $15 million, followed by 2106.90.10.00 with $9.1 million; there was a 63.97% less import value with respect to the first sub-heading. Third is the subheading 2004.10.00.00 with $6.2 million, which represents 47% less than the second sub-heading. Finally, in fourth and fifth place are the subheadings 1507.90.90.00 and 2007.99.92.00 with $5.4 and $4.2 million, respectively. There was a decrease in imports by 14.61% between the third and fourth sub-headings, and 28.59% between the fourth and fifth.

Illustration 3: Behavior of imports by tariff sub-heading for 2012

	Tarrif Sub-heading	Value in FOB thousands of dollars
1	2101.11.00.00	17111,42
2	2106.90.10.00	10184,32
3	2004.10.00.00	6677,4
4	2007.99.92.00	5795,45
5	1507.90.90.00	5724,86
6	2101.12.00.00	4959,84
7	2103.90.20.00	4423,39
8	2101.20.00.00	4169,22
9	1901.90.90.00	4094,48
10	1602.50.00.00	3422,48
11	2103.90.90.00	2214,77
12	1509.10.00.00	2158,04
13	2104.10.10.00	1621,01
	TOTAL	**72556,68**



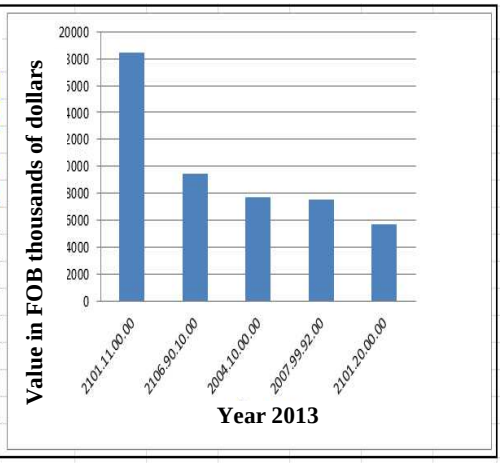
Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In illustration No. 3, according to data from the Central Bank of Ecuador, we can see the top 13 tariff sub-heading FOB values for imports in 2012; the total sum was $72 million. The following paragraph details the imports of the top 5 sub-headings.

The tariff sub-heading 2101.10.00.00 had the highest level of imports, reaching a total of $17 million, followed by 2106.90.10.00 with $10 million; there was a 68.01% lower value of imports for the second sub-heading compared to the first. Third is the subheading 2004.10.00.00 with $6 million, which represents 52.50% less imports than the second sub-heading. Finally, in fourth and fifth place are the subheadings 2007.99.92.00 and 1507.90.90.00 with $5.75 and $5.72 million, respectively. There was a difference in imports value of 15.21% between the third and fourth sub-headings, and 1.23% between the fourth and fifth.

Illustration 4: Behavior of imports by tariff sub-heading for 2013

	Tarrif Sub-heading	Value in FOB thousands of dollars
1	2101.11.00.00	18469,59
2	2106.90.10.00	9490,65
3	2004.10.00.00	7702,07
4	2007.99.92.00	7505,59
5	2101.20.00.00	5681,88
6	2103.90.20.00	4991,6
7	1901.90.90.00	4799,91
8	2104.10.10.00	4026,91
9	2101.12.00.00	3870,17
10	1509.10.00.00	3830,33
11	1602.50.00.00	3180,1
12	1507.90.90.00	2832,24
13	2103.90.90.00	2827,38
	TOTAL	79208,42



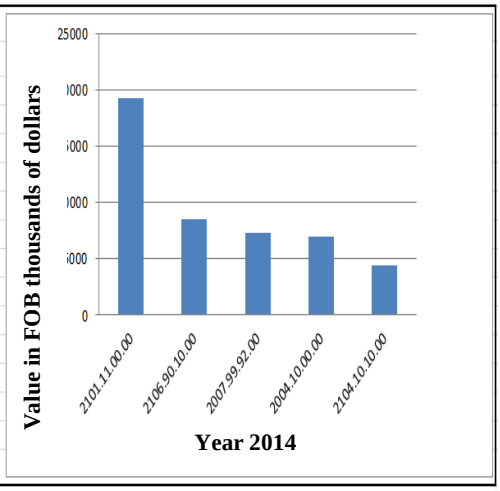
Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In illustration No. 4, according to data from the Central Bank of Ecuador, we can see the top 13 tariff sub-heading FOB values for imports in 2013; the total sum was $79 million. The following paragraph details the imports of the top 5 sub-headings.

The tariff sub-heading 2101.10.00.00 had the highest level of imports, reaching a total of $18 million, followed by 2106.90.10.00 with $9.4 million; there was a 94.61 % lower value of imports for the second sub-heading compared to the first. Third is the sub-heading 2004.10.00.00 with $7.7 million which represents 23.22% less imports compared to the second sub-heading. Finally, in fourth and fifth places are the subheadings 2007.99.92.00 and 2101.20.00.00 with $7.5 and $5.6 million, respectively. There was a difference in imports value of 2.62% between the third and fourth sub-headings, and 32.09% between the fourth and fifth.

Illustration 5: Behavior of imports by tariff sub-heading for 2014

	Tarrif Sub-heading	Value in FOB thousands of dollars
1	2101.11.00.00	19272,3
2	2106.90.10.00	8576,95
3	2007.99.92.00	7307,71
4	2004.10.00.00	7008,8
5	2104.10.10.00	4377,2
6	2103.90.20.00	4295,63
7	1602.50.00.00	3075,53
8	2103.90.90.00	2968,05
9	1509.10.00.00	2923,46
10	2101.20.00.00	2737,15
11	1901.90.90.00	2461,18
12	2101.12.00.00	1846,68
13	1507.90.90.00	1023,76
	TOTAL	67874,4



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In illustration No. 5, according to data from the Central Bank of Ecuador, we can see the top 13 tariff sub-heading FOB values for imports in 2014; the total sum was $67.8 million. The following paragraph details the imports of the top 5 sub-headings.

The tariff sub-heading 2101.10.00.00 had the highest level of imports, reaching a total of $19.2 million, followed by 2106.90.10.00 with $8.5 million; there was a 124.70 lower value of imports for the second sub-heading compared to the first. Third is the sub-heading 1 2007.99.92.00 with $7.3 million, which represents 17.36% less imports compared to the second sub-heading. Finally, in fourth and fifth place are the subheadings 2004.10.00.00 and 21.04.10.10.00 with $7.0 and $4.3 million, respectively. There was a difference in imports value of 4.26% between the third and fourth sub-headings, and 60.12% between the fourth and fifth.

As shown in the above illustrations, for each year, the FOB value of imports varies by tariff sub-heading. The total FOB value of imports was detailed from 2010 to 2014; thus, the top 5 tariff sub-items with the highest FOB import values were established for that time period

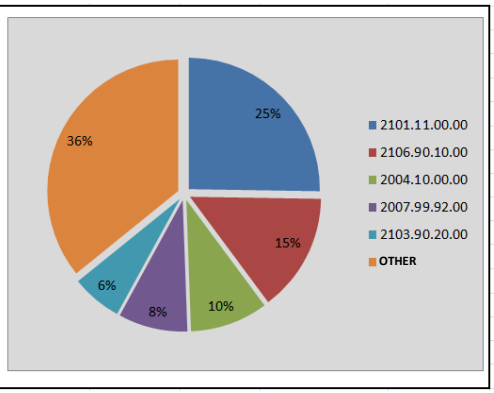
Table 1: Behavior of imports by tariff sub-heading from 2010 to 2014

TOTAL IMPORTS BY TARIFF SUB-HEADING FROM 2010 TO 2014								
	TARIFF SUB-HEADING	FOOD PRODUCT	Unit: FOB Value in thousands of dollars					
			2010	2011	2012	2013	2014	TOTAL
1	2101.11.00.00	Extracts, essences, and concentrates	14,970.47	15,029.42	17,111.42	18,469.59	19,272.30	**84,853.20**
2	2106.90.10.00	Powders for the preparation of puddings, creams, ice creams, desserts, jellies, and the like	10,947.21	9,165.48	10,184.32	9,490.65	8,576.95	**48,364.61**
3	2004.10.00.00	Potatos	4,862.71	6,234.11	6,677.40	7,702.07	7,008.80	**32,485.09**
4	2007.99.92.00	Purees and pastas	4,303.46	4,229.85	5,795.45	7,505.59	7,307.71	**29,142.06**
5	2103.90.20.00	Condomintes and seasonings, composites	3,439.49	3,869.58	4,423.39	4,991.60	4,295.63	**21,019.69**
6	1507.90.90.00	Other (only for processed, canned, and packaged food products)	4,047.24	5,439.29	5,724.86	2,832.24	1,023.76	**19,067.39**
7	1901.90.90.00	Other (only for processed, canned, and packaged food products)	3,671.14	3,901.80	4,094.48	4,799.91	2,461.18	**18,928.51**
8	2101.20.00.00	Tea and mate extracts, essences, and concentrates and preperations compossed of these extracts, essences, or concentrates compossed of tea o mate	2,358.84	2,284.85	4,169.22	5,681.88	2,737.15	**17,231.94**
9	1602.50.00.00	Of the bovine species	2,217.46	3,082.36	3,422.48	3,180.10	3,075.53	**14,977.93**
10	2101.12.00.00	Preperations compossed of extracts, essences, o concentrates or compossed of coffee	1,641.01	1,596.08	4,959.84	3,870.17	1,846.68	**13,913.78**
11	2104.10.10.00	Preperations for soups, stews, or broths	1,734.96	1,643.32	1,621.01	4,026.91	4,377.20	**13,403.40**
12	1509.10.00.00	Virgin	1,727.62	1,834.07	2,158.04	3,830.33	2,923.46	**12,473.52**
13	2103.90.90.00	Condomintes and seasonings, composites	1,739.07	1,836.38	2,214.77	2,827.38	2,968.05	**11,585.65**

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Illustration 6: Representation of imports by tariff sub-heading from 2010 to 2014

	Tarrif Sub-heading	Imports (%) Period 2010 – 2014
1	2101.11.00.00	24,51
2	2106.90.10.00	14,14
3	2004.10.00.00	9,33
4	2007.99.92.00	8,3
5	2103.90.20.00	6,04
6	OTHER	34,75
	TOTAL	**100**



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In No. 1 table and illustration No. 6 we see the 5 sub-tariff items that have greater representation from 2010 to 2014; sub-heading 2101.11.00.00, corresponding to extracts, essences, and concentrates, has the largest FOB value of imports with a total of $84.8 million or 24.51%. In second place is powders for the preparation of puddings, creams, ice cream, desserts, gelatins, and the like, its sub-heading is 2106.90.10.00 and had a FOB value of $48.3 million or 14.14%; this is 75% less than imports for the first tariff sub-heading. Third are potatoes (2004.10.00.00) with a FOB value of $32.4 million, representing 9.33%, 51.55 % less than the second place tariff sub-heading. Third are purees and pastes (2007.99.92.00) with an FOB value of $29.1 million of dollars or 8.30%, a difference of 12.40% compared to the third place tariff sub-heading. Finally, in fifth place are condiments and mixed seasonings (2103.90.20.00) with a FOB value of $21 million or 6.04%, 37.4% less than the fourth place tariff sub-heading.

The remaining 8 tariff sub-headings are classified as “OTHER” as these do not require food laboratory testing by the UDALAB; these represent 34.75% of total imports during the period 2010-2014.

To better understand the behavior of the imports of the five, aforementioned sub-heading tariffs, the FOB value of monthly imports will be analyzed. Information over a

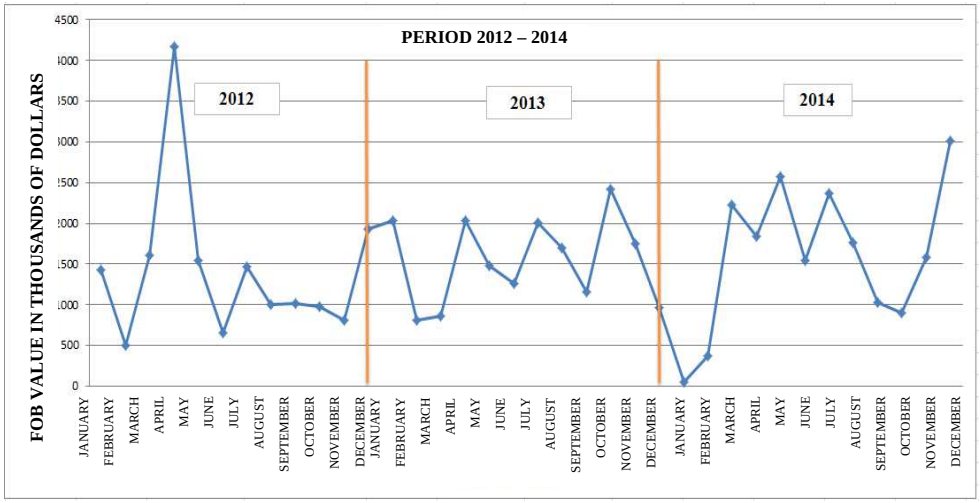
three year period will be taken, one before the implementation of COMEX Resolution 116 and one after; this is done in order to see any difference after the entry into force of the resolution.

Table 2: Total monthly imports of sub-heading 2101.10.00.00, from 2012 to 2014

BEHAVIOR OF TOTAL MONTHLY IMPORTS IN MONTHS FROM 2012 TO 2014			
	Unit: FOB value in thousands of dollars		
MONTHS	**2012**	**2013**	**2014**
JANUARY	1,429.66	2,034.43	55.51
FEBRUARY	506.35	813.20	371.47
MARCH	1,610.75	856.76	2,230.87
APRIL	4,165.17	2,035.94	1,840.55
MAY	1,546.78	1,485.51	2,578.70
JUNE	661.03	1,260.30	1,541.22
JULY	1,467.54	2,002.03	2,370.05
AUGUST	1,000.36	1,694.68	1,765.16
SEPTEMBER	1,009.94	1,162.03	1,022.39
OCTOBER	973.26	2,413.34	905.75
NOVEMBER	808.89	1,748.70	1,576.35
DECEMBER	1,931.75	962.74	3,014.33
TOTAL	**17,111.48**	**18,469.66**	**19,272.35**

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Illustration 7: Behavior of total imports in months of sub-heading 2101.10.00.00, from 2012 to 2014



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

As shown in table No. 2 and illustration No. 7, the behavior of imports of sub-heading 2101.10.00.00 during the period 2012-2014 varies significantly; February of 2012 experienced the biggest drop in imports to $506 thousand. Conversely, in the month of April, imports increased significantly, reaching a peak of $4.1 million. The illustration shows a trend of highs and lows over the months, reaching a total of $1.9 million in imports in the month of December.

During 2013, the behavior is just as varied; imports in the month of February of this sub-heading experienced the biggest drop, with a total of $813 thousand. October experienced the highest amount, reaching a total of $2.4 million.

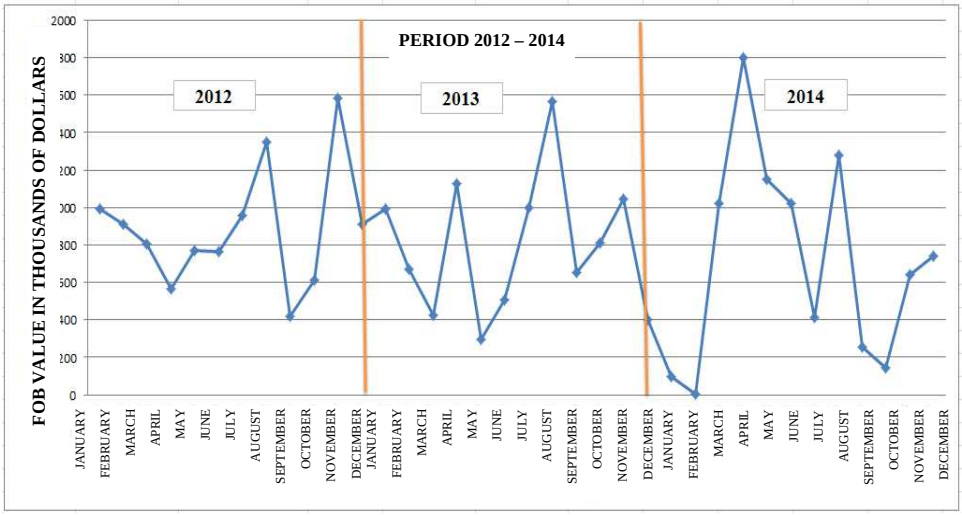
With the entry into force of COMEX Resolution 116, as of December 2013, we can see how imports reduced. In January 2014, there was a total of $55 thousand in imports, the lowest value of imports; however, despite the restriction, starting in February, imports began to fluctuate; reaching a grand total of $3 million in December, the highest value for imports for the whole year.

Table 3: Total monthly imports of sub-heading 2106.90.10.00, from 2012 to 2014

BEHAVIOR OF TOTAL MONTHLY IMPORTS IN MONTHS FROM 2012 TO 2014			
	Unit: FOB value in thousands of dollars		
MONTHS	**2012**	**2013**	**2014**
JANUARY	993.04	993.04	96.16
FEBRUARY	911.41	669.18	3.62
MARCH	804.69	423.13	1,020.21
APRIL	564.10	1,127.83	1,803.40
MAY	768.17	294.01	1,152.09
JUNE	764.38	505.18	1,020.71
JULY	959.99	998.67	413.89
AUGUST	1,351.49	1,566.28	1,281.98
SEPTEMBER	418.28	651.64	257.07
OCTOBER	613.68	813.30	141.71
NOVEMBER	1,584.19	1,045.78	642.26
DECEMBER	912.88	402.65	743.89
TOTAL	**10,646.30**	**9,490.69**	**8,576.99**

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Illustration 8: Behavior of total imports in months of sub-heading 2106.90.10.00, from 2012 to 2014



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table No. 3 and illustration No. 8 shows the behavior of monthly imports of sub-heading 2106.90.10.00.00 from 2012 to 2014. During the first year it shows that imports declined from January to April; from May, imports begin to grow, reaching a limit of $1.3 million in August. In September, imports fell again to $418 thousand but recovered in November, reaching the highest amount of imports for the reference year with a total of $1.5 million. Finally, in December, imports decreased again to a total of $912 thousand.

Likewise, in 2013, we see that the behavior of imports shows no consistency. Between April and May, imports dropped from $1.1 million to $294 thousand. The month of August experienced the highest number of total imports at $1.5 million.

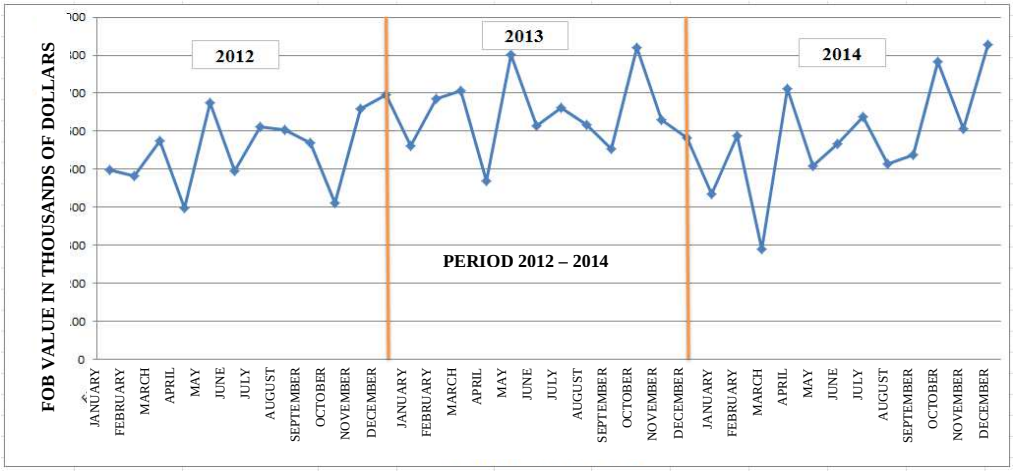
Finally, with the entry into force of COMEX Resolution 116 in December of 2013, we can see a significant decrease in imports in February of 2014; however, in March, imports began to grow, reaching $1.8 million in April. From May on, imports continued to fluctuate, ending the year with a total of $743 thousand dollars.

Table 4: Total monthly imports of sub-heading 2004.10.00.00, from 2012 to 2014

BEHAVIOR OF TOTAL MONTHLY IMPORTS IN MONTHS FROM 2012 TO 2014			
	Unit: FOB value in thousands of dollars		
MONTHS	**2012**	**2013**	**2014**
JANUARY	498.85	562.62	435.12
FEBRUARY	483.18	684.99	587.31
MARCH	575.03	706.96	289.46
APRIL	399.40	469.72	711.84
MAY	673.90	800.85	509.42
JUNE	494.94	614.32	565.75
JULY	610.71	661.50	638.87
AUGUST	604.55	616.92	514.28
SEPTEMBER	570.17	552.97	538.66
OCTOBER	412.42	818.66	782.16
NOVEMBER	658.96	629.06	607.58
DECEMBER	695.33	583.55	828.39
TOTAL	**6,677.44**	**7,702.12**	**7,008.84**

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Illustration 9: Behavior of total imports in months of sub-heading 2004.10.00.00, from 2012 to 2014



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

According to table No. 4 and illustration No. 9, the behavior of imports of tariff sub-heading 2004.10.00.00 from 2012 to 2014 is quite uneven. During 2012, imports were overall high; in May, they reached a peak of $673 thousand. The least amount of imports for 2012 was experienced in April, with a total of $399 thousand. In April of 2013, imports dropped to a total of $469 thousand; in October, the highest amount of imports was recorded with a total of $818 thousand.

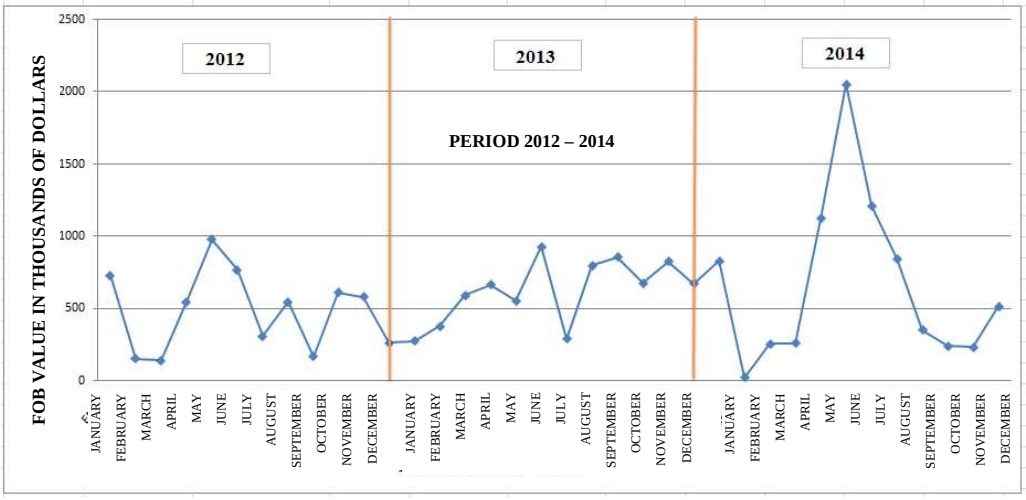
Finally, with the entry into force of COMEX Resolution 116 in early December 2013, we can see that imports fall in January; starting in February 2014, imports began to fluctuate. March recorded the lowest amount of imports for the year with a total of $289 thousand; December had the highest number of imports for 2014 with a total of $828.39 thousand.

Table 5: Total monthly imports of sub-heading 2007.99.92.00, from 2012 to 2014

BEHAVIOR OF TOTAL MONTHLY IMPORTS IN MONTHS FROM 2012 TO 2014			
	Unit: FOB value in thousands of dollars		
MONTHS	**2012**	**2013**	**2014**
JANUARY	729.23	274.44	828.39
FEBRUARY	153.00	376.79	21.78
MARCH	143.15	591.43	256.12
APRIL	546.80	665.41	260.73
MAY	976.33	553.34	1,121.22
JUNE	767.74	929.24	2,049.37
JULY	307.78	289.69	1,211.56
AUGUST	546.65	796.87	844.39
SEPTEMBER	168.06	856.06	351.22
OCTOBER	611.96	675.82	241.87
NOVEMBER	579.92	825.63	232.10
DECEMBER	264.87	670.93	515.56
TOTAL	**5,795.49**	**7,505.65**	**7,934.31**

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Illustration 10: Behavior of total imports in months of sub-heading 2007.99.92.00, from 2012 to 2014



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

In table No. 5 and figure No. 10, the behaviors of imports of sub-heading 2007.99.92.00 are shown during the period of 2012 to 2014. In 2012, we can see that imports vary, as the data in March show the biggest drop to $143 thousand; May had the largest amount of imports with a total of $976 thousand. In 2013, we can see that in the early months of that year imports increased; but, from April to May, imports went from $665 to $553 thousand. In June of that same year, imports reached its peak for the year at $929 thousand; suddenly however, in July, imports fell to $289 thousand, this was the largest decrease in imports for the year.

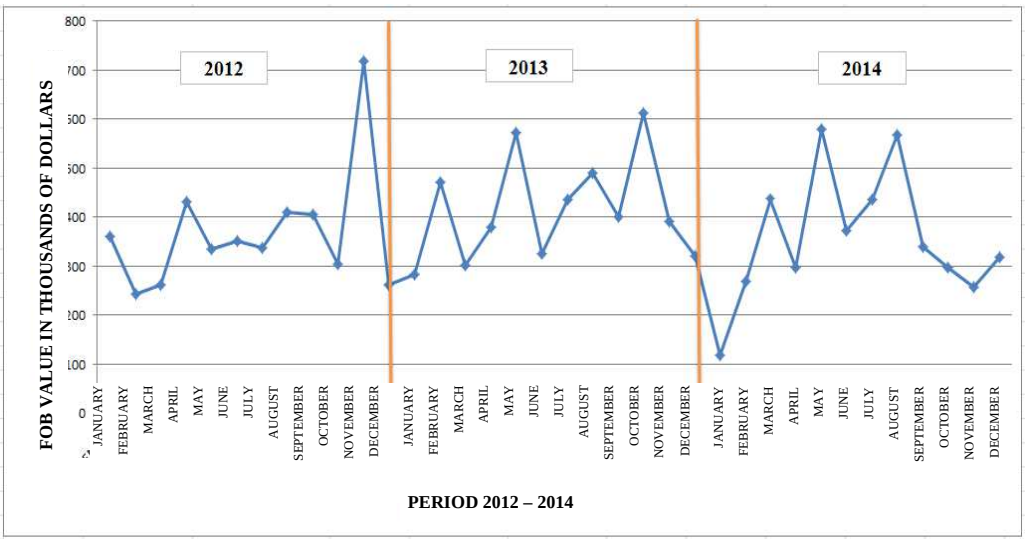
Finally, in December, with the entry into force of COMEX Resolution 116, imports fell. At the beginning of 2014, in January, the level of imports increased; but, there was a dramatic decrease in February, going from $828 to $21 thousand. Imports recovered in June, reaching its maximum amount of $2 million; however, the downward trend continued mostly for the year until December, where imports recovered slightly, reaching an amount of $515 thousand.

Table 6: Total monthly imports of sub-heading 2103.90.20.00, from 2012 to 2014

BEHAVIOR OF TOTAL MONTHLY IMPORTS IN MONTHS FROM 2012 TO 2014			
	Unit: FOB value in thousands of dollars		
MONTHS	**2012**	**2013**	**2014**
JANUARY	361.32	282.37	119.84
FEBRUARY	244.57	472.34	269.30
MARCH	262.36	302.83	438.62
APRIL	431.71	378.98	298.32
MAY	334.07	573.57	580.57
JUNE	352.53	326.58	371.75
JULY	336.68	436.31	436.59
AUGUST	409.51	491.33	567.48
SEPTEMBER	406.70	401.00	340.32
OCTOBER	304.48	612.36	297.36
NOVEMBER	717.70	391.72	257.74
DECEMBER	261.83	322.26	317.79
TOTAL	**4,423.46**	**4,991.65**	**4,295.68**

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Illustration 11: Behavior of total imports in months of sub-heading 2103.90.20.00, from 2012 to 2014



Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table No. 6 and illustration No. 11 show the behavior of monthly imports of sub-heading 2103.90.20.00.00 from 2012 to 2014. During the first year it shows that imports varied; in the month of November there was a total of $717 thousand and in December there was a total of $261 thousand. In 2013, imports fluctuated greatly. October stood out with a total of $612 thousand, the highest volume of imports for the year. The month of January had a total of $282 thousand which had the lowest recorded volume of imports for the year.

Finally, with the entry into force of COMEX Resolution 116, imports for December 2013 and January 2014 fell from $322 to $119 thousand. In the months of February and March, imports increased; however, they fell again in April. In May, import volumes peaked for the year with a value of $580 thousand; by the end of the year, after a lot of variation in totals, imports maintained at $317.79 thousand.

After analyzing monthly imports by tariff sub-heading for the period 2012-2014, we concluded that imports by months are quite unbalanced in each sub-heading as ups and

downs were observed month after month; and, due to the entry into force of COMEX Resolution 116, imports in most of the five cases declined during this period. Nevertheless, according to the analysis, imports began to recover over the course of 2014. Accordingly, the food laboratory UDALAB, regardless of tariff sub-heading, should be aware that there are high import seasons, as well as off seasons.

1.3 Analysis of importers and laboratories accredited by the OAE

Table 7: Importers of tariff sub-heading 2101.10.00.00 during the period 2010-2014

Importers of tariff sub-heading 2101.10.00.00 during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	WHOLEBUSINESS S.A.	1	CORPORACION DISTRIBUIDORA DE ALIMENTOS S.A. CORDI
2	KOMOLY TRAVEL	2	INT FOOD SERVICES CORP.
3	SOLUBLES INSTANTANEOS	3	NESTLE ECUADOR S.A.
		4	PYDACO CIA. LTDA.
		5	SUPERMERCADOS LA FAVORITA C A
		6	PRODUCTOS MINERVA CIA LTDA

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table 8: OAE-accredited laboratories that test extracts, essences, and concentrates (2101.11.00.00) during the period 2010-2014

OAE-accredited laboratories that test extracts, essences, and concentrates (2101.11.00.00) during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	LABORATORIO LAZO	1	LABORATORIO GUIJARRO LASA S.A.
2	SGS DEL ECUADOR	2	LABORATORIO MULTIANALITYCA
3		3	LABORATORIO OSP

Prepared by: Romero, Pamela **Source:** Ecuadorian Accreditation Organization

Table No. 7 shows the importers of sub-heading 2101.10.00.00 during the period 2010-2014. In total there are 9 importers nationwide, 3 of them are located in Guayaquil and 6 of them are located in Quito.

Table No. 8 shows the number of OAE accredited laboratories performing tests on extracts, essences, and concentrates under the sub-heading 2101.10.00.00 from 2010 to 2014. In this context, there are a total of 6 laboratories, 3 in the city of Guayaquil and 3 in Quito. We can safely conclude that the food laboratory, UDALAB, does not need to service this sub-item as there are no companies that import this item in the city of Cuenca. Although there are importers in the cities of Quito and Guayaquil, the aforementioned importers obviously prefer the comfort and services of accredited laboratories in their own cities. If they were to use the services of UDALAB in Cuenca it would only mean higher costs and inconveniences for the company.

Table 9: Importers of tariff sub-heading 2106.90.10.00 during the period 2010-2014

Importers of tariff sub-heading 2106.90.10.00 during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	AJECUADOR S.A.	1	ABCALSA S.A.
2	ARTEGELATO ECUADOR S.A.	2	ALITECNO COMERCIO E INSUMOS PARA IND. ALIMENTOS
3	BRISVAN S.A.	3	ALPINA PRODUCTOS ALIMENTICIOS ALPIECUADO
4	CANDYPLANET S.A.	4	AMERICANA DE COMERCIO AMEXCO CIA LTDA
5	COMDERE S.A.	5	COMERCIALIZADORA ADEUCARPI CIA.LTDA
6	DIARJO S.A.	6	DIBEAL CIA. LTDA.
7	DINEILY S.A.	7	DIRICOFOOD SOLUTIONS S.A.
8	DISTRIBUIDORA DESCALZI S.A.	8	DISTRIBUIDORA IMPORTADORA DIPOR S.A.
9	DONUT HOUSE S.A.	9	DSM BAKERY INGREDIENTS - ECUADOR S.A.
10	FOLIT S.A.	10	ECUESSENCE CIA LTD.
11	IMPORTADORA EL ROSADO S.A.	11	FORNASINI SALVADOR MARIO NINO
12	INDUSTRIAS LACTEAS TONI S.A.	12	GOOD FOOD DEL ECUADOR GFECU S.A
13	INMOCORI S.A.	13	INDUSTRIAL SURINDU S.A.
14	ITALGIMA S.A.	14	INT FOOD SERVICES CORP.
15	KEYSTONE DISTRIBUTION ECUADOR S.A.	15	LEVAPAN DEL ECUADOR S. A.
16	KRAFT FOODS ECUADOR S.A.	16	OBSIDIAN CIA. LTDA.
17	MELOSITOS GOURMET	17	PRODUCTOS MINERVA CIA. LTDA.
18	PROLACHIV S.A.	18	ROJAS DE D'ALIA ANA LUCIA
19	SUJOLI IMPORTACIONES CIA. LTDA.	19	SCHERING PLOUGH DEL ECUADOR S.A.
20	SUMESA S.A.	20	SUPERMERCADOS LA FAVORITA C A
21	SUNKOVA S.A.	21	SYQUEM QUIMICOS Y SERVICIOS S.A.
		#	CUENCA
		1	DISTRIBUIDORA DE PRODUCTOS JUCREMO JCC CIA.LTDA
		2	EQUINDECAEQUIPOS PARA LA INDUSTRIA ALIMENTICIA

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table 10: OAE-accredited laboratories that test powders for the preparation of puddings, creams, ice cream, desserts, gelatins, and the like (2106.90.10.00) during the period 2010-2014

OAE-accredited laboratories that test powders for the preparation of puddings, creams, ice cream, desserts, gelatins, and the like (2106.90.10.00) during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	LABORATORIO DE ALIMENTOS PROCESADOS DE ARCSA	1	LABORATORIO DE ALIMENTOS PROCESADOS DE ARCSA
2	LABORATORIO LAZO	2	LABORATORIO GUIJARRO LASA S.A.
3	LABORATORIO DEL PROGRAMA DE TECNOLOGÍA DE ALIMENTOS – PROTAL	3	LABORATORIO MULTIANALITYCA
4	SGS DEL ECUADOR-LABORATORIO SECTOR AGRI	4	LABORATORIO OSP
		5	LABORATORIO SEIDLABORATORY CIA. LTDA

Prepared by: Romero, Pamela **Source:** Ecuadorian Accreditation Organization

Table No. 9 shows the importers of sub-heading 2106.90.10.00 during the period 2010-2014. There are a large number of importers of this sub-heading, a total of 44 nationwide; 21 are located in the city of Guayaquil, 21 in Quito, and 2 in the city of Cuenca.

Table No. 10 shows the number of accredited laboratories performing OAE testing on powders for the preparation of puddings, creams, ice cream, desserts, gelatins, and the like under tariff sub-heading 2106.90.10.00 from 2010 to 2014. In this context, there are a total of 9 laboratories, 4 located in the city of Guayaquil and 5 in the city of Quito. Consequently, we conclude that UDALAB could consider servicing this tariff sub-heading as there are at least 2 importers in the city of Cuenca; the laboratory may offer its services as the best option before sending the samples to Quito or Guayaquil. In addition, according to table No. 12, there is no accredited laboratory by the OAE to perform tests for these products in the city of Cuenca; thus, there is currently no competition for UDALAB in Cuenca.

Table 11: Importers of the tariff sub-heading 2004.10.00.00 during the period 2010-2014

Importers of the tariff sub-heading 2004.10.00.00 during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	CONSORCIO CEVALLOS SANCHEZ S.A. CONSORCESA	1	DISTRIBUIDORA IMPORTADORA DIPOR S.A.
2	IMPORTADORA EL ROSADO S.A.	2	INT FOOD SERVICES CORP.
3	IMPORTADORA MANUEL PESANTEZ & HIJOS CIA. LTDA.	3	KYPROSS S.A.
4	KEYSTONE DISTRIBUTION ECUADOR S.A.	4	PROCESADORA NACIONAL DE ALIMENTOS C.A. PRONACA
5	KONERU S.A.	5	SUPERMERCADOS LA FAVORITA C A
6	LOGISTICA DE ALIMENTOS LOGALISA S.A.		
7	SUD FOOD SERVICE S.A. SUDFOODSA		
8	TROPICALIMENTOS S.A.		
9	VECONSA S.A.		

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table 12: OAE-accredited laboratories that test potatoes (2004.10.00.00) during the period 2010-2014

OAE-accredited laboratories that test potatoes (2004.10.00.00) during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	LABORATORIO DE ALIMENTOS PROCESADOS DE ARCSA	1	LABORATORIO DE ALIMENTOS PROCESADOS DE ARCSA
2	SGS DEL ECUADOR-LABORATORIO SECTOR AGRI	2	

Prepared by: Romero, Pamela **Source:** Ecuadorian Accreditation Organization

Table No. 11 shows importers of the sub-heading 2004.10.00.00 during the period 2010-2014. In total there are 14 importers nationwide, 9 of which are located in Guayaquil and 5 of them are located in Quito.

Table No. 12 shows the number of OAE-accredited laboratories performing tests on potatoes under the sub-heading 2004.10.00.00 from 2010 to 2014. In this context, there are a total of 3 laboratories, 2 in the city of Guayaquil and 1 in Quito. We can presume that UDALAB is not needed to test potatoes; because, as we can see in the tables, both importers and laboratories are in the cities of Quito and Guayaquil. UDALAB would be unproductive if they promoted their services to importers in Quito and Guayaquil; since, as previously explained, these would unnecessarily need to send samples to laboratories in Cuenca when they already have labs in their own cities.

Table 13: Importers of tariff sub-heading 2007.99.92.00 during the period 2010-2014

Importers of tariff sub-heading 2007.99.92.00 during the period 2010-2014			
#	**GUAYAQUIL**	#	**QUITO**
1	ABASTECIMIENTOS INDUST.IMP.Y EXP. S.A. ABIMEXPORT	1	ALPINA PRODUCTOS ALIMENTICIOS ALPIECUADO
2	AJECUADOR S.A.	2	DIRICOFOOD SOLUTIONS S.A.
3	BANAPUREE S.A.	3	ECUADOR BOTTLING COMPANY CORP.SUCURSAL ECUADOR
4	BEBIDAS ARCACONTINENTAL ECUADOR ARCADOR S.A	4	ECUAJUGOS S.A.
5	BIOALIMENTOS CIA. LTDA.	5	FROZEN TROPIC CIA. LTDA.
6	DELISODA S.A.	6	LEVAPAN DEL ECUADOR S. A.
7	ECUAVEGETAL S.A.	7	THE TESALIA SPRINGS COMPANY
8	EXOFRUT S.A.		
9	IMPORTADORA CANDYLAN S.A.		
10	IMPORTADORA EL ROSADO S.A.	#	**CUENCA**
11	INDUSTRIAS LACTEAS TONI S.A.		
12	QUICORNAC S.A.	1	LACTEOS SAN ANTONIO C.A.
13	SUMESA S.A.	2	ORTIZ JACOME DE COMERCIO CIA.LTDA.
14	TROPICALIMENTOS S.A.		
15	VVK ALIMENTOS CIA. LTDA.		
16	FUTURCORP S.A.		

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table 14: OAE-accredited laboratories that test purees and pastes (2007.99.92.00) during the period 2010-2014

OAE-accredited laboratories that test purees and pastes (2007.99.92.00) during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	SGS DEL ECUADOR-LABORATORIO SECTOR AGRI	1	LABOLAB CÍA. LTDA.
2	LABORATORIO LAZO	2	LABORATORIO MULTIANALITYCA
		3	LABORATORIO OSP

Prepared by: Romero, Pamela **Source:** Ecuadorian Accreditation Organization

Table No. 13 shows importers of the sub-heading 2007.99.92.00 during the period 2010-2014. Similarly there are a large number of importers in this sub-heading, a total of 25 nationwide, of which 16 of them are located in the city of Guayaquil, 7 in Quito, and 2 in the city of Cuenca.

Table No. 14 shows the number of OAE-accredited laboratories performing tests on purees and pastes under tariff sub-heading 2007.99.92.00 from 2010 to 2014. In this context, there are a total of 5 laboratories, 2 located in the city of Guayaquil and 3 in the city of Quito. Considering the above, we could say that UDALAB could offer their services to the two importers located in the city of Cuenca, as the importers in Quito and Guayaquil would probably opt for the services offered by laboratories in their own cities. As of 2014, there is no accredited laboratory by the OAE to perform tests for these products in the city of Cuenca; thus, there is currently no competition for UDALAB in Cuenca.

Table 15: Importers of tariff sub-heading 2103.90.20.00 during the period 2010-2014

Importers of tariff sub-heading 2103.90.20.00 during the period 2010-2014					
#	GUAYAQUIL	#	QUITO	#	CUENCA
1	COMDERE S.A.	1	ALITECNO COMERCIO E INSUMOS	1	ALIMENTOS ECUATORIANOS LOS ANDES S.A.
2	COMERCIALICVAR CIA. LTDA.	2	AMERICANA DE COMERCIO AMEXCO CIA LTDA	2	CASA COMERCIAL ALMEIDA CIA. LTDA.
3	EMBUTSER S.A.	3	CARLITA SNACKS CARLISNACKS CIA. LTDA.		
4	EMPRESA PESQUERA ECUATORIANA S.A. (EMPESEC)	4	CARSNACK S.A.		
5	GALAPESCA S.A.	5	DATUGOURMET CIA.LTDA	#	QUEVEDO
6	ICHIBAN S.A.	6	DISTRIBUIDORA ALIMONY S.A.		
7	IMPORTADORA EL ROSADO S.A.	7	DISTRIBUIDORA IMPORTADORA DIPOR S.A.	1	ORIENTAL INDUSTRIA ALIMENTICIA O.I.A. CIA.LTDA.
8	INDUSTRIAS ALIMENTICIAS ECUATORIANAS S.A	8	INT FOOD SERVICES CORP.		
9	NEGOCIOS INDUSTRIALES REAL NIRSA S.A.	9	PRONACA		
10	PASTELO S.A.	10	SPORTPLANET S.A.	#	MANTA
11	PHILLIPS SEAFOOD OF ECUADOR C.A.	11	SU YU LIN		
12	PROD.ALIMENT.Y LICORES PROALCO CIA.LTD.	12	CRANDON DEL ECUADOR	1	IND.ECUAT.PROD.DE ALIMENTOS C.A.
13	PRODUPLANT S.A.	13	DIBEAL CIA. LTDA.		
14	PUNTO CALIENTE S.A. PUNCALSA	14	DISNAC S. A.		
15	QUIMICA SUIZA INDUSTRIAL DEL ECUADOR QSI S.A.	15	FABRICA JURIS C. LTD		
16	RIKOCOM ALIMENTOS S.A.	16	GOOD FOOD DEL ECUADOR GFECU S.A		
17	SAZONADORES DEL PACIFICO C.LTDA.	17	INDUSTRIA AGRICOLA EXP. INAEXPO		
18	SUMESA S.A.	18	NESTLE ECUADOR S.A.		
19	SUPERCINES S.A.	19	PAPIZZEC CIA. LTDA.		
20	TIOSA S.A.	20	QUALA ECUADOR S.A.		
21	TROPICALIMENTOS S.A.	21	QUIMICA COMERCIAL CIA.LTDA.		
		22	SNACKS AMERICA LATINA ECUADOR		
		23	SUPERMERCADOS LA FAVORITA C A		
		24	THE EXOTIC BLENDS CO. BLEXOTIC S.A.		

Prepared by: Romero, Pamela **Source:** Central Bank of Ecuador

Table 16: OAE-accredited laboratories that test condiments and mixed seasonings (2103.90.20.00) during the period 2010-2014

OAE-accredited laboratories that test condiments and mixed seasonings (2103.90.20.00) during the period 2010-2014			
#	GUAYAQUIL	#	QUITO
1	AVILÉS Y VÉLEZ "AVVE"	1	LABORATORIO GUIJARRO LASA S.A.
2	LABORATORIO LAZO	2	LABORATORIO MULTIANALITYCA
3	SGS DEL ECUADOR-LABORATORIO SECTOR AGRI	3	LABORATORIO OSP

Prepared by: Romero, Pamela **Source:** Ecuadorian Accreditation Organization

Using Table No. 15 importers can see the sub-heading 2103.90.20.00 during the period 2010-2014. Nationally there are 49 importers, of which 21 of them are located in the city of Guayaquil, 24 in Quito, 2 in the city of Cuenca, 1 in the city of Quevedo, 1 in the city of Manta.

Table No. 16 shows the number of OAE-accredited laboratories performing tests on condiments and mixed seasonings under tariff sub-heading 2103.90.92.00 from 2010 to 2014. In this context, there are a total of 6 laboratories, of which 3 of them are located in the city of Guayaquil and 3 in the city of Quito. We can presume that UDALAB does not need to test condiments and mixed seasonings for importers in Quito or Guayaquil; because, as we can see in the tables, both importers and laboratories are in the cities of Quito and Guayaquil. UDALAB would be unproductive if they promoted their services to importers in Quito and Guayaquil; since, as previously explained, these would

unnecessarily need to send samples to laboratories in Cuenca when they already have labs in their own cities or in cities in closer proximity. However, UDALAB could offer their services to the two importers located in the city of Cuenca, as the importers in Quito and Guayaquil would probably opt for the services offered by laboratories in their own cities. As of 2014, there is no accredited laboratory by the OAE to perform tests for these products in the city of Cuenca; thus, there is currently no competition for UDALAB in Cuenca.

After analyzing importers and laboratories it was concluded that, regardless of FOB value of imports obtained during the period 2010-2014, the sub-items with which UDALAB can work are:

- 2106.90.10.00: Powders for the preparation of puddings, creams, ice creams, desserts, jellies, and the like;

- 2007.99.92.00: Purees and pastes;

- 2103.90.20.00: Condiments and mixed seasonings.

These items have been chosen because they differ from others in that they have at least 2 importers in the city of Cuenca, where UDALAB could offer their services in the future. Importers of the sub-items mentioned, i.e. potential future customers of UDALAB, located in the city of Cuenca are: *Distribuidora de productos Jucremo Cia Ltda, Equindeca, Lácteos San Antonio, Ortiz Jácome de Comercio, Alimentos Ecuatorianos los Andes,* and *Casa Comercial Almeida*.

Finally, it would be useless for UDALAB to work with the sub-heading 2101.10.00.00, despite it having the highest FOB import value for the period 2010-2014; there are no importers in the city of Cuenca of this product for which UDALAB could offer their services. Potential customers of this sub-heading are in the cities of Quito and Guayaquil where existing accredited laboratories can offer the same services; the same applies to

the sub-heading 2004.10.00.00 which unfortunately has the third highest FOB import value in the period 2010-2014.

1.4 Frequency of imports

It is important to determine the frequency with which the importers of Cuenca are entering the country with their chosen products, in order for UDALAB to have a clear idea of how many tests they should cover in any given year and identify which importers would be good clients if they achieve international accreditation. Consequently, during 2014, after the came into force of COMEX Resolution 116, the following has been identified:

Table 17: Frequency of imports by tariff sub-heading and importer in the city of Cuenca in 2014

RUC	Importer	Tariff sub-heading	Product	# of times imported in 2014
390011024001	LACTEOS SAN ANTONIO	2007.99.92.00	Apple and peach pulp	7
190167488001	EQUINDECA	2106.90.10.00	Neutral stabilizer	2
190147398001	JACOME Y ORTIZ	2007.99.92.00	Apple and pear puree	1
190336603001	ALIMENTOS EC. LOS ANDES	2103.90.20.00	TABASCO BRAND (PEPPER SAUCE)	1

Prepared by: Romero, Pamela **Source:** Ecuapass / Central Bank of Ecuador

In table No. 17 it can be seen that during 2014, after the came into force of COMEX Resolution 116, *Lácteos San Antonio* is the company that has the most imports, with the exception of apple and peach pulp. Second is *Equindeca* with only 2 importations of neutral stabilizer. Finally, *Jacome y Ortiz* and *Alimentos Ecuatorianos los Andes* are located in last place with only 1 import for the year of Apple and pear puree and *Tabasco* Brand (pepper sauce), respectively.

The importers, *Casa Comercial Almeida* and *Distribuidora de productos Jucremo* have not been included in the table above because they haven't imported restricted products since 2011 and 2014; consequently, we can determine these two importers are not prospective clients for UDALAB. However, as can be seen in the table above, the three chosen sub-headings remain.

Finally, after analyzing the frequency of imports, we can conclude that if UDALAB achieved ISO / IEC 17025 accreditation on select products they must perform approximately eleven additional tests per year; unfortunately, up until 2014, there are only four importers located in Cuenca that require these services.

1.5 Determining the scope of accreditation - test method

The National Council Quality, in its Resolution No. 001-2008, determines that it is the duty of the state to safeguard the health and safety of residents and avoid environmental pollution and damage to the ecological systems; so, for such effects, it is necessary to promote compliance with standards and technical regulations for both domestically produced and imported products. Such technical regulations, in order to achieve compliance, must have legitimate objectives defined solely in terms of the properties of use, employment, and performance of products and services to which they correspond and not by their design or descriptive characteristics (National Council Quality).

Against this background, since for each product within each sub-heading there is an international standard and individual technical requirements, the tests required may vary; but, given the nature of each sub-heading's products most have common characteristics and thus require similar tests.

For each sub-heading, some of the necessary analyses are shown in the following tables, these were determined using a reference product for each sub-heading.

Test methods for sub-heading 2106.90.10.00: Powder for the preparation of puddings, creams, ice cream, desserts, gelatins, and the like

Table 18: Physicochemical requirements for sub-heading 2106.90.10.00

REQUIREMENT	TEST METHOD
Total Fat	ISO 8262-2, or ISO 7328 or AOAC 33.8.05 (952.06)
Dairy fat	NTE INEN 012
Total Solids	NTE INEN 014 (ISO 3728 or AOAC 33.8.03) (941.08)
Dairy protein	NTE INEN 016
Weight/volume	AOAC 33.8.01 (968.14)
Cholesterol	NTE INEN 729
Artificial colors	Arata / thin layer chromatography

Source: Technical Regulation INEN 070

Table 19: Microbiological requirements for sub-heading 2106.90.10.00

REQUIREMENTS	TEST METHOD
Counts of mesophilic microorganisms, CFU / g	NTE INEN 1529-5 (ISO 4833 or ISO 6610)
Counts of coliforms, CFU / g	NTE INEN 1529-7 (ISO 4832)
Counts of E. Coli, NMP / g	NTE INEN 1529-8 (ISO 4831)
Counts of molds and yeasts, CFU / g	NTE INEN 1529-15 (ISO 6611)
Detection of salmonella / 25 g	NTE INEN 1529-15 (ISO 6785 or ISO 6579)
Bacillus cereus CFU / g	AOAC 980.31/983.26

Source: Technical Regulation INEN 070

Test methods for sub-heading 2007.99.92.00: Purees and pastes

Table 20: Physicochemical requirements for sub-heading 2007.99.92.00

FRUIT	Scientific Name	Minimum soluble solids NTE INEN 380
Acerola cherry	*Malphigia sp*	6,0
Apricot	*Prunus armeniaca* L.	11,5
Cranberry	*Vaccinium myrtillus* L. *Vaccinium corymbosum* L. *Vaccinium angustifolium*	10,0
Araza fruit	*Eugenia stipitata*	4.8
Babaco	*Carica pentagona* Heilb	5,0
Banana	*Musa*, spp	21,0
Borojo fruit	*Borojoa* spp	7,0
Gooseberry	*Averrhoa carambola*	5,0
Plum	*Prunus domestica* L.	12,0
Coconut (1)	*Cocos nucifera* L.	5,0
Coconut (2)	*Cocos nucifera* L.	4,0
Peach	*Prunus pérsica* L.	9,0
Strawberry	*Fragaria* spp	6,0
Red raspberry	*Rubus idaeus* L.	7,0
Blackberry	*Rubus occidentalis* L.	11,0
Guanabana	*Anona muricata* L.	11,0
Guava	*Psidium guajava* L.	5,0
Kiwi	*Actinidia deliciosa*	8,0
Litchi fruit	*Litchi chinensis*	11,0
Lime	*Citrus aurantifolia*	4,5
Limon	*Citrus limon* L.	4,5
Mandarin orange	*Citrus reticulata*	10,0
Mango	*Mangifera indica* L.	11,0
Apple	*Malus domestica* Borkh	6,0

Source: Ecuadorian Technical Standard INEN 2337

Table 21: Microbiological requirements for sub-heading 2007.99.92.00

	n	m	M	c	Test Method
Coliform MPN / cm^3	**3**	**< 3**	**-**	**0**	**NTE 1529-6**
Fecal Coliform MPN / cm^3	**3**	**< 3**	**-**	**0**	**NTE INEN 1529-8**
Clostridium spores count sulfite reducers CFU / cm^3	**3**	**< 10**	**-**	**0**	**NTE INEN 1529-18**
REP standard plate count CFU / cm^3	**3**	**1.0×10^2**	**1.0×10^3**	**1**	**NTE INEN 1529-5**
Molds and yeasts count UP / cm^3	**3**	**1.0×10^2**	**1.0×10^3**	**1**	**NTE INEN 1529-10**

Source: Ecuadorian Technical Standard INEN 2337

Test methods for sub-heading 2103.90.20.00: Condiments and seasonings

Table 22: Physicochemical requirements for sub-heading 2103.90.20.00

REQUIREMENT	UNIT	TOMATO DRESSING		TEST METHOD
		Min	Max	
Soluble solids at 20 degrees celcius excluding salt	% (m/m)	18	-	NTE INEN 380
pH	--	-	4.5	NTE INEN 389

Source: Ecuadorian Technical Standard INEN 2525

Table 23: Pollutants for sub-heading 2103.90.20.00

REQUIREMENTS	UNIT	MAXIMUM LIMIT	TEST METHOD
Arsenic, As	mg/kg	0.2	NTE INEN 269
Lead, Pb	mg/kg	0.3	NTE INEN 271
Copper, Cu	mg/kg	5	NTE INEN 270
Tin, Sn	mg/kg	250	NTE INEN 385
Mercury, Hg	mg/kg	0.05	AOAC 952.14

Source: Ecuadorian Technical Standard INEN 2525

Table 24: Microbiological requirements for sub-heading 2103.90.20.00

REQUIREMENT	n	c	m	M	TEST METHOD
Mold content (hyphae), number of positive fields in 100 fields (Howard's method), %			40	-	NTE INEN 1529-12
Aciduric bacteria CFU / g	5	0	< 10	-	NTE INEN 1529-5 using thermoacidurans agar, incubated at 55 degrees celcius for 48 hours

Source: Ecuadorian Technical Standard INEN 2525

In the tables above we can see the microbiological and physicochemical requirements for certain tariff sub-heading products. Consequently, it was determined that INEN rules allow some testing with INEN exclusive methods and by AOAC methods. Later on we will investigate if UDALAB performs all of the required testing methods.

Conclusions

With COMEX Resolution 116 coming into force, many importers have experienced problems when importing products. Foodstuffs that are within the Resolution are of interest to UDALAB as the INEN accepts tests from a laboratory accredited by the OAE.

Therefore, through import statistics for the period 2010-2014, followed by a study of monthly imports by sub-heading, an analysis of the number of importers and number of accredited laboratories, we determined that the sub-headings that UDALAB could service are: 2106.90.10.00, 2007.99.92.00, and 2103.90.20.00, corresponding to powders for the preparation of puddings, creams, ice cream, desserts, gelatins and the like; purees and pastes; and condiments and mixed seasonings.

If UDALAB wants the ISO / IEC 17025 accreditation it must perform tests on products of the three sub-headings chosen; thus, the lab will have at least a total of four importers in Cuenca who can promote their services, which would mean more work for the laboratory and thus more revenue. It is important that UDALAB thoroughly analyzes the methods and types of tests of these three sub-items, as well as the differences between the products.

Finally, in order to offer tests for food products that these four importers in Cuenca require, UDALAB will have the opportunity not only to get international accreditation ISO / IEC 17025, but will also be the pioneering laboratory in the city of Cuenca in having the faculty and approval of the OAE to perform tests on imported products. However, it is important to emphasize that the city of Cuenca has universities such as the University of Cuenca, the Salesian Polytechnic University, and the Catholic University of Cuenca which have food laboratories; although, for now, they are not accredited by the OAE. If these institutions did receive accreditation in the future it would mean competition for UDALAB.

CHAPTER 2: ANALYSIS OF THE INTERNATIONAL STANDARD ISO / IEC 17025

Introduction

ISO / IEC 17025: 2005 is responsible for the regulation of laboratory proficiency testing and calibration.

The first version of the requirements and specifications for the competence of testing laboratories began with the implementation of ISO / IEC Guide 25, which was replaced years later by the ISO / IEC 17025.

ISO / IEC 17025 referred to the ISO 9001 and 9002, which was amended by the ISO 9001:2000 and updated to the ISO / IEC 17025. In 2005, the second version of the standard was created, certain clauses of the content of the ISO 9001:2000 were incorporated and amended, which concludes that laboratories comply with ISO / IEC 17025 and meet the requirements of ISO 9001.

In this chapter we will discuss the International Standard, specifically the administrative and technical aspects; identifying those requirements, processes, and demands that the rule details.

2.1 Management Requirements

2.1.1 Organization

According to the International Standard ISO / IEC 17025, a laboratory must be an entity with legal responsibility, so that compliance with the requirements of the International Standard satisfies customers, authorities, and organizations providing recognition. It is important that the laboratory management system covers permanent installations in the

laboratory, as well as those installed outside the permanent site, and that the laboratory also carries out various activities for testing and should define the staff's responsibilities in each area to avoid potential conflicts of interest.

In addition, the laboratory should have both management and technical staff, it should have the authority to perform their tasks, and collaborate on the implementation, maintenance, and improvement of the management system. In this sense, it is everyone's responsibility to initiate actions to prevent or minimize deviations from the management system or testing procedures which may occur in the laboratory.

2.1.2 Management system

According to the ISO / IEC 17025:2005, and according to the scope of activities of the laboratory, it must implement and maintain an appropriate quality management system and processes. The different systems, policies, procedures, and instructions shall be documented to ensure the quality of the results. All documentation must be available and known by the relevant staff.

With respect to the quality management system, the laboratory must have a quality manual as the standard requires, it should refer to the procedures used in technical support and laboratory activities, and should also outline the duties of those responsible for ensuring compliance with this standard. Top management is responsible for the issuance and review of the manual. As basic requirements the manual should include:

a) Professional and good practice commitment from senior management to customers.
b) A statement of the type of service provided by the laboratory; likewise in charge by management.
c) The purpose of implementing the quality management system.
d) A requirement that all personnel concerned with testing activities are familiar with the documentation regarding quality and policies; and

e) The commitment of the management of compliance with the international standard and continuous improvement of the management system.

In this context it is important to note that senior management is challenged to provide evidence of the implementation of the management system and continuous improvement thereof; revealing to its employees the importance of complying with the legal requirements of the standard and duties to its clients.

2.1.3 Control of documents

In this section the International Standard describes the responsibility that the laboratory has to establish procedures for control of documents that are part of the management system, such documents shall be reviewed and approved by the authorized laboratory personnel prior to issue. Importantly, documents may be constantly reviewed and modified only by those who made the original in order to ensure compliance with the applicable requirements; plus, the documents should have a date of issuance or revision, page numbering, and a brand that indicates the end of the document and the persons responsible.

When possible, the amended text or the new section must be identified in the annexes. Finally, the amendment of documents by hand is allowed until the new version is edited.

NOTE 1: In this context the term “document” can mean “policy statements, procedures, specifications, calibration tables, charts, manuals, posters, notices, memoranda, software, drawings, plans, etc. They may be on various media, whether in paper or electronic media, and can be digital, analog, photographic, or written.”[1]

2.1.4 Review of requests, offers, and contracts

[1] International Standard ISO/IEC 17025, Pg. 4

Similarly, this standard requires the laboratory to establish procedures for the proper handling of requests, offers, and contracts. Oral or written agreements entered into tests on a product must record the following:

a) The documentation of the methods used.
b) The certainty that the laboratory has the capability and resources to meet the requirements related to testing.
c) The test method used, capability of meeting the requirements of customers.

It is necessary and appropriate for any difference between the order and the contract established to be resolved before starting any work. With respect to the contract, the customer is to be mentioned on any deviation that arises. The contract must be acceptable to the customer and to the lab. If the contract needs to be modified once the work has begun, it will be done throughout the review process with all parties duly informed.

Finally, during the execution of the work, the lab must keep records of all conversations with customers that are related to the demands, requirements, and/or expected results.

2.1.5 Purchasing of services and supplies

The International Standard ISO / IEC 17025 states that the laboratory must have an appropriate procedure for the selection and purchase of supplies and services it needs. The lab must ensure that the materials used are inspected and verified to comply with the standard specifications or requirements defined in the test methods.

The laboratory should evaluate the suppliers and must also maintain the respective record of the evaluations, as well as the list of approved suppliers.

2.1.6 Customer Service

Considering that customers value and recognize good communication, and consulting, the laboratory should always be available to cooperate with clients and their requests. The international standard specifications state that the customer should have access to areas where the tests are conducted, and also have the right to receive the objects used by the laboratory for verification.

In the same context, it is important to mention that during all work performed the laboratory must keep the client informed about its activities. If there are any delays or major deviations the customer must be made aware.

Consequently, the laboratory may get positive or negative feedback. Surveys, complaints, and reviews of tests are an example of feedback, which will be useful to the laboratory in improving its management system and related activities.

2.1.7 Control of tests or nonconforming work

According to the requirements and specifications of the International Standard, when the result of the work of the laboratory does not comply with the procedure or the requirements agreed upon initially with the customer, the laboratory should have a policy and procedures to address the situation. In this context, such policies and procedures shall ensure that:

a) The respective responsibilities and authorities are assigned when they have identified the nonconforming work. If necessary, they should halt the work and test reports should be retained.
b) An assessment of the nonconforming work is made.
c) Immediate correction of the nonconforming work is made.
d) If necessary, customer is notified and work is recalled.
e) Responsibility for authorizing the resumption of work is established.

NOTE: “nonconforming work or problems with the management system or with testing activities or calibration points management system and technical operations can be identified. Customer complaints, quality control, instrument calibration, checking of consumable materials, observation or supervision of staff, verification of test reports, and calibration certificates, management review, and internal or external audits are examples.”[1]

2.1.8 Control of records

The Regulations of the ISO/IEC 17025 specifies that it is essential that the laboratory has a reliable and safe place for the storage of records. All records must be legible and must be preserved so that they are readily retrievable. The lab should set a period of retention of records, whether on paper or in digital form.

2.1.9 Internal audits

Based on the requirements of the International Standard, periodically, and with set dates in a calendar, the laboratory must conduct internal audits of its activities to verify compliance with the requirements of the management system and the International Standard. The audit should consist of the evaluation of the management system including testing activities. Only qualified persons will be responsible for such audits. If as a result of audits doubts about the effectiveness of laboratory operations is found, validity of the test results should promptly take the corresponding corrective actions. For these reasons it is important that the area being audited be recorded, as well as the results and possible corrective actions that may have arisen as a result of the findings.

On the other hand, the intervention of directorates is important. In this regard, they must annually perform a review of all processes performed in the laboratory. Complaints,

[1] International Standard ISO/IEC 17025, Pg. 7

corrective actions, assessments by external bodies, reports from management, and results of internal audits, are elements to consider for review by the directorate.

2.2 Technical requirements

2.2.1 Overview

The accuracy and reliability of test results depend on certain elements; such as: human factors, installations, test methods, sampling, handling, etc. Consequently, the laboratory should consider all these factors for good performance and implementation of activities.

2.2.2 Personnel

According to this standard, it is necessary to ensure the competence of the people who work in the laboratory in the fields of operation of equipment, testing, evaluating results, etc. Each person must be able, show abilities, skills and education in the field of work required.

The laboratory is responsible for compliance with the specified requirements for certification of personnel; these requirements can be constituted as a regulation, laboratory standard or simply a requirement by the customer. The profiles of the jobs should be updated and defined in different areas. The management will be responsible for formulating the goals, policies, and procedures with respect to education and training of staff; permits of members to perform certain activities should be registered, available, and sorted according to the date of confirmation of the authorization.

It is desirable that the personnel responsible for opinions and interpretations, in addition to having a qualified work in the laboratory, have a knowledge of the technology used in

the manufacture of the tested products, as well as knowledge of the applicable requirements of legislation and standards.

2.2.3 Accommodation and environmental conditions

It is a requirement of the international standard that all facilities, including power and lighting sources, facilitate laboratory work; especially in conducting tests. The staff responsible must ensure that the environmental conditions do not affect results; the lab should take extra care to ensure separation from neighboring areas to avoid possible cross contamination. The administration should take steps to ensure proper cleanliness and order within the laboratory.

2.2.4 Methods of testing, and calibration and validation of methods

This standard requires that laboratory testing apply the respective methods and procedures for all activities, these include: sampling, handling, storage, and preparation of items. It is optional the estimating of uncertain measurements, as well as statistics techniques for data analysis.

When the customer does not specify the methods to be used, the laboratory must use test methods that achieve customer satisfaction. It is recommended that international, regional, and national standards be published; ensuring that the latest methods are used.

2.2.5 Non-standard methods

If the use of non-standard methods is required, i.ee different methods developed by the laboratory, the method to be used must first be approved by the client. It should be noted that the method to be developed must be validated before use; validated means

confirmation by examination and provision of objective evidence that the requirements for a specific use are met.

For new test methods, the following information should be included:[1]

a) Proper identification;
b) The scope;
c) The description of the type of item to be tested or calibrated;
d) Parameters or quantities and ranges to be determined;
e) Appliances and equipment, including technical performance requirements;
f) Reference standards and reference materials required;
g) Environmental conditions required and any stabilization period needed.
h) The description of the procedure, including the following information:
    - Placement of identification marks, handling, transporting, storing and preparation of items;
    - Verification is done before starting work;
    - The verification of the correct functioning of the equipment and, where required, calibration and adjustment before each use;
    - The method of recording the observations and results;
    - Safety measures to be observed.
i) The criteria or requirements for approval or rejection;
j) Data to be recorded and method of analysis and presentation;
k) Uncertainty, or the procedure for estimating uncertainty.

2.2.6 Estimation of measurement uncertainty

According to the standard, the laboratory performing its own calibrations shall enforce appropriate procedures for estimating uncertainty of measurement.

[1] International Standard ISO/IEC 17025, Pg. 14

"In some cases, the nature of the test method may preclude rigorous calculation, metrologically and statistically valid measurement uncertainty. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. A reasonable estimate should be based on knowledge of the performance of the method and on the measurement scope and shall make use, for example, experience and validation of data"[1]

NOTE 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: [2]

- The requirements of the test method;
- Customer requirements;
- The existence of narrow limits on which decisions on conformance to a specification are based.

2.2.7 Equipment

International Standard requires that testing laboratories have all the equipment necessary for their different activities ranging from sampling, measurement, testing, processing, and data analysis. Should the need arise for off-site equipment, the lab should ensure that it complies with the requirements of the International Standard.

Within the equipment, the lab should also consider the software the laboratory uses. Before using a computer or software, the lab must verify that the correct operation is performed by authorized personnel only, who in turn must have the appropriate manual for the use and handling of said equipment. Equipment that has been subjected to misuse or overload, and as a result gives inconclusive results, should be isolated from laboratory service.

[1] International Standard ISO/IEC 17025, Pg. 23
[2] International Standard ISO/IEC 17025, Pg. 15

Finally, the lab should take into account the following concerning the usage of standard equipment used in testing:[1]

a) The identification of equipment and its software;
b) The manufacturer's name, model identification, serial number, or other unique identification;
c) Checks that equipment complies with the specification.
d) Current location, where appropriate;
e) The manufacturer's instructions, if available, or reference to their location;
f) Dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
g) The maintenance plan, where appropriate, and maintenance carried out to date;
h) Any damage, malfunction, modification, or repair of equipment.

2.2.8 Traceability of measurements

According to the International Standard, the program for calibration of equipment for testing laboratories should be designed based on the International System of Units (SI). In case of uncertainty, product calibration should not affect the total uncertainty of the test result.

2.2.9 Sampling

According to ISO/IEC 17025:0025, it is required that the laboratory have a strategic plan for the sampling of products, these should be based on statistical methods and take into account the factors to be controlled and managed to ensure the validity of results.

[1] International Standard ISO/IEC 17025, Pg. 17

Note 1: sampling is a defined procedure that takes part of a substance, material, or product to provide a representative sample of the whole for testing or calibration. In some cases (e.g., in forensic analysis), the sample may not be representative but is determined by availability.[1]

In this context, the laboratory must have the proper procedures, statistics, environmental conditions, and identification of the people involved that allow it to record data and transactions with respect to sampling.

2.2.10 Handling of test items or calibration

The manipulation of the test products is very important during the process; the International Standard requires that the laboratory have procedures for the transportation, receipt, handling, and protection of such products.

Items or products to be tested must be easily identifiable, and are not to be confused with other products being tested; if necessary, the laboratory should be subdivided into groups of items.

In the absence of sufficient information of the item to be tested, the standard requires that the laboratory inform the customer and receive instructions accordingly before beginning any work.

2.2.11 Quality assurance of test results

The results of the test shall be recorded with the utmost care and accuracy, this is required under the rules of ISO/IEC 17025:2005. Resulting data should be stored so that

[1] International Standard ISO/IEC 17025, Pg. 20

it can easily identify trends and statistical techniques. The review of the results should be reviewed and may include items such as:[1]

- The regular use of certified reference materials or internal quality control using secondary reference materials,
- Participation in interlaboratory comparisons or proficiency testing programs.
- Duplication of tests or calibrations using the same method or different methods.
- Retesting or recalibration of retained items.
- The correlation of results for different characteristics of an item.

All selected methods should be based on the volume and type of work to be performed

2.2.12 Reporting results

The reports issued by the laboratory results must be expressed clearly, objectively, and unambiguously. The test report should contain all information necessary for interpretation that the client requires.

Each report shall include the following:[2]

- Title
- Name and address of the laboratory.
- Identification information, such as a serial number.
- Customer identification, at least name and address of the customer.
- The method used.
- Description and status of the products tested.
- Date of receipt of the products tested.
- Date of the test.
- Reference test method used by the laboratory.

[1] (Norma Internacional ISO/IEC 17025 ,Pág 20)
[2] (Norma Internacional ISO/IEC 17025 ,Pág 22)

- If a statement of the estimated uncertainty of measurement is necessary.
- Test results with their respective measures.
- Names, positions, and signatures of persons responsible for issuing the test report.
- If appropriate and necessary, interpretations and opinions.
- When necessary, a statement that the results have been obtained solely from the tested items.

2.2.13 Modifications

The substantive amendments to be made to a test report should be issued in the form of a new document including the statement "*Supplement to the test report, serial number xxx.*" Such amendments shall meet all the specified requirements of this standard.

Conclusions

The International Standard ISO 17025 is the result of the evolution of the ISO family. Thanks to the adaptation of this standard, food laboratories can enjoy the prestige of having the accreditation of an international rule by the OAE. This standard addressed the management side, as well as the technical aspect, of laboratory maintenance. The International Standard requires laboratories to apply a quality management system and technical processes based on a professional commitment and good practices by senior management to customers.

It is important that food laboratories that meet the requirements of the International Standard are placed in a preferential position above the other laboratories without accreditation, as customers remain confident in these laboratories. This is because the control of records, the conducting of tests, the sampling process, statistical techniques, and uncertainty measurements are activities that should be performed with absolute

attention and care by the staff, and their activities should be within the legal framework required by the International Standard.

Finally, it can be noted that laboratories seeking international accreditation, and are part of an institution or Company, should clearly define their responsibilities in relation to the activities of tests and their entire management. For each area, qualified personnel should receive training for continuous improvement, and maintain a schedule for internal and external audits. Also, to complete and conduct tests, laboratories should transport, receive, handle, and store samples using the proper equipment, as well as isolate all samples to avoid contamination.

CHAPTER 3: CURRENT STATE OF UDALAB

Introduction

The University of Azuay, within its projects in the community, has publicly made available a food laboratory known as UDALAB; it began in 2011 and is located at Av. 24 de Mayo 7-77 and Hernán Malo, Faculty of Science and Technology.

The lab is a subsidiary of the University of Azuay that carries out chemical and microbiological analysis in water, soil, and food; and also has the ISO 9001:2008, which regulates quality management systems and requirements. In this chapter, the current situation of the laboratory, based on the above standard, will be discussed.

3.1 Food Laboratory UDALAB

UDALAB was created as a laboratory that provides services to the general public and at the same time contributes to the interests of the University in both teaching and research.

In this context, UDALAB offers the services of physical-chemical and microbiological tests on food, water, and soil. With the scope of the following tests:[1]

Water analysis: Acidity, alkalinity, aluminum, cadmium, calcium, chloride, copper, color, conductivity, chromium, COD (chemical oxygen demand), total hardness, fluoride, phosphorus, iron, lithium, magnesium, manganese, nickel, nitrate, nitrite, nitrogen ammonia, total nitrogen, dissolved oxygen, pH, lead, potassium, dissolved solids, settleable solids, total solids, sulfate, turbidity, zinc.

Soil analysis: cation exchange (sodium, calcium, magnesium, and potassium), sodium, calcium, magnesium, potassium, phosphorus, total nitrogen, and pH.

[1] UDALAB Quality manual, Pgs. 5-6

Food nutrition analyzes: moisture, ash, acidity, protein, fat, fiber, density, pH.

Microbiological analysis: Total mesophilic, total and fecal coliforms, molds and yeasts, enterobacteriaceae, staphylococcus aureus, salmonella spp., listeria spp.

3.2 Profile of the Organization

According to the UDALAB quality manual, the following general laboratory data is as follows:

Name: University of Azuay, Laboratory Services "UDA Laboratories"
Address: Av. 24 de Mayo 7-77 and Hernán Malo
Phone: (07) 409-1000 ext. 441
Tax ID: 0190131777001
Webpage: http://www.uazuay.edu.ec/laboratorios
Number of employees: 6

The following is the personnel who currently work in the food laboratory:

- María Fernanda Rosales - **Director General**
- Mónica Tinoco - **UDALAB Director of Quality**
- Dr. Piercosimo Tripaldi - **UDALAB Technical Director**
- Ximena Orellana - **CONSEP Tech**
- Johanna Tacuri - **Microbiology Laboratory Analyst**
- Andrés Pérez - **Laboratory Assistant**

3.3 Quality policy

The quality policy, managed by the Laboratory Directorate General and formed by the Dean of Research, is handled based on the **SGCUDAL-POL-001 UDA Laboratories Manual**.

The Directorate General is committed to:[1]

- Ensure legal compliance.
- Ensure the reliability of the results.
- Maintain competent staff.
- Ensure that instruments, equipment, and methods are adequate to maintain quality of the testing and results.
- Ensure the confidentiality of customer results.
- Ensure continuous improvement of laboratory processes.
- Meet the stated objectives.
- Ensure customer satisfaction.

3.4 Quality management system

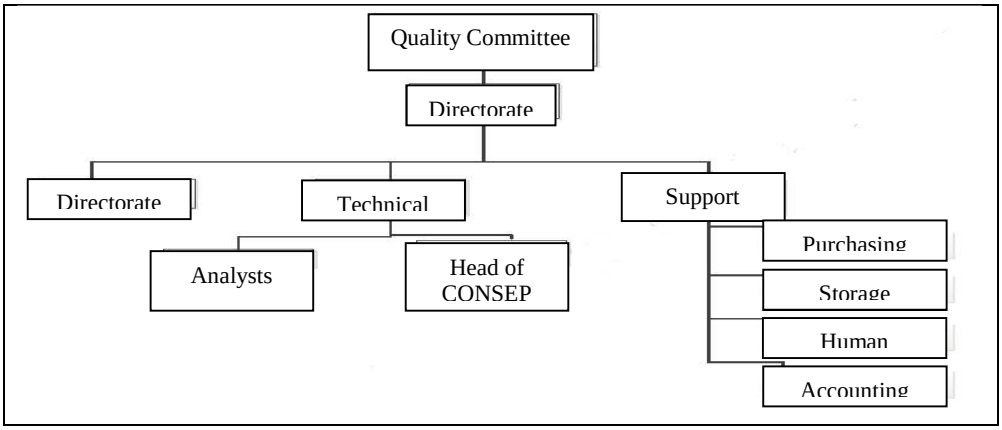
In the UDALAB quality manual it states that the laboratory maintains a system of quality management, based on the applicable requirements in ISO 9001:2008, "Quality Management Systems." UDALAB, through the Directorate General Laboratory, shall establish, document, implement, and maintain continuous improvement of the effectiveness of its quality management system. Each year a compliance review of the points based on the procedure DEUDAL-P-001 should take place.

[1] UDALAB Quality Manual, Pg. 21

It is important to mention that the qualification of personnel and training activities are of great interest to the institution to improve its Quality Management System. These activities are carried out through the work of the Human Resources Department, with the cooperation and participation of external experts in the laboratory.

3.5 Organizational Structure of UDALAB

Illustration 12: Organizational structure of UDALAB



Author: UDALAB **Source:** UDALAB Quality Manual

As shown in Illustration No. 12, the structural organization of the laboratory is very organized. At the head is the Quality Committee, followed by the General Directorate, and then the following departments: Directorate of Quality, Technical Directorate, and Support from different departments (Purchasing, Storage, HR, and Accounting).

The Quality Committee consists of: the Director General of Laboratory Services, the Deputy Rector, the Dean of the Faculty of Science and Technology, Administrative Finance Dean, the Director of Quality, and the Technical Director; these all have the following functions:[1]

[1] UDALAB Quality Manual, Pg. 9

- Strengthen and evaluate laboratory services.
- Strengthen the view of monitoring oriented to continuous improvement.
- Institutional commitment to continuous improvement.
- Provide added value over action strategies of laboratory services.
- Approve the Quality Manual.
- Provide information to interested parties on the implementation and monitoring of the Improvement Plan.
- Detect problems for the implementation of concrete actions.
- Establish appropriate communication channels between laboratories services and the University of Azuay, along with customers and suppliers.
- Plan and allocate tasks, and exercise regular monitoring of the implementation thereof.
- Inform the highest authority of the University of Azuay through its delegate.

The Directorate General has the following responsibilities:[1]

- The responsibility and authority to ensure that the management system implemented will be maintained, updated, and respected at all times.
- Coordinate directly with the Directorate General on policy decisions, objectives, and resources of the laboratory.
- Billing, financial reports, and taxes to the Department. Accounting of the UDA.
- Signing results and authorize their delivery to customers.
- Schedule internal and external audits required by the Quality System.
- Document review management system implemented.
- Together with the Director General, review and management of measurement, analysis, and continuous improvement of laboratories.
- Manage customer satisfaction.
- Petty cash management.
- In addition, take care of the customer and billing when warranted.

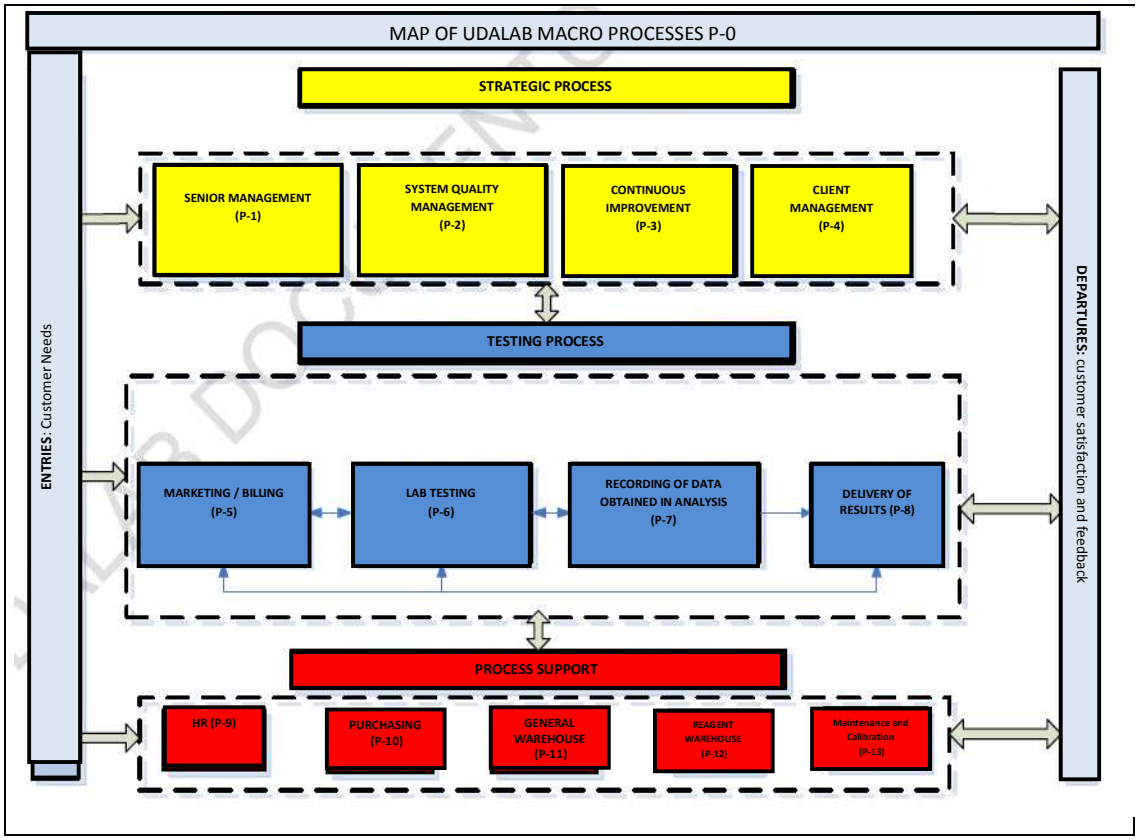
[1] UDALAB Quality Manual, Pg. 9

The Technical Department meanwhile has the responsibility to provide the resources for full compliance with the required standards in the operations of UDALAB

Finally, support departments are split into Warehouse, Purchasing, Accounting and Human Resources as described in the UDALAB Quality Manual, these work synergistically for the proper development of laboratory activities and customer satisfaction.

The following table shows the process map of UDALAB and the relationship between the different departments.

Illustration 13: UDALAB Process map



Author: UDALAB **Source:** UDALAB Quality Manual

3.6 Control of quality records

UDALAB keeps all their quality records documented by encoding of name, code, and version of each file; thus, the lab ensures that information is recoverable in addition to being protected in physical and digital form.

3.7 Responsibility, authority, and communication

According to the UDALAB Quality Manual, the authorities and responsibilities of personnel are defined according to the "Methodology for the outlining of job profiles (FL)" format. In this guide, the actions and responsibilities of each relevant employee in the quality management system are detailed. The personnel working in UDALAB are competent, i.e. they have an adequate educational background, as well as having the skills and experience required by the laboratory.

Internal communication of the laboratory is extremely important for the development of activities; therefore, internal mail is constantly handled with return receipts, written communication, and regular meetings.

3.8 Scope

According to the UDALAB Manual, the laboratory is divided into two test laboratories: the chemical laboratory and microbiological laboratory. Once the sample is received, the lab proceeds to analyze, report, and produce test results.

It should be noted that UDALAB does not perform sampling operations; rather, as mentioned before, the lab receives samples provided by customers for conducting the tests.

3.9 Equipment, suppliers, and documentation

UDALAB, in order to conduct reliable, secure, and updated tests, details in its Quality Manual that equipment and reagents used undergo maintenance and internal controls from time to time. It is for this reason that the laboratory ensures that their computers are:[1]

[1] UDALAB Quality Manual, Pg. 32

- Calibrated and verified with the necessary adjustments
- Identified to help determine its calibration
- Protected against adjustments that would invalidate the measurement result
- Protected against damage during handling, maintenance, and storage.

For recruitment and approval of suppliers, UDALAB is based on the evaluation procedure and approval of suppliers ADMUDAL-P-002.

With regard to documentation, the laboratory performs testing operations based on internal or external documentation. Authorized personnel for the management of information consists of the Director General, Quality Director, and Technical Director, these are responsible for reviewing, approving, and recording all documents; whether they are management procedures, instructions, and/or test results. Thus, the confidentiality of information and user satisfaction is guaranteed.

Finally, all documentation issued by the laboratory is registered electronically and physically, complying with the SGCUDAL-P-002 due process control document, which states the following:[1]

a) Approval of documents to verify that the content is appropriate to the documentation requirements.
b) Review and update documents as necessary and approved again when they are modified.
c) Ensures that changes and the current revision status of documents are identified.
d) Ensures that appropriate revisions of applicable documents are available at points of use through the physical file.
e) Ensures that documents remain legible and readily identified by name, code, and date of issue.

[1] UDALAB Quality Manual, Pg. 19

f) Ensures that documents of external origin are identified and their distribution controlled.
g) Prevents the unintended use of obsolete documents by storing them in the "obsolete" folder as historical documentation.

3.10 Customer Service

Good customer service is paramount to UDALAB. In the Quality Manual, it states that the General Directorate is responsible for the applicable requirements made by the customer. It is for this reason that UDALAB maintains, in a documented and formal manner, the customer requirements with regard to the tests to be conducted; and, through the SGCUDAL-P-012 procedure manual for samples, the following is defined:[1]

a) The requirements specified by the customer, through invoices, are approved by the customer; indicating therein, when deemed relevant, the requirements in terms of delivery activities.
b) Requirements not stated by the customer but necessary for the proper use of the product.
c) Statutory and regulatory requirements related to the product.
d) Additional requirements specified by UDALAB.

When customers want the sample to be returned, the laboratory has written in its Quality Manual that this will be maintained and manipulated insomuch that the client will not have any problems.

Finally, authorized personnel will analyze complaints, suggestions, and reports obtained from customer evaluations, with the aim of finding opportunities for improvement.

[1] Manual de Calidad UDALAB, Pág. 27

3.11 Review of requirements related to the product

According to the UDALAB Quality Manual, the laboratory, before committing to the testing of a certain product, makes a review of the requirements. Based on the sampling procedure SGCUDAL-F-001, the laboratory ensures that:[1]

a) Customer requirements are clearly defined and recorded in writing.
b) The installed capacity of UDALAB is able to meet the defined requirements.

All customer requirements are recorded in writing; and, once the sample is received in the laboratory, the management is responsible for the conservation of the sample.

3.12 Monitoring and measurement of product

According to the UDALAB Quality Manual, the results of chemical and microbiological tests determine the final result of the tests; however, the final report will have to be reviewed and signed by the Technical Director and Quality Director before it is issued.

3.13 Control of product conformity

In case of disagreements with the product, UDALAB, through its Quality Manual, specifies that through the management, supplies, and nonconforming equipment, SGCUDAL-P-007, any nonconforming product shall be identified. Furthermore, the respective records evidencing such complaints will be kept; equally, UDALAB will undertake corrective and preventive actions as appropriate.

3.14 Purchasing process

[1] Manual de Calidad UDALAB, Pág. 28

Through the Quality Manual, UDALAB ensures that the procurement process is appropriate.

The ADMUDAL-F-011 order registration for supplies, materials, reagents, and equipment is used to ensure the proper information is included for processing purchases. This record included: [1]

- The product ordered.
- The amount and presentation.
- The specific characteristics of the product, if necessary.
- The qualified supplier of the product, reactive, or requested equipment is recommended.

3.15 Verification of purchased product

Inputs, reactive materials, and equipment, before entering operation, are tested and reviewed according to the reception procedure in warehouse Boudal-P-001. Later on, payment and inventory of the sample is taken.

3.16 Identification and traceability

The UDALAB Quality Manual states that the laboratory should identify the test, as well as samples. By recording the test under SGCUDAL-F-011, SGCUDAL-F-018, and SGCUDAL-F001 registration codes, the laboratory maintains order and prevents confusion.

It is important to mention that UDALAB also has reports of physical, chemical, and microbiological tests.

[1] UDALAB Quality Manual, Pg. 29

3.17 Internal audits

For UDALAB, audits are objective processes that take into account the areas audited, the results of previous audits, and audit managers; those performing the audit must be impartial since they cannot audit their own work.

The UDALAB audit program, in accordance with the provisions of the Quality Manual, is handled by the Quality Director. The criteria for the audits are based on the SGCUDAL-P-006 internal auditing process.

3.18 Techniques of analysis and test methods

UDALAB uses analysis techniques based on INEN and AOAC technical standards. According to experts of the laboratory, in the case of our selected products: powders for desserts, gelatins, puddings, creams, ice cream, and the like; purees and pastes; and mixed seasonings; tests are performed based on the AOAC standard because this method is very similar to the INEN method but much faster.

By analyzing the test methods required for each selected product in Chapter 1, it was determined that UDALAB meets the requirements under AOAC standards, using the *Compact Dry* method, priced at $18 per test. However, the determination of soluble solids of puree and pastes, seasonings, and various condiments are an exception, since the laboratory does not perform this test under any particular method.

3.19 Revenues and expenditures

Table 25: Revenues and expenditures of UDALAB in 2014

2014 UDALAB FINANCIAL BUDGET	
REVENUE	**USD**
TESTS	11749.9
TOTAL REVENUE	**11749.9**
EXPENDITURES	
MINOR MEDICAL INSTRUMENT	66.18
CLEANING MATERIALS	83.73
CONSTRUCTION MATERIALS	11.83
OFFICE MATERIALS	334.96
LAB MATERIALS	1758.14
MEDICINE AND PHARMACEUTICAL PRODUCTS	27.04
OTHER	237.36
TOTAL EXPENDETURES	**2519.24**
ANNUAL INCOME	**9230.66**

Prepared by: Romero, Pamela **Source:** UDALAB auxiliary budget

Using Table No. 25, we see the UDALAB income and expenses for the period of 2014. A total of $11,749.90 was recorded as income by performing various tests. The laboratory expenses totaled to an amount of $2,519.24; a difference of $9,230.66.

It is noteworthy that UDALAB, as a laboratory, does not cover the salary of its staff, these areas are covered by the University of Azuay as a dependent laboratory. The staff are recognized as employees of the University of Azuay and not as direct personnel linked exclusively to UDALAB; other activities by the staff may include teaching and working in the laboratory.

Finally, the lab takes in approximately 30 water and food samples per month, 360 per year; one person performs microbiological tests and another is in charge of physico-chemical tests. The price per test ranges from $16 to $18 depending on the type of test to be performed.

3.20 Data analysis

The Directorate General is responsible for data analysis. In this context, the following information will be reviewed:[1]

- Results of internal audits
- Monitoring of indicators of quality management
- Results of the review of actual and potential nonconformity
- Analysis of customer complaints
- Analysis of the results of supplier evaluations

3.21 Exclusions

According to the ISO 9001:2008 guide, personnel must plan and control the design of the product; however, as indicated in the Quality Manual, UDALAB focuses solely on testing based on *Standard Methods for Water and Wastewater*, AOAC, and INEN standards.

[1] UDALAB Quality Manual, Pg. 34

Similarly, according to ISO 9001:2008, “the organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been provided.”[1] Nevertheless, UDALAB, through its Quality Manual, indicates the possible shortcomings of the products identified during the course of their analysis.

Conclusions

UDALAB, being part of the University of Azuay, functions as a service to the community and the students. The laboratory performs tests for soil, water, and food. The laboratory consists of two areas, chemistry and microbiology, and has trained staff for various activities.

It is noteworthy that UDALAB does business under the requirements of ISO 9001. Consequently, the laboratory is committed to customers in the proper conduct of its activities and quality processes, with internal audits, and training of basic processes.

UDALAB has an organization and process map showing that there is a real connection between areas that work together for the proper performance of the activities within the laboratory.

The laboratory meticulously manages its documents, and takes care of the areas, equipment, and supplies. UDALAB handles both the receiving of the sample and the testing thereof, but not it does not make the product.

UDALAB currently works with INEN and AOAC standards; AOAC standards are best used as these have shorter processes. In the case of our three selected sub-headings, in

[1] International Standard 9001:2008, Fourth edition, pg. 12

conducting tests using the *Compact Dry* method, UDALAB offers tests at an average price of $18.

Finally, by analyzing revenue and expenditures of the lab in 2014, it was determined that UDALAB takes in more money than it spends. However, in considering the salary of the staff, we can conclude that the aim of UDALAB is to serve students and the community at large as the lab is subsidized by the University.

CHAPTER 4: CLOSING THE GAP BETWEEN THE CURRENT STATE OF UDALAB AND SPECIFICATIONS OF THE ISO/IEC 17025:2005

Introduction

ISO 9001 and ISO 17025 are international standards, but maintain their difference in terms of requirements and demands.

Currently the food laboratory of the University of Azuay, UDALAB, has the prestige of being certified under ISO 9001, for that reason in this chapter we try and identify the gap between the above standard and ISO 17025 in order that in the future the lab can be accredited by the OAE for meeting the requirements of the International Standard ISO 17025. By receiving said accreditation, the lab can provide services to importers who need tests on their products for entry into the country.

4.1 Missing requirements of the ISO/IEC 17025 certification for UDALAB

4.1.1 ISO 9001:2008 and ISO/IEC 17025 standards

The international standard ISO/IEC 17025, produced in 2005 exclusively for the regulation of testing activities, including sampling of testing and calibration laboratories, has many more requirements than the ISO 9001 specifications, which only gives the specifications and requirements for the development of a quality management system.

In this context, it is important to note that ISO/IEC 17025 has the requirements of ISO 9001, but does not require this certification as a prerequisite. Consequently, we reach the conclusion that the ISO 17025 is a complement to the quality management system raised in the ISO 9001, developed specifically for testing and calibration laboratories.

4.1.2 Liability

While UDALAB can maintain its legal dependence on the University of Azuay, within the requirements of ISO 17025, it is essential that if it aspires for accreditation, under this standard, separation of the lab must be undergone by defining the exclusive space of the lab for tests rather than academic activities. In the case of students or individuals who need to enter the accredited laboratory and use the equipment, they must be certified and trained to use said equipment.

Free access to the lab that students currently have is an important factor that could stall laboratory accreditation.

4.1.3 Sampling

According to the international standard ISO / IEC 17025, UDALAB would have to perform the entire process of sampling and analysis, not just be responsible for receiving and analyzing samples as before. In this sense, the laboratory must implement a logistics system that allows transport, receiving, handling, and protection of the sample to be tested.

4.1.4 Test methods and instruments

Based on our selected products, it was determined that UDALAB performed trial tests based on INEN and AOAC standards. However, in order for UDALAB to receive international accreditation ISO/IEC 17025 for powder desserts, purees and pastes, and condiments and seasonings it would need to perform the tests based on the INEN or AOAC standards. Depending on the product and regulations, INEN standards include a more lengthy and costly process; thus UDALAB must invoke this method, unless INEN validates the methods currently being used at the lab.

In addition, the laboratory should implement two new tests, such as soluble solids and clostridium spores count, the same tests that are required for two of the products chosen. Currently, nothing compels importers to use UDALAB, they usually send their samples to Guayaquil or Quito.

On the other hand, through an audit, it was determined that the laboratory needed a few instruments such as vacuum oven with a temperature controller, set to 70 °C ± 1 °C, and weigh-substances bottles (instruments, which although small, are expensive according to Monica Tinoco, Director of Quality at UDALAB). If the laboratory does not implement these instruments it will not be able to perform the tests according to INEN rules.

4.1.5 Measurement of uncertainty

According to the UDALAB Quality Manual, measurement of uncertainty and statistical techniques for the analysis of the data are optional; but, because these processes are within the ISO/IEC 17025 accreditation requirements, the laboratory should include activities in the process of the measurement of uncertainty, traceability, as well as the use of statistical techniques for data analysis.

4.1.6 Personnel

Although UDALAB has trained staff for carrying out its activities, the laboratory should make an adjustment since ISO/IEC 17025 requires more complex activities and processes.

Activities such as the sampling process and the possible division of the laboratory activities are examples of actions that require a greater number of people to operate UDALAB.

4.1.7 Access to the laboratory

Because UDALAB belongs to the University of Azuay, students can use the laboratory for different academic activities. Consequently, this free access to the lab is a problem for UDALAB to achieve ISO 17025 accreditation; so, if it wants to get accreditation it must find a way for only authorized personnel to have access to the laboratory, thus separating the areas exclusively for the realization of accredited tests and the area in which students can enter and perform their academic activities.

4.1.8 Cost of Accreditation ISO/IEC 17025

Seeking accreditation of ISO / IEC 17025 involves inspections, reviews, requests, etc. According to an invoice for OAE services (see Annex II), accreditation costs are divided as follows:

General Accreditation Process:

- Initial opening of proceedings: $200

Evaluation Process:

- In situ (lead evaluator): $ 1440 / 3 day trial
- In situ (Evaluator 1): $ 960 / 2-day trial
- In situ (Evaluator 2): $ 960 / 2-day trial
- Documentary: $ 640 / 2-day trial

Accreditation certificate:

- Accreditation certificate: $600

Annual fee:

- Use of logo and registration fee: $500

All these costs represent a total investment of approximately $5,300.

Furthermore, the OAE staff must travel to the city of Cuenca for the respective evaluations, the logistical expenses will be charged to the laboratory. Taking into account the days of evaluation, and number people (3), the approximate extra cost is about $800.

4.1.9 Training, consulting, and logistics

In order to ensure that UDALAB meets the requirements of the OAE, prior to obtaining accreditation, it is necessary for the laboratory to retain training and consulting services for implementing the ISO/IEC 17025. In the case of SGS Ecuador, certified by the OAE, they maintain the following costs to provide consulting and training required by UDALAB:

Table 26: Investment for training and consulting

CONCEPT	ESTIMATED DAYS FOR CONSULTING	TOTAL INVESTMENT IN USD
Consulting on the implementation of the Quality Management System for Laboratories	30	9,000.00
Workshops for the implementation of the Quality Management System for Laboratories	3	900.00
Total cost of consulting	33	9,900.00

Prepared by: Romero, Pamela **Source:** SGS Ecuador

Table 27: Logistics investment

Logistics Costs	Amounts (USD)
Plane Tickets	1,600.00
Food	420.00
Lodging	800.00
Taxis to Airport in Quito	600.00
Transportation	200.00
Training Materials	90.00
Total	3,710.00

Source: SGS Ecuador

As shown in tables No. 26 and 27, provided by SGS Ecuador, the price of consulting and training for our chosen product is $9900 + VAT, with a total of approximately 33 days of consulting, and the total logistics costs is $3,710 + VAT. Consequently, UDALAB would need to cover a total cost of $15,243.20.

4.1.10 Tests and Revenue

If UDALAB achieves international accreditation ISO / IEC 17025 in the products of the three selected sub-headings, then it should perform about 11 tests annually, as discussed in Chapter 1.

Taking into account the methods and types of testing required for food products identified in Chapter 1, and in order to estimate the price at which UDALAB could offer their services, we have used the prices of UBA Analytical Laboratory (UBALAB) (see Annex III) as a benchmark, a food laboratory in the city of Guayaquil with accreditation ISO / IEC 17025. This lab charges the following amounts for the following tests:

Powders for the preparation of puddings, creams, ice cream, desserts and the like

Table 28: UBA-LAB prices of the tests required for powders for the preparation of puddings, creams, ice cream, desserts and the like

TEST	PRICE IN USD
Total fat	16
Dairy fat	18
Total solids	22
Dairy protein	28
Weight	7
Volume	8
Cholesterol	70
Artifical colors	45
Aerobic mesophilic	12
Total coliforms	12
Fecal coliforms	12
E. Coli	14
Salmonella	20
Fungi and yeasts	18
Subtotal	302
VAT 12%	36.24
TOTAL:	**338.24**

Prepared by: Romero, Pamela **Source:** UBALAB

According to table No. 28, it can be concluded that the total tests required for powders for the preparation of puddings, creams, ice cream, desserts and the like will have an approximate cost of $338.24. For this sub-item, we concluded in Chapter 1 that UDALAB would have to perform 2 annual imports, approximately $676.48 in revenue per year. Nevertheless, one should consider that the sub-heading is quite broad, depending on the specific product, values may vary.

Puree and pastes

Table 29: UBALAB prices of tests required for puree and pastes

TEST	PRICE IN USD
Soluble solids	20
Aerobic mesophilic	12
Total coliforms	12
Fecal coliforms	12
Clostridium sulfite reduction	35
Fungi and yeasts	18
Subtotal	109
VAT 12%	13.08
TOTAL:	**122.08**

Prepared by: Romero, Pamela **Source:** UBALAB

According to table No. 29 we can conclude that the total amount for the tests required for puree and pastes will cost approximately $122.08. According to Chapter 1, UDALAB would have to take in eight annual imports; the approximate revenue for the laboratory would be $976.64 per year. Nevertheless, one should consider that the sub-heading is quite broad, depending on the specific product, values may vary.

Seasonings and mixed condiments

Table 30: UBA-LAB prices of the tests required for seasonings and mixed condiments

TEST	PRICE IN USD
Soluble solids	20
Ph	10
Lead	23
Copper	23
Arsenic	23
Tin	23
Mercury	23
Fungi	18
Subtotal	163
VAT 12%	19.56
TOTAL:	**182.56**

Prepared by: Romero, Pamela **Source:** UBALAB

According to table No. 30 it can be concluded that the total tests required for seasonings and mixed condiments will cost approximately $182.56. According to Chapter 1, UDALAB would have to take in one annual import; the approximate revenue for the laboratory would be $182.56 per year. Nevertheless, one should consider that the sub-heading is quite broad, depending on the specific product, values may vary.

Consequently, according to tables No. 28, 29, and 30, it can be determined that the food laboratory UDALAB, by carrying out the tests required by the regulations for the products selected, will receive an estimated $1,835.68 per year; an amount that, compared to the initial investment ($ 21,343.20) on the basis of accreditation, training, consulting, and logistics, becomes an almost insignificant value because these services will be for 4 importers in the city of Cuenca, which together add up to only 11 imports per year.

If UDALAB, in 2014, by conducting various test, received $11,749.90, increased the total number of tests by 11 they would receive $13,585.58, which represents an increase in revenue of 15.62%. We must consider that the prices that UDALAB charges for its test should cover the cost of new testing methods that could potentially be higher than at present. Consequently, one could say that the extra revenue obtained by the lab from 11 new tests annually is even less significant if one considers the extras aforementioned by conducting tests under ISO/IEC 17025.

Conclusions

ISO / IEC 17025 is a complement to ISO 9001; one could say that if UDALAB is certified by ISO 9001 then it would also meet the demands of ISO/IEC 17025.

Moreover, in the technical part required by ISO / IEC 17025, there are various parameters focused exclusively on the implementation of tests. So, if UDALAB wants to get accreditation in testing of powders for puddings, creams, ice cream, gelatin, purees and pastes, and seasonings and condiments, it should work in areas such as the transport of the sample, determination of uncertainty, incrementing of staff, acquisition of new materials, and testing under INEN standards.

In the economic aspect, it was determined that UDALAB must invest a lot of money for accreditation, specifically consulting, logistics, and training. $ 21,343.20 for accreditation is a large sum compared to the extra revenue that would be received ($1835.68). Thus, UDALAB must not only question the investment, but it should also consider the more lengthy and costly tests by adapting to new methods, the acquisition of new materials, among others.

Finally, the structural and functional dependence that UDALAB has with the University of Azuay represents a major obstacle to achieve accreditation. It is therefore essential that UDALAB find an exclusive space where only authorized and qualified personnel can work

CONCLUSIONS AND RECOMMENDATIONS

Since 2013, following the entry into force of COMEX Resolution 116, many importers have been experiencing problems when importing certain food products. These foodstuffs need an INEN certificate of recognition as a document of prior control to enter the country.

There is the possibility of importing restricted food products if they have the test reports of a laboratory accredited by the OAE, as long as there is no accredited body issuing INEN certifications. These laboratories must meet the specifications and requirements of the international standard ISO/IEC 17025.

Currently, UDALAB is a laboratory working under the ISO 9001 standard, so it can be concluded that the laboratory meets the requirements of the management part of the ISO/IEC 17025. UDALAB is not compliant in the technical and economic aspect of ISO/IEC 17025 accreditation, specifically in the separation of the laboratory where students access should not be permitted, the implementation of an uncertainty measurement system, sample handling, and the application of INEN testing methods. Nevertheless, due to an economic and market study, it was concluded that the implementation of the international standard ISO/IEC 17025 UDALAB would not be profitable or feasible for the following reasons:

- The lack of importers in the city of Cuenca; which together, imported a total of 11 times a year. Potential customers that need laboratories with ISO/IEC 17025 are in the cities of Quito and Guayaquil where there are already laboratories performing such tests.

- For the field of imports, restricted products require completed tests, insomuch that the laboratory should implement further tests depending on the product. It would be impractical if UDALAB did not perform all required tests, as the main goal is to help importers. Furthermore, the application of the INEN rules required by ISO/IEC 17025 requires the most exclusive

INEN test methods, for which the laboratory would have to renew their processes, extend the scope of it tests, and consider increasing materials, which would result in more costs to the laboratory.

- The income that could be received by those 11 trials annually is only 15.62% more than the lab normally receives per year. As discussed above, the costs of accreditation, training, and logistics for the implementation of ISO / IEC 17025 are quite high.

Knowing that UDALAB is a laboratory service to the community and students, the opportunity to invest in the implementation of the ISO/IEC 17025 standard for food products, not necessarily imports but for products that require this certification to be marketed, is recommended in the local market. Through these tests, UDALAB may recover investment costs more quickly.

If UDALAB considers the above recommendation, it is important to think of an alternative to the academic ties that the laboratory has with the University of Azuay; the constant flow of students to the lab is a factor in sample contamination and equipment-calibration, which hinders the lab from achieving accreditation.

Given that the basis of accreditation is the same for any product, as time goes on, UDALAB could service more products according to market needs; thus, the lab would have a wider array of services and therefore revenue would increase.

BIBLIOGRAPHY

Central Bank of Ecuador. (S.F.). Retrieved on August 1, 2014, of http://www.portal.bce.fin.ec/vto_bueno/seguridad/ComercioExteriorEst.jsp

Comex, C. E. (S. F.). Resolution No. 002-2014. Retrieved on August 13, 2014

Ecuador, O. d. (2015). Proforma for services. Retrieved on March 12, 2015

The National Quality Council. (S.F.). Retrieved on November 16, 2014, of http://www.ecomint.com.ec/inen.htm

Exterior, C. d. (S.F.). Resolution N 116. Retrieved on September 21, 2014, of http://www.aduana.gob.ec/archivos/Boletines/2013/resolucion%20116.pdf

Exterior, M. d. (S.F.). PRO ECUADOR. Retrieved on September 10, 2014, of http://www.proecuador.gob.ec/exportadores/requisitos-para-exportar/incoterms/fob-franco-a-bordo/

Huber, D. L. (S. F.). Knowledge and application of ISO / IEC 17025. Retrieved on August 2, 2014

ISO. (15 May 2005). International Standard ISO / IEC 17025. Retrieved on August 2, 2014

ISO. (November 15, 2008). International Standard ISO 9001. Retrieved on August 3, 2014

Standardization, I. E. (2008). NTE INEN 2337. Retrieved on April 15, 2015

Standardization, I. E. (2010). NTE INEN 2525. Retrieved on April 8, 2015

Standardization, I. E. (S. F.). NTE INEN 1517 gelatin dessert. Determination of moisture. Retrieved on October 7, 2014

Standardization, I. E. (S. F.). NTE INEN 1519 dessert cocnentracion gelatina.Determinacion of hydrogen ion. Retrieved on October 8, 2014

Standardization, I. E. (S. F.). NTE INEN 1529 6. Microbiological food.

Standardization, I. E. (S. F.). NTE INEN 1529-10. Microbilógico food control. Molds and yeasts. Retrieved on October 28, 2014

Standardization, I. E. (S. F.). RTE INEN 070. Retrieved on August 9, 2015

Ecuadorian Accreditation Organization. (S.F.). Retrieved on August 14, 2014, of http://acreditacion.oae.gob.ec/index.php?option=com_wrapper&view=wrapper&Itemid=155

SGS, I. C. (May 4, 2015). Offer Consulting. Retrieved on April 24, 2015

UBALAB. (2015). LAB Quote UBA. Retrieved April 1, 2015

UDALAB, L. d. (June 5, 2013). Quality manual. Uncontrolled document. Retrieved on July 15, 2014

ANNEXES

Annex I: Food products restricted by Resolution 116 of the COMEX

Annex II: Proforma OAE services

Annex III: Quote UBALAB, testing on food products

Productos alimenticios restringidos por la Resolución 116 COMEX

	Sub-partida	Descripción de la Mercancía	Documento de Control Previo	Observaciones
1	0207120000	Sin trocear, congelados	CERTIFICADO DE RECONOCIMIENTO	
2	0207250000	Sin trocear, congelados	CERTIFICADO DE RECONOCIMIENTO	
3	0207420000	Sin trocear, congelados	CERTIFICADO DE RECONOCIMIENTO	
4	0207520000	Sin trocear, congelados	CERTIFICADO DE RECONOCIMIENTO	
5	0208100000	De conejo o liebre	CERTIFICADO DE RECONOCIMIENTO	
6	0209101000	Tocino sin partes magras	CERTIFICADO DE RECONOCIMIENTO	
7	0209109000	Los demás	CERTIFICADO DE RECONOCIMIENTO	
8	0209900000	Las demás	CERTIFICADO DE RECONOCIMIENTO	
9	0210110000	Jamones, paletas, y sus trozos, sin deshuesar	CERTIFICADO DE RECONOCIMIENTO	
10	0210190000	Las demás	CERTIFICADO DE RECONOCIMIENTO	
11	0210200000	Carne de la especie bovina	CERTIFICADO DE RECONOCIMIENTO	
12	0210999000	Los demás	CERTIFICADO DE RECONOCIMIENTO	
13	0402101000	En envases de contenido neto inferior o igual a 2,5 kg	CERTIFICADO DE RECONOCIMIENTO	

14	0402109000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
15	0402211100	En envases de contenido neto inferior o igual a 2,5 kg	CERTIFICADO DE RECONOCIMIENTO	
16	0402211900	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
17	0402219100	En envases de contenido neto inferior o igual a 2,5 kg	CERTIFICADO DE RECONOCIMIENTO	
18	0402219900	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
19	0402291100	En envases de contenido neto inferior o igual a 2,5 kg	CERTIFICADO DE RECONOCIMIENTO	

20	0402291900	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
21	0402299100	En envases de contenido neto inferior o igual a 2,5 kg	CERTIFICADO DE RECONOCIMIENTO	
22	0402299900	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
23	0402911000	Leche evaporada	CERTIFICADO DE RECONOCIMIENTO	
24	0402919000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
25	0402991000	Leche condensada	CERTIFICADO DE RECONOCIMIENTO	
26	0402999000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que

				se ofrecen como tal para la venta directa al consumidor
27	0403100000	Yogur	CERTIFICADO DE RECONOCIMIENTO	
28	0403901000	Suero de mantequilla	CERTIFICADO DE RECONOCIMIENTO	
29	0403909000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
30	0405100000	Mantequilla (manteca)	CERTIFICADO DE RECONOCIMIENTO	
31	0405200000	Pastas lácteas para untar	CERTIFICADO DE RECONOCIMIENTO	
32	0406100000	Queso fresco (sin madurar), incluido el del lactosuero, y requesón	CERTIFICADO DE RECONOCIMIENTO	
33	0406200000	Queso de cualquier tipo, rallado o en polvo	CERTIFICADO DE RECONOCIMIENTO	
34	0406300000	Queso fundido, excepto el rallado o en polvo	CERTIFICADO DE RECONOCIMIENTO	
35	0406400000	Queso de pasta azul y demás quesos que presenten vetas producidas por Penicillium	CERTIFICADO DE RECONOCIMIENTO	

		roqueforti		
36	0406904000	Con un contenido de humedad inferior al 50% en peso, calculado sobre una base totalmente desgrasada	CERTIFICADO DE RECONOCIMIENTO	
37	0406905000	Con un contenido de humedad superior o igual al 50% pero inferior al 56%, en peso, calculado sobre una base totalmente desgrasada	CERTIFICADO DE RECONOCIMIENTO	
38	0406906000	Con un contenido de humedad superior o igual al 56% pero inferior al 69%, en peso, calculado sobre una base totalmente desgrasada	CERTIFICADO DE RECONOCIMIENTO	
39	0406909000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
40	0408110000	Secas	CERTIFICADO DE RECONOCIMIENTO	

41	0408190000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
42	0408910000	Secos	CERTIFICADO DE RECONOCIMIENTO	
43	0408990000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
44	0901211000	En grano	CERTIFICADO DE RECONOCIMIENTO	
45	0901212000	Molido	CERTIFICADO DE RECONOCIMIENTO	
46	0901220000	Descafeinado	CERTIFICADO DE RECONOCIMIENTO	
47	0901900000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
48	0902100000	Té verde (sin fermentar) presentado en envases inmediatos con un contenido	CERTIFICADO DE RECONOCIMIENTO	

		inferior o igual a 3 kg		
49	0902200000	Té verde (sin fermentar) presentado de otra forma	CERTIFICADO DE RECONOCIMIENTO	
50	0902300000	Té negro (fermentado) y té parcialmente fermentado, presentados en envases inmediatos con un contenido inferior o igual a 3 kg	CERTIFICADO DE RECONOCIMIENTO	
51	0902400000	Té negro (fermentado) y té parcialmente fermentado, presentados de otra forma	CERTIFICADO DE RECONOCIMIENTO	
52	0903000000	Yerba mate.	CERTIFICADO DE RECONOCIMIENTO	
53	0904120000	Triturada o pulverizada	CERTIFICADO DE RECONOCIMIENTO	
54	0904221000	Paprika (Capsicum annuum,)	CERTIFICADO DE RECONOCIMIENTO	
55	0904229000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
56	0905200000	Triturada o pulverizada	CERTIFICADO DE RECONOCIMIENTO	

57	0906200000	Trituradas o pulverizadas	CERTIFICADO DE RECONOCIMIENTO	
58	0907200000	Triturados o pulverizados	CERTIFICADO DE RECONOCIMIENTO	
59	0908120000	Triturada o pulverizada	CERTIFICADO DE RECONOCIMIENTO	
60	0908220000	Triturado o pulverizado	CERTIFICADO DE RECONOCIMIENTO	
61	0908320000	Triturados o pulverizados	CERTIFICADO DE RECONOCIMIENTO	
62	0910120000	Triturado o pulverizado	CERTIFICADO DE RECONOCIMIENTO	
63	0910200000	Azafrán	CERTIFICADO DE RECONOCIMIENTO	
64	0910300000	Cúrcuma	CERTIFICADO DE RECONOCIMIENTO	
65	0910910000	Mezclas previstas en la Nota 1 b) de este Capítulo	CERTIFICADO DE RECONOCIMIENTO	
66	0910991000	Hojas de laurel	CERTIFICADO DE RECONOCIMIENTO	
67	0910999000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
68	1103110000	De trigo	CERTIFICADO DE RECONOCIMIENTO	
69	1103130000	De maíz	CERTIFICADO DE RECONOCIMIENTO	
70	1211200000	Raíces de ginseng	CERTIFICADO DE RECONOCIMIENTO	
71	1211300000	Hojas de coca	CERTIFICADO DE RECONOCIMIENTO	
72	1211903000	Orégano (Origanum vulgare)	CERTIFICADO DE RECONOCIMIENTO	

73	1211905000	Uña de gato (Uncaria tomentosa)	CERTIFICADO DE RECONOCIMIENTO	
74	1211906000	Hierbaluisa (Cymbopogon citratus)	CERTIFICADO DE RECONOCIMIENTO	
75	1211909000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
76	1501100000	Manteca de cerdo	CERTIFICADO DE RECONOCIMIENTO	
77	1507901000	Con adición de sustancias desnaturalizantes en una proporción inferior o igual al 1%	CERTIFICADO DE RECONOCIMIENTO	
78	1507909000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
79	1508900000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que

				se ofrecen como tal para la venta directa al consumidor
80	1509100000	Virgen	CERTIFICADO DE RECONOCIMIENTO	
81	1509900000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
82	1510000000	Los demás aceites y sus fracciones obtenidos exclusivamente de aceituna, incluso refinados, pero sin modificar químicamente, y mezclas de estos aceites o fracciones con los aceites o fracciones de la partida 15.09.	CERTIFICADO DE RECONOCIMIENTO	
83	1511900000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor

84	1512191000	De girasol	CERTIFICADO DE RECONOCIMIENTO	
85	1512290000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
86	1514190000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
87	1514990000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
88	1515290000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
89	1515500000	Aceite de sésamo (ajonjolí) y	CERTIFICADO DE RECONOCIMIENTO	

		sus fracciones		
90	1515900000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
91	1517100000	Margarina, excepto la margarina líquida	CERTIFICADO DE RECONOCIMIENTO	
92	1517900000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
93	1518009000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
94	1601000000	Embutidos y productos similares de carne, despojos o sangre; preparaciones alimenticias a base de estos	CERTIFICADO DE RECONOCIMIENTO	

		productos.		
95	1602100000	Preparaciones homogeneizadas	CERTIFICADO DE RECONOCIMIENTO	
96	1602311000	En trozos sazonados y congelados	CERTIFICADO DE RECONOCIMIENTO	
97	1602319000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
98	1602321000	En trozos sazonados y congelados	CERTIFICADO DE RECONOCIMIENTO	
99	1602329000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
100	1602391000	En trozos sazonados y congelados	CERTIFICADO DE RECONOCIMIENTO	

101	1602399000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
102	1602410000	Jamones y trozos de jamón	CERTIFICADO DE RECONOCIMIENTO	
103	1602420000	Paletas y trozos de paleta	CERTIFICADO DE RECONOCIMIENTO	
104	1602490000	Las demás, incluidas las mezclas	CERTIFICADO DE RECONOCIMIENTO	
105	1602500000	De la especie bovina	CERTIFICADO DE RECONOCIMIENTO	
106	1602900000	Las demás, incluidas las preparaciones de sangre de cualquier animal	CERTIFICADO DE RECONOCIMIENTO	
107	1901101000	Fórmulas lácteas para niños de hasta 12 meses de edad	CERTIFICADO DE RECONOCIMIENTO	
108	1901109100	A base de harinas, sémolas, almidones, féculas o extractos de malta	CERTIFICADO DE RECONOCIMIENTO	
109	1901109900	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta

				directa al consumidor
110	1901902000	Manjar blanco o dulce de leche	CERTIFICADO DE RECONOCIMIENTO	
111	1901909000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
112	1904100000	Productos a base de cereales obtenidos por inflado o tostado	CERTIFICADO DE RECONOCIMIENTO	
113	1904200000	Preparaciones alimenticias obtenidas con copos de cereales sin tostar o con mezclas de copos de cereales sin tostar y copos de cereales tostados o cereales inflados	CERTIFICADO DE RECONOCIMIENTO	
114	2004100000	Papas (patatas)	CERTIFICADO DE RECONOCIMIENTO	
115	2004900000	Las demás hortalizas y las mezclas de hortalizas	CERTIFICADO DE RECONOCIMIENTO	

116	2005100000	Hortalizas homogeneizadas	CERTIFICADO DE RECONOCIMIENTO	
117	2005200000	Papas (patatas)	CERTIFICADO DE RECONOCIMIENTO	
118	2005400000	Arvejas (guisantes, chícharos) (Pisum sativum)	CERTIFICADO DE RECONOCIMIENTO	
119	2005510000	Desvainados	CERTIFICADO DE RECONOCIMIENTO	
120	2005590000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
121	2005600000	Espárragos	CERTIFICADO DE RECONOCIMIENTO	
122	2005700000	Aceitunas	CERTIFICADO DE RECONOCIMIENTO	
123	2005800000	Maíz dulce (Zea mays var. saccharata)	CERTIFICADO DE RECONOCIMIENTO	
124	2005991000	Alcachofas (alcauciles)	CERTIFICADO DE RECONOCIMIENTO	
125	2005992000	Pimiento piquillo (Capsicum annuum)	CERTIFICADO DE RECONOCIMIENTO	
126	2005999000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta

				directa al consumidor
127	2007100000	Preparaciones homogeneizadas	CERTIFICADO DE RECONOCIMIENTO	
128	2007911000	Confituras, jaleas y mermeladas	CERTIFICADO DE RECONOCIMIENTO	
129	2007912000	Purés y pastas	CERTIFICADO DE RECONOCIMIENTO	
130	2007991100	Confituras, jaleas y mermeladas	CERTIFICADO DE RECONOCIMIENTO	
131	2007991200	Purés y pastas	CERTIFICADO DE RECONOCIMIENTO	
132	2007999100	Confituras, jaleas y mermeladas	CERTIFICADO DE RECONOCIMIENTO	
133	2007999200	Purés y pastas	CERTIFICADO DE RECONOCIMIENTO	
134	2101110000	Extractos, esencias y concentrados	CERTIFICADO DE RECONOCIMIENTO	
135	2101120000	Preparaciones a base de extractos, esencias o concentrados o a base de café	CERTIFICADO DE RECONOCIMIENTO	
136	2101200000	Extractos, esencias y concentrados de té o de yerba mate y preparaciones a base	CERTIFICADO DE RECONOCIMIENTO	

		de estos extractos, esencias o concentrados o a base de té o de yerba mate		
137	2103100000	Salsa de soja (soya)	CERTIFICADO DE RECONOCIMIENTO	
138	2103200000	«Ketchup» y demás salsas de tomate	CERTIFICADO DE RECONOCIMIENTO	
139	2103301000	Harina de mostaza	CERTIFICADO DE RECONOCIMIENTO	
140	2103302000	Mostaza preparada	CERTIFICADO DE RECONOCIMIENTO	
141	2103901000	Salsa mayonesa	CERTIFICADO DE RECONOCIMIENTO	
142	2103902000	Condimentos y sazonadores, compuestos	CERTIFICADO DE RECONOCIMIENTO	
143	2103909000	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
144	2104101000	Preparaciones para sopas, potajes o caldos	CERTIFICADO DE RECONOCIMIENTO	
145	2104102000	Sopas, potajes o caldos, preparados	CERTIFICADO DE RECONOCIMIENTO	
146	2104200000	Preparaciones alimenticias	CERTIFICADO DE RECONOCIMIENTO	

		compuestas homogeneizadas		
147	2105001000	Helados que no contengan leche, ni productos lácteos	CERTIFICADO DE RECONOCIMIENTO	
148	2105009000	Los demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
149	2106901000	Polvos para la preparación de budines, cremas, helados, postres, gelatinas y similares	CERTIFICADO DE RECONOCIMIENTO	
150	2106908000	Fórmulas no lácteas para niños de hasta 12 meses de edad	CERTIFICADO DE RECONOCIMIENTO	
151	2201100000	Agua mineral y agua gaseada	CERTIFICADO DE RECONOCIMIENTO	
152	2201900000	Los demás:	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
153	2202900010	Bebidas energizantes, incluso gaseadas	CERTIFICADO DE RECONOCIMIENTO	

154	2202900090	Las demás	CERTIFICADO DE RECONOCIMIENTO	Solamente para productos alimenticios procesados, envasados y empaquetados que se ofrecen como tal para la venta directa al consumidor
155	2209000000	Vinagre y sucedáneos del vinagre obtenidos a partir del ácido acético.	CERTIFICADO DE RECONOCIMIENTO	

Autor: Pamela Romero **Fuente:** Resolución 116 COMEX

SERVICIO DE ACREDITACIÓN ECUATORIANO - SAE

Servicio de Acreditación Ecuatoriano

PROFORMA POR SERVICIOS

FECHA: *2015-04-27*

TARIFAS POR SERVICIOS

NOTAS:
El Laboratorio tiene que realizar todo el proceso de acreditación a través del portal web del SAE
Se añade un día de evaluación para el evaluador líder por la elaboración del informe y presentación a la Comisión de Acreditación

INSTITUCION	CONTACTO	DESCRIPCION	DIAS DE EVALUACION	dd di	Valor unitario	COSTO
UDALAB Laboratorios de Alimentos	*Pamela Romero* pames-7842@hotmail.com	*APERTURA DEL EXPEDIENTE*	*1*		$ 200,00	$ 200,00
		COSTOS DE EVALUACION IN SITU (Evaluador Lider)	*3*		$ 480,00	$ 1.440,00
		COSTOS DE EVALUACION IN SITU (Evaluador1)	2		$ 480,00	$ 960,00
		COSTOS DE EVALUACION IN SITU (Evaluador2)	2		$ 480,00	$ 960,00
		COSTOS EVALUACION DOCUMENTAL	2		$ 320,00	$ 640,00
		USO DEL LOGO	1		$ 500,00	$ 500,00
		CERTIFICADO DE ACREDITACIÓN	1		$ 600,00	$ 600,00
				TOTAL A CANCELAR		**$5.300,00**

Evaluación Inicial Laboratorio UDALAB
NOTA: Esta es una proforma referencial. *Se añade un día de evaluador líder por elaboración y presentación de informe a la comisión. El costo de uso de logo y certificado se cancelara cuando se otorge la acreditación.*

IMPORTANTE: **FORMAS DE PAGO**

1) CHEQUE **CERTIFICADO** A NOMBRE DEL SERVICIO DE ACREDITACIÓN ECUATORIANO

2) TRANSFERENCIA BANCARIA O DEPÓSITO BANCARIO

BANCO DEL PICHINCHA
Cuenta Corriente No. 3397742704
PRESTACIÓN DE SERVICIOS
Código: 130108

BANCO DE GUAYAQUIL
Cuenta Corriente No 28921322
PRESTACIÓN DE SERVICIOS
Código: 130108

A nombre de: Organismo de Acreditación Ecuatoriano

3) EFECTIVO:

SERVICIO DE ACREDITACIÓN ECUATORIANO
RUC: 1768141520001
DIRECCION: Calle Robles 653 y Av. Amazonas, Edif: PROINCO-CALISTO, piso 5, of. 509
TELEFONOS: 02 2902879; 02 2903499

Tenga en cuenta: *Una vez realizado el pago, sírvase enviar copia del mismo al correo tesoreria@acreditacion.gob.ec con los siguientes datos para la emisión de la factura:*

Razón Social:
Número del RUC:
Dirección:
Teléfono:

Elaborado por:
Cristina Rodríguez-Polit
Técnico de Área de Laboratorios
Cristina Rodríguez

Servicio de Acreditación Ecuatoriano

Aprobado por:
Directora de Área de Laboratorios
Mónica Torres

COTIZACION
UBA -1544-2015

Guayaquil, 30 de Abril del 2015

Sr. (es)

Atención: Ing. Pamela Romero

Ciudad.

El "***Laboratorio Analítico UBA"*** pone a su disposición nuestra experiencia de mas de 20 años en la aplicación y desarrollo científico de métodos analíticos instrumentales en las áreas de ***CROMATOGRAFIA*** (HPLC, HPTLC, GC, TLC, TLC-FID), ***ESPECTROFOTOMETRIA*** (UV/VIS, Fluorescencia, Absorción atómica) y ***ESPECTROMETRIA*** (Masas, MS/MS), para apoyarlos con nuestros servicios de análisis químicos y asesoría técnica en la búsqueda de soluciones a sus problemas analíticos y de control de calidad en alimentos, productos farmacéuticos, residuos ambientales, cosméticos, etc.

Por la presente y en atención a vuestro requerimiento, nos permitimos poner a su consideración nuestros servicios analíticos en el área de control de Calidad en Productos.

CONTROL DE CALIDAD				
Tipo de muestra	Polvos para preparación de budines, cremas, helados, postres			
Muestreo	Acorde a normas nacionales e internacionales. En caso de muestreo por parte del cliente, el mismo es responsable de su manejo, preservación y envío hasta nuestras instalaciones. De ser el caso, favor aplicar las siguientes recomendaciones: • Enviar muestras por duplicado • Envasar en recipientes sellados y bien etiquetados • Proteger de la luz solar durante el transporte			
PARAMETRO	**METODO**	**COSTO /análisis (USA $)**	**Límite Detección**	**Entrega de Resultados (días)**
Grasa Total	AOAC 952.06 / (Folch 1957)	**16**	-	6
Grasa Láctea	NTE INEN 012	**18**	-	
Solidos Totales	INEN 014	**22**	-	
Proteína Láctea	NTE INEN 016	**28**	-	5
Peso	AOAC 968.14	**7**	-	4
Volumen	AOAC 968.14	**8**	-	4
Colesterol	NTE INEN 729	**70**	2.0	6
Colorantes	Arata/Cromatografía	**45**	-	4

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR

Aerobios Mésofilos	BAM-FDA CAP. #3 2001	**12**	10 UFC/g	3
Coliformes Totales	BAM-FDA CAP. #4 2002	**12**	10 UFC/g	6
Coliformes Fecales	BAM-FDA CAP. #4 2002	**12**	10 UFC/g	
E.Coli	BAM-FDA CAP. #4 2002	**14**	3.00 NMP/g	
Salmonella	BAM-FDA CAP. #5 2007	**20**	Aus/Pres	
Hongos y Levaduras	INEN 1529-10 1998	**18**	100 UFC/g	

CANTIDAD DE MUESTRA: 0.5 – 1.0 Kg

ENTREGA DE RESULTADOS: Ver tabla de tiempo de entrega de resultados

VALIDEZ DE LA OFERTA: 30 días; contado a partir de la fecha de emisión de la presente

CONDICIONES GENERALES :

- Enviar muestras perfectamente selladas y etiquetadas. En lo posible usar recipientes plásticos o vidrio de color negro y evitar la presencia de aire en el interior. Durante el transporte evitar la incidencia directa de rayos solares sobre la muestra
- Las muestras que ingresan al laboratorio, luego de las 15:00 horas son consideradas muestras del día siguiente
- Las muestras una vez analizadas, son almacenadas en el departamento de contramuestras por un periodo de 15 días, o el tiempo a acordar con el cliente.
- * Los costos indicados NO incluyen IVA

Formas de pago:

- Cheque a nombre de **EXCELENCIA QUIMICA S.A**.; a la entrega de la muestra o contra entrega de resultados
- Transferencia a nuestra cuenta **CORRIENTE #: 4987314 del BANCO DEL PACIFICO**

En caso de requerir mayor información respecto a la presente cotización, favor no dude en contactarnos. Agradeciendo de antemano por la atención brindada a la presente, y a la espera de poder servirlos, se suscribe de Usted.

Atentamente,

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR

_____
M. Sc. Nelson Montoya V.
Gerente General

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR

COTIZACION
UBA -1546-2015

Guayaquil, 30 de Abril del 2015

Sr. (es)

Atención: Ing. Pamela Romero

Ciudad.

El "***Laboratorio Analítico UBA"*** pone a su disposición nuestra experiencia de mas de 20 años en la aplicación y desarrollo científico de métodos analíticos instrumentales en las áreas de ***CROMATOGRAFIA*** (HPLC, HPTLC, GC, TLC, TLC-FID), ***ESPECTROFOTOMETRIA*** (UV/VIS, Fluorescencia, Absorción atómica) y ***ESPECTROMETRIA*** (Masas, MS/MS), para apoyarlos con nuestros servicios de análisis químicos y asesoría técnica en la búsqueda de soluciones a sus problemas analíticos y de control de calidad en alimentos, productos farmacéuticos, residuos ambientales, cosméticos, etc.

Por la presente y en atención a vuestro requerimiento, nos permitimos poner a su consideración nuestros servicios analíticos en el área de control de Calidad en Productos.

CONTROL DE CALIDAD				
Tipo de muestra	Purés y pastas			
Muestreo	Acorde a normas nacionales e internacionales. En caso de muestreo por parte del cliente, el mismo es responsable de su manejo, preservación y envío hasta nuestras instalaciones. De ser el caso, favor aplicar las siguientes recomendaciones: • Enviar muestras por duplicado • Envasar en recipientes sellados y bien etiquetados • Proteger de la luz solar durante el transporte			
PARAMETRO	**METODO**	**COSTO /análisis (USA $)**	**Límite Detección**	**Entrega de Resultados (días)**
Sólidos Solubles	NTE INEN 380	**20**	-	6
Aerobios mesofilos	BAM-FDA CAP. #3 2001	**12**	100 UFC/g	
Coliformes Totales	BAM-FDA CAP. #4 2002	**12**	3.00 NMP/g	
Coliformes Fecales	BAM-FDA CAP. #4 2002	**12**	3.00 NMP/g	
Clostridium Sulfito Reductor	INTERNO (Ref INVIMA/BAM)	**35**	10	
Hongos y Levaduras	INEN 1529-10 1998	**18**	100 UFC/g	

CANTIDAD DE MUESTRA: 0.5 – 1.0 Kg

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR

ENTREGA DE RESULTADOS: Ver tabla de tiempo de entrega de resultados

VALIDEZ DE LA OFERTA: 30 días; contado a partir de la fecha de emisión de la presente

CONDICIONES GENERALES :

- Enviar muestras perfectamente selladas y etiquetadas. En lo posible usar recipientes plásticos o vidrio de color negro y evitar la presencia de aire en el interior. Durante el transporte evitar la incidencia directa de rayos solares sobre la muestra
- Las muestras que ingresan al laboratorio, luego de las 15:00 horas son consideradas muestras del día siguiente
- Las muestras una vez analizadas, son almacenadas en el departamento de contramuestras por un periodo de 15 días, o el tiempo a acordar con el cliente.
- * Los costos indicados NO incluyen IVA

Formas de pago:

- Cheque a nombre de **EXCELENCIA QUIMICA S.A**.; a la entrega de la muestra o contra entrega de resultados
- Transferencia a nuestra cuenta **CORRIENTE #: 4987314 del BANCO DEL PACIFICO**

En caso de requerir mayor información respecto a la presente cotización, favor no dude en contactarnos. Agradeciendo de antemano por la atención brindada a la presente, y a la espera de poder servirlos, se suscribe de Usted.

Atentamente,

_____
M. Sc. Nelson Montoya V.
Gerente General

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR

COTIZACION
UBA -1545-2015

Guayaquil, 30 de Abril del 2015

Sr. (es)

Atención: Ing. Pamela Romero

Ciudad.

El "***Laboratorio Analítico UBA"*** pone a su disposición nuestra experiencia de mas de 20 años en la aplicación y desarrollo científico de métodos analíticos instrumentales en las áreas de ***CROMATOGRAFIA*** (HPLC, HPTLC, GC, TLC, TLC-FID), ***ESPECTROFOTOMETRIA*** (UV/VIS, Fluorescencia, Absorción atómica) y ***ESPECTROMETRIA*** (Masas, MS/MS), para apoyarlos con nuestros servicios de análisis químicos y asesoría técnica en la búsqueda de soluciones a sus problemas analíticos y de control de calidad en alimentos, productos farmacéuticos, residuos ambientales, cosméticos, etc.

Por la presente y en atención a vuestro requerimiento, nos permitimos poner a su consideración nuestros servicios analíticos en el área de control de Calidad en Productos.

CONTROL DE CALIDAD				
Tipo de muestra	Condimentos y sazonadores			
Muestreo	Acorde a normas nacionales e internacionales. En caso de muestreo por parte del cliente, el mismo es responsable de su manejo, preservación y envío hasta nuestras instalaciones. De ser el caso, favor aplicar las siguientes recomendaciones: • Enviar muestras por duplicado • Envasar en recipientes sellados y bien etiquetados • Proteger de la luz solar durante el transporte			
PARAMETRO	METODO	**COSTO /análisis (USA $)**	**Límite Detección**	**Entrega de Resultados (días)**
Sólidos Solubles a 20 ºC	NTE INEN 380	**20**	-	6
pH	NTE INEN 389	**10**	-	
Plomo (Pb)	AOAC 972.25	**23**	0.01	
Cobre (Cu)	AOAC 986.15	**23**	0.01	5
** Arsénico (As)	AOAC 986.15	**23**	0.02	6
** Estaño (Sn)	INEN INEN 385	**23**	-	
** Mercurio (Hg)	AOAC 971.21	**23**	0.0005	
Hongos	INEN 1529-10 1998	**18**	100 UFC/g	

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR

CANTIDAD DE MUESTRA: 0.5 – 1.0 Kg

ENTREGA DE RESULTADOS: Ver tabla de tiempo de entrega de resultados

VALIDEZ DE LA OFERTA: 30 días; contado a partir de la fecha de emisión de la presente

CONDICIONES GENERALES :

- Enviar muestras perfectamente selladas y etiquetadas. En lo posible usar recipientes plásticos o vidrio de color negro y evitar la presencia de aire en el interior. Durante el transporte evitar la incidencia directa de rayos solares sobre la muestra
- Las muestras que ingresan al laboratorio, luego de las 15:00 horas son consideradas muestras del día siguiente
- Las muestras una vez analizadas, son almacenadas en el departamento de contramuestras por un periodo de 15 días, o el tiempo a acordar con el cliente.
- * Los costos indicados NO incluyen IVA

Formas de pago:

- Cheque a nombre de **EXCELENCIA QUIMICA S.A**.; a la entrega de la muestra o contra entrega de resultados
- Transferencia a nuestra cuenta **CORRIENTE #: 4987314 del BANCO DEL PACIFICO**

En caso de requerir mayor información respecto a la presente cotización, favor no dude en contactarnos. Agradeciendo de antemano por la atención brindada a la presente, y a la espera de poder servirlos, se suscribe de Usted.

Atentamente,

_____
M. Sc. Nelson Montoya V.
Gerente General

Av. Carlos L. Plaza Dañin, Cdla. La FAE, Mz 20 Solar 12 (Frente al primer bloque de la Atarazana)
PBX: 2288578, 2397185, 2287195 Cel.: 0984780671
e.mail: nmontoya@uba-lab.com
nmontoya@mail.com
Guayaquil-ECUADOR