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Letter to the Editor

Nov/25, 2020

Response justifying objections to the article: *Kostov et al. Biopreservation of emulsified food and cosmetic products by synergistic action of probiotics and plant extracts: a Franco-Bulgarian perspective*, published in *Food Science and Applied Biotechnology*, 2020, Vol. 3., Iss. 2, pp. 167-184, <https://doi.org/10.30721/fsab2020.v3.i2.93>.

Dr. Philip Anthony Geis, PhD (philageis)

This responds to “**Biopreservation of emulsified food and cosmetic products by synergistic action of probiotics and plant extracts: a Franco-Bulgarian perspective**” by *Kostov et al.* (1) and attempts to clarify the technical and regulatory requirements regarding cosmetic preservation. In this cited article, authors considered reports of a cosmetic product formulated with a probiotic as nominal cosmetic preservative. The criterion for efficacy was based on failure to detect at one day and 1 year *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli* or “Fungi and Yeast” microorganisms in cosmetic emulsion containing specified probiotics. These target microbes apparently were not inoculated but apparently were presumed, if detected, to be production contaminants, in practice apparent indicators of inadequate Good Manufacturing Practices (GMP’s). Based on absence of detections and a surviving probiotic population, effective preservation was concluded, and relevant products were claimed to be “...microbiologically safe for use.”.

Although preservatives offer limited additional protection to GMP’s in prevention of microbial contamination in manufacturing, their primary objective is protection versus contamination in use. EU statutory requirements demand that cosmetic products are “safe under normal or reasonably foreseeable conditions of use” (2). The US FDA’ similarly requires cosmetics to be safe “when consumers use them according to directions in the labeling, or in the customary or expected way” (3). This In use aspect of microbial quality is function of preservative and package and is critical in context of cosmetic preservation as blindness and even death have been reported as consequence of in-use microbial contamination (4,5). As specified by industry standards, compendial methods and regulatory requirement, effectiveness of cosmetic preservation is determined by performance

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in challenge testing by which high levels of potential microbial contaminants (including isolates of the above-named microorganisms) are added to the product and kill rates/levels of this inoculum assessed through 28 days and compared to standards (6,7,8,9). Challenge testing is applied not only to product as made but also to aged product to confirm preservative efficacy through anticipated use life (10,11). Challenge testing of as-made and appropriately-aged cosmetics is a regulatory expectation if not minimal requirement of virtually all nations (e.g. 2,3,13,14), responsible scientific policy organizations (e.g. 15) and, as cited above, the technical expectation of industry.

The protocol addressed by Kostov et al. does not appropriately evaluate cosmetic preservative efficacy, and results presented are inadequate to support the conclusion that cosmetics preserved with specified probiotics “were microbiologically safe for use.”

Answer of the Authors

To: The Editor in Chief of **Food Science and Applied Biotechnology**

To: The Members of the Editorial Board

Dear colleagues,

Referring to the opinion expressed by the Editorial Board in relation to the paper ***Biopreservation of emulsified food and cosmetic products by synergistic action of probiotics and plant extracts: a Franco-Bulgarian perspective***, on behalf of the co-authors, I would herewith like to draw your attention to the following:

The scientific paper presented contains a brief review of the approaches which will be implemented in the research project financed under the Rila programme. The aim of this paper was to present a short overview of the objects and tasks of the project and the state of the art of the research which would serve as a starting point for the team working on the project. The paper was presented at the Food Science, Engineering and Technologies 2019 International Scientific Conference and was referred for publication in the journal by the Editorial Board where you serve as members.

The scientific paper presented underwent the anonymous peer review that is standard for the journal and having made all the changes recommended by the two reviewers, it was approved for publication in the journal by you, in your capacity as Editorial Board members. The whole review, correction, acceptance and final publication process lasted almost a year. During that time, no critical comments were made regarding the scientific content of the paper. All critical comments contained in the anonymous peer review were carefully considered and given the respective answers, which, I hope, you became familiar with.

Immediately after the publication of the paper, the Editor-in-Chief received a letter from Dr Phil Geis, who presented his opinion on part of the materials involved in the application of our approaches to the biological preservation of cosmetic products. We do not intend to launch into any scientific debates with Dr Geis, since he already received an answer of the corresponding

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author of our article. Nevertheless, as stated in this letter, Dr Phil Geis' opinion and recommendations are highly valued and we will take them into account in the course of our research.

We reproduce below the e-mail sent by Dr Phil Geis to the corresponding author of the review and our comments related to his different concerns:

“I read the above titled article with interest and had some questions and comments regarding its consideration of cosmetic quality. The relevant citations are not accessible, so it is not possible to know the protocol executed.” Since our article is not an original research article but a review, the exact procedures are described in detail in each cited reference. Therefore, we sent Dr Geis one reference he could not access.

“However, it is not apparent that a challenge was executed. Please be aware that a product made and packaged unopened does not become contaminated over time is a very trivial element of cosmetic microbiological quality. This is expected, and failure in this aspect would indicate gross contamination in making.”

It is true that no challenge test was executed. In our case, while this cannot be considered as a contamination, products were voluntarily inoculated with probiotic strains, since as mentioned in the abstract and in the introduction, some emulsified food and cosmetic products are good candidates to deliver probiotics. Regarding the statement “a product made and packaged unopened does not become contaminated over time”, this is true for a sterilized product in its package or following an aseptic filling. As stated in the introduction, if a cosmetic or food product is used to deliver probiotics, the situation is somewhat different: any thermal treatment in package is no more possible: “Despite its efficiency, this combination of a thermal treatment with the addition of antimicrobial additives in the formulation of emulsified products cannot be applied to probiotics and to a lesser extent to most of plant extracts since it would result in their thermal inactivation.”

“Microbiological quality is judged by performance in a challenge test”

(see https://cosmeticsbusiness.com/news/article_page/What_kind_of_testing_is_mandatory_for_cosmetic_products_in_the_EU/160464 and specifics summarized by Microchem Laboratories - <http://microchemlab.com/information/new-eu-cosmetic-regulation-requirements>) by which high levels of potential microbial contaminants are added and kill rates/levels are compared to standards (e.g. EP AET* or ISO 11930**). These standards are applied not only to product as made but also aged to the expected shelf life of the products. The intent is to protect products as made but more importantly in use. Cosmetics are readily contaminated in use and must remain microbiologically stable in this use/exposure through years of shelf life and use.”

Challenge tests will be performed in future work. It is common for research activities that monitoring of quality indices is not performed following standards. Since the products are not commercialized, the goal is often to get first experimental results. In a review, articles are cited, therefore, comments regarding materials and methods have to be sent to the cited authors, who are able to discuss their experimental procedure and results.

Specific comments refer to Tables 2a and 2b.

2a. "TBA" (assume "TAB" in 2a was a typo) counts in Table2a. Assume author's method was validated and did not count the formulated lactobacilli. The counts in batch 1 clearly exceeded typical industry standards (<100 cfu/g) and reveal inadequate preservation."

These products were prepared in a lab and not under industrial conditions.

"2b. Unless the identified bacteria and fungi (please be aware - yeast are fungi) were inoculated, these data are fairly meaningless to microbiological quality. Here too, counts exceed industry standards. That *S. aureus* was recovered from the unpreserved control merely shows poor hygiene of production."

Dr Phil GEIS is right, "fungi and yeasts" should be replaced by "yeasts and moulds" (pages 174 and 175).

"Neither table offers any preserved product control."

Again, thermal treatment or addition of preservatives would result in probiotics inactivation and this control would not give valuable information since it is already known that a sterile product made and packaged unopened does not become contaminated over time.

"Based on results presented, it is not apparent or even suggestive that probiotics would be effective for cosmetic preservation. It is also relevant that cosmetic preservative systems are very rarely composed on only parabens."

As can be seen in Table 2B, creamy cosmetic emulsions formulations containing *Propionibacterium freudenreichii ssp. shermanii* NBIMCC 328 strain have a significantly lower mesophilic aerobic and facultative anaerobic bacteria count after 1 year storage at room temperature than formulations with other probiotic strains and control formulation without any probiotic strains. Besides its probiotic properties, this strain is thus a good candidate for bio-preservation of this product: this should now be evaluated by performing challenge tests.

"Further, probiotics will be labour intensive/expensive to standardize and formulate and are of doubtful benefit to cosmetics (beyond marketing hype). One should also be concerned with the genome of strain used - some can include genetic potential for antibiotic resistance. In the lactobacilli, these may have no significance but their potential transmission to other bacteria - potential contaminants - could be a concern."

The role of the scientific community is to put in light the respective advantages/benefits and drawbacks/risks related to any innovation. It can thus not be considered that probiotics would have no benefit to cosmetics in any situation, while we also share the opinion of the necessity of a benefits/risk evaluation like for any innovation. In order to substantiate the hypothesis that probiotics delivery by cosmetics could be beneficial in some situations, we sent Dr Phil GEIS some references of articles (see our letter):

"Finally, while inoculation of cosmetic products with probiotics is far less common than inoculation of foods (namely to produce fermented milk), this possibility merits exploration as stated in many recent articles (e. g. « "Living" and "probiotic" cosmetics: modern view and definitions »).

Tkachenko et al. (2017), <https://journals.onaft.edu.ua/index.php/foodtech/article/view/735>

<accessed on October 23rd 2020>).

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Indeed, besides marketing hype, as recently pointed out by Butler et al. (2020), some probiotic products could be a novel topical cosmetic ointment for the management of atopic dermatitis or other disorders associated with the skin although this should be further investigated. Another example stated in Denkova et al. (2013) article is face masks, which are the first Bulgarian probiotics used as cosmetics.

Butler E, Lundqvist C, Axelsson J (2020). *Lactobacillus reuteri* DSM 17938 as a novel topical cosmetic ingredient: a proof of concept clinical study in adults with atopic dermatitis. *Microorganisms* 8:1026.

We understand quite well scepticism with these orientations which necessitate further investigations and would be of interest only for a limited number of cosmetic products. We share the opinion that concerns regarding safety of probiotics use such as the risk of potential transmission of antibiotic resistance to other bacteria should be addressed.”

Scientific developments are based on continuous debates between scientists aiming to achieve the best possible results to the benefit of society. Therefore, we consider our paper a platform for scientific discussions which would lead to improvements in the quality of life of modern people by improving the quality of the cosmetic products placed on the market. Removing the part suggesting that the possibility that besides their probiotics properties, some probiotics strains would also be beneficial for the preservation of cosmetic products in which they are incorporated would thus in our opinion not be appropriate.

“Erratum” is something used when there is a factual error in an article or review. Unless someone is able to demonstrate that this is the case, we do not feel that this is necessary for this review.

Dear Editorial Board members, you are most probably aware of the fact that creating an option for editing a research paper after its publication may lead to dangerous precedents which may later be used for purposes of questionable character.

The only errors are “translation” or “typographic errors” can be corrected.

We, the co-authors of the paper, believe that the Editorial Board may find it expedient to extend an invitation to Dr Phil Geis to submit a scientific publication in the area of the biological preservation of cosmetic products, which would definitely be of mutual benefit.

Yours sincerely,

Prof. Georgi Kostov, DSc

University of Food Technologies, Plovdiv