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European Scientific League for Probiotics

Quality control of probiotics, the ESLP initiative

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ESLP President

PreProPed2016

Ghent, 29th April



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European Scientific League for Probiotics

1. Introduction & Environment
2. ESLP
 - Mission
 - Scientific Committee
 - ESLP Quality Label
3. Case Study : 4 years experience in Belgium
4. Next steps



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1. Introduction & Environment



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Did you know that everything
has started
more than 100 years ago ?

PubMed
About 1.500
new
publications in
2015

WHO – FAO
Probiotics
definition
2001

Y. Metchnikoff
Nobel Price
1908



Microbiota and Research programmes *with public subventions*



Gut microbiota, human health and diseases
Obesity & chronic inflammatory bowel diseases



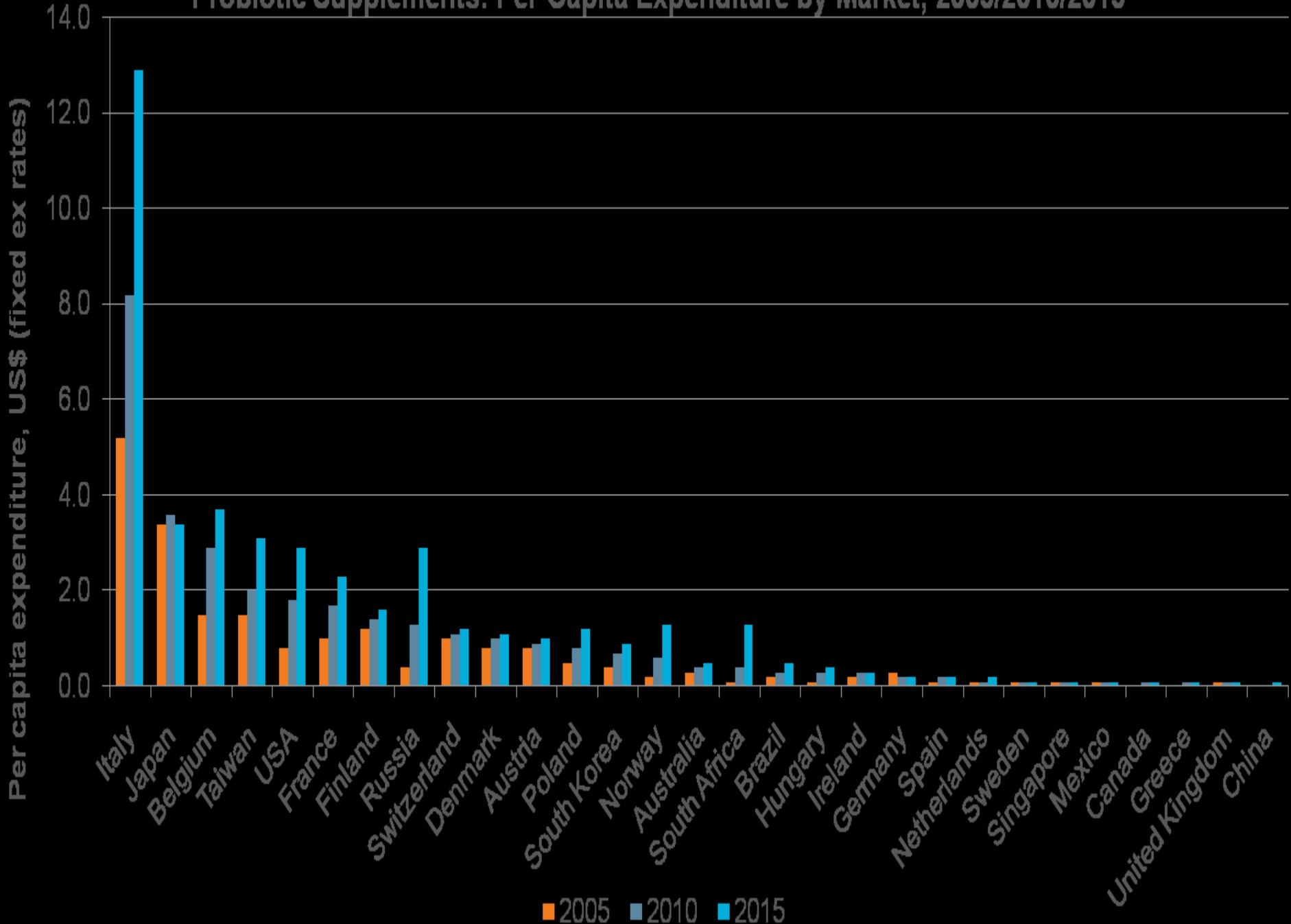
Microbiota & microbiome effects on

- diseases development
- brain development



Human Microbiome Project
USA (NIH)

Probiotic Supplements: Per Capita Expenditure by Market, 2005/2010/2015





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- Since the late 20th century, our knowledge of *bacteria* has increased exponentially.
- Numerous Food supplements based on Lactobacilli, Bifidobacteria, etc., have been introduced in Belgium and in Europe over the last 10 years.
- Quality problems mainly with Food supplements in Quality survey in the past
- New EFSA legal disposition related to claims



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Quality survey in 2001



ELSEVIER

International Journal of Food Microbiology 81 (2002) 1–10

INTERNATIONAL JOURNAL OF
Food Microbiology

www.elsevier.com/locate/ijfoodmicro

Identification and antibiotic susceptibility of bacterial isolates from probiotic products

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^bBCCM_{TM}/LMG Bacteria Collection, K.L. Ledeganckstr. 35, B-9000 Ghent, Belgium

Received 20 May 2001; received in revised form 27 December 2001; accepted 16 April 2002

**Product quality investigation of 55 West-European probiotic
products:**

30 dried food supplements and 25 dairy products.



Probiotics Supplements & Regulatory in Europe

EC : « Probiotic » banned towards
consumers

due to the « health effect » in its definition

EFSA: No Health claim accepted for
Probiotics

only « lactose intolerance » accepted for yoghurts

Health claim guidance recently published by EFSA



Probiotics Food supplements *EFSA Reglementation and local Authorithies*



- Strict implementation, no flexibility
- B to B communication recently allowed



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Probiotics market - Food supplements *Digest segment Evolution*

- 2008: High Competition & Very High Growth
- 2013: High Competition & Slow Growth



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Nowadays all parties involved agree on the need for a Quality Label to differentiate “quality products” from “*cowboy* products”.



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2.1. ESLP Mission



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- Non-profit association founded in 2011
- ESLP Quality Label



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- By ESLP Quality Label granting, highlight qualitative products (mono-, multi-strain) delivered through Pharmacy
- Promote scientific research and technological innovations in the Probiotics area



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2.2 ESLP

Scientific Committee



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ESLP Members & Scientific Committee

SPECIALITY

Prof. S. Vermeire, KU Leuven
Prof. K. Verbeke , KU Leuven
Dr. J-P. Langhendries, Rocourt
Dr. J. Simar, Brussels

Dr. G. Donders, Consultant KUL & Ulg
Belgian Society Menopause representative

Prof. B. Pot, Pasteur Institute Lille
Prof. G. Daube, University of Liege
Prof. V. Delcenserie, University of Liege

GASTRO-ENTEROLOGY
Head of Fermentation Lab.
NEONATOLOGY & PAEDIATRICS

GYNECOLOGY - OBSTETRICS

MICROBIOLOGY



Een label voor probiotica

Ieder jaar zal de vereniging aan verdienstrijke producten een label toekennen. In België schrijft niet minder dan 77% van de artsen probiotica voor. Toch bestaan er niet voor alle beschikbare producten even robuuste wetenschappelijke argumenten. Het aantal producten is 'schamele' 8,1 miljard dollar, maar vijf jaar later had deze vrijwel het dubbele bereikt, met een resultaat van 15,9 miljard. De cijfers tonen een explosief de hoogte ingaan.

4 PROBIOTIQUES SOIGNEZ VOTRE FLORE!
Pas de système immunitaire efficace sans une flore intestinale performante. « Tout



GfK Survey by General practitioners & pharmacists

GfK

European Scientific League for Probiotics

September 2012

Studie van GfK over de perceptie van probiotica bij Belgische apothekers.

Apothekers associëren probiotica spontaan met gunstige gastro-intestinale effecten en vervolgens met bacteriën, levende micro-organismen en een positieve rol bij de immuniteit.

E gezondheid

Blog "Blog van de redactie"

NIEUW LABEL VOOR PROBIOTICA



Wellicht hebt u al gehoord van probiotica. Maar weet u welk probioticum u precies nodig heeft? De juiste keuze kan immers een groot verschil uitmaken.

The European Scientific League for Probiotics (ESLP) assigns its probiotics sold in pharmacies in Belgium. The identification of scientifically documented probiotics is now easier.

Il ressort de cette enquête que les MG associent souvent spontanément les probiotiques aux bénéfices gastro-intestinaux qui en résultent. Une majorité les considère comme des micro-organismes vivants (58%), des bactéries et levures ayant des effets positifs pour la santé (55%), notamment sur

Le prix apparaît aussi être un critère de choix des probiotiques, poursuit cet expert. « Il faut savoir que l'accessibilité des probiotiques, au niveau de leur prix, est aujourd'hui meilleure qu'il y a quelques années. Certains



ESLP Communication

E-learning programme for General Practitioners



Accreditation valid till 1 /10 /2017



ipc
2015

INTERNATIONAL SCIENTIFIC CONFERENCE
PROBIOTICS AND PREBIOTICS™

23rd – 25th June 2015 21th-23th June 2016
Budapest Budapest



« ESLP as Scientific Partner »

- IPC is the biggest scientific conference worldwide, solely focusing on probiotics and prebiotics for scientists, researchers, product developers, industry participants, pharmaceutical, medical, health and regulatory professionals as well as venture capitalists and investors.
- The aim of the conference is to learn about recent advances, likely future developments and to exchange scientific ideas and experiences in our field all within a unique environment. It is our intention to further confirm IPC as the leading scientific conference on probiotics and prebiotics. Every year the conference attracts up to 500 leading scientists, opinion leaders, clinical study managers, medical doctors and dieticians from over 80 countries.



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2.3 ESLP *Quality Label*



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- The ESLP label is a “Quality Label” created exclusively for specialties based on documented specific strains & associations and sold through pharmacies
- The ESLP Quality Label is assigned on spontaneous application
- The ESLP Quality Label is assigned after qualitative and quantitative microbiological analyses have been carried out by an independent laboratory (***Quality Partner SA***).



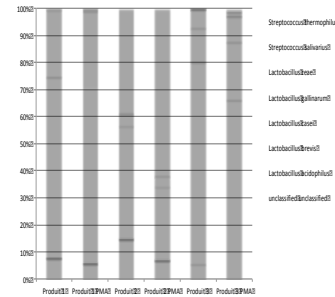
An **initial quantitative analysis** certifying that the specific strain (s) concerned are live and present in sufficient quantities (maximum 1 log difference from the amount stated on the packaging and in the instructions for the proprietary medicinal product).

A **second quantitative analysis** conducted nine months later certifying that the specific strain (s) concerned are live and present in sufficient quantities (maximum 1 log difference from the amount stated on the packaging and in the instructions for the proprietary medicinal product).

Qualitative analysis with strain identification (DNA).



Quality control



European
Scientific
League
Probiotics

<http://www.probioleague.org/>



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3. FOUR YEARS EXPERIENCE ON THE BELGIAN MARKET





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ESLP Label brands versus Probiotics Market

% Labellised products after 2 years

Units

Submitted files: 75 %

ESLP label : 30 %



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Probiotics market - Food supplements
***Faster growth for ESLP Granted
Brands / companies than the Market***
in Value & Units (%)

Digest Segment	<u>Growth</u>	-----
ESLP granted 	double digit	



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4. Next steps



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- ESLP label:
 - Internationalisation of the Quality Label
 - Belgium : 4th brand/company labelled
5th pending

- Communication & Education

- Further support research and technological innovations and communication in the Probiotics field



1. **Food Supplement**
2. *Medical Food*
3. *Medical device ?*
4. *Drugs*



EFSA

EMA



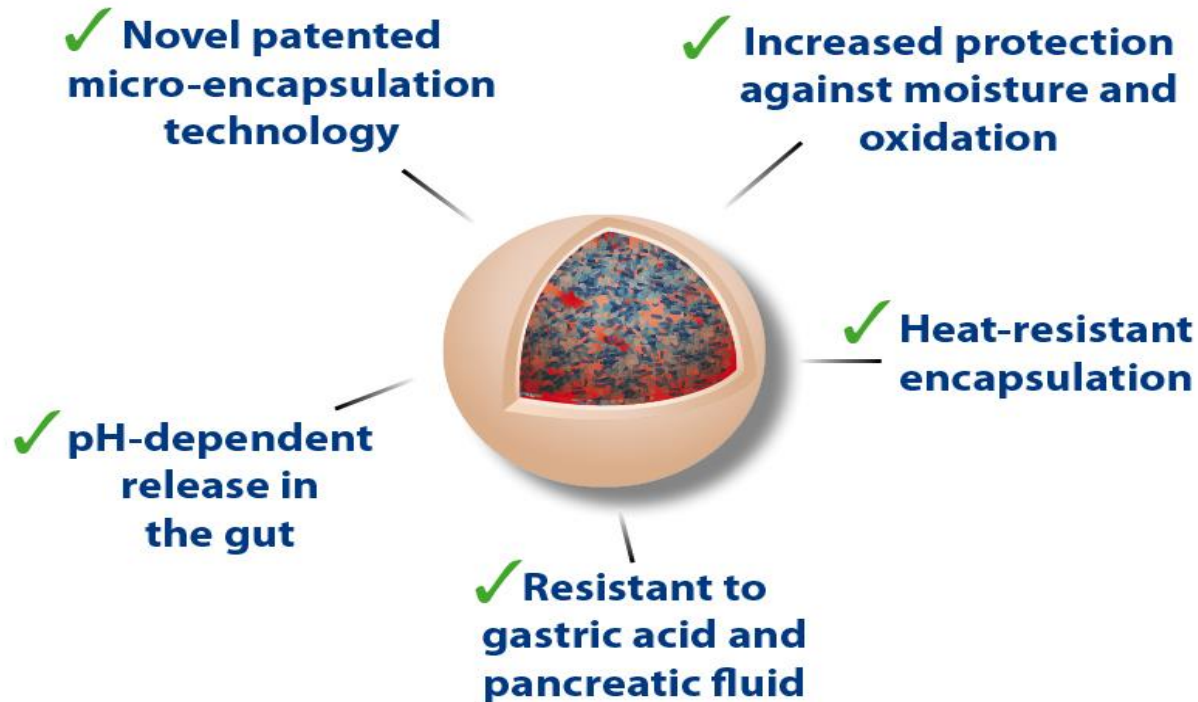
Probiotic strains



Fragile



micro-encapsulation technology





artificial model of digestive tract : **TWINSHIME®**

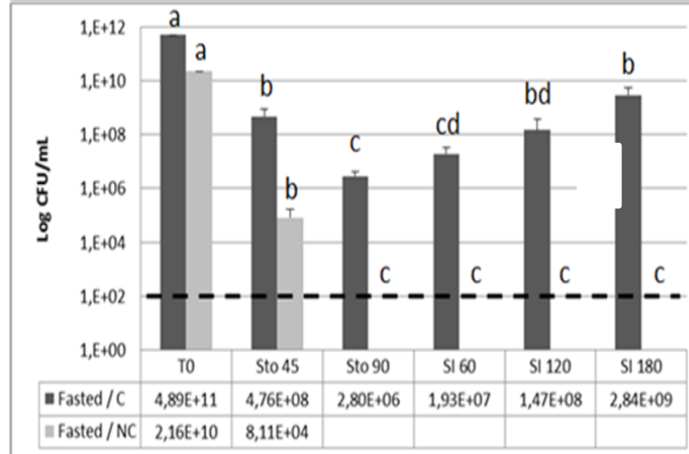
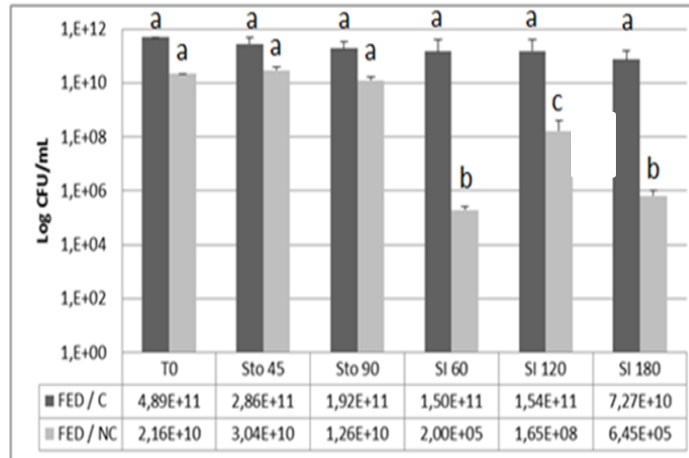


SHIME®: Simulator of the Human Intestinal Microbial Ecosystem

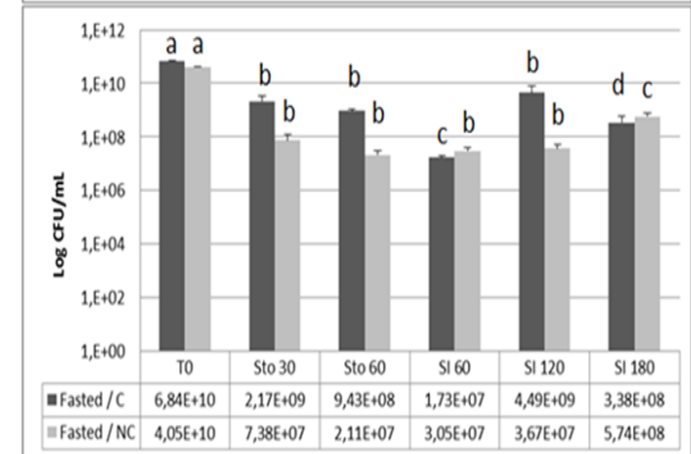
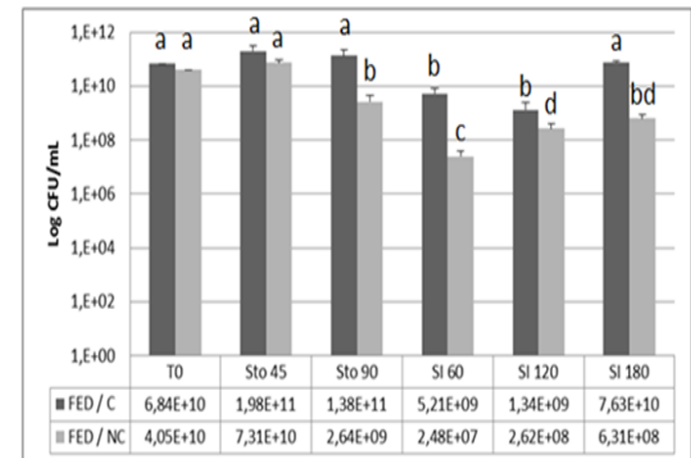


Probiotics & microencapsulation

L. rhamnosus



B. animalis subsp. lactis





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Thank you

www.probioleague.org

contact@probioleague.org