

Article

Research and Development of a New Sustainable Functional Food under the Scope of Nutravigilance

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Abstract: Background: The New Global Economy is represented by a series of major features, such as the use of green energy, the reduction of the carbon footprint in all industrial and civil fields, as well as finding alternative food resources. Our main objective was the research of a sustainable food product with a special nutritional purpose in the vision of nutravigilance, developed in Romania, as an adjuvant in the repair of gastric mucosa. Methods: The materials used in the research and development of the new food are the following: inulin, lactoferrin, sericin, and sodium bicarbonate. The new adjuvant food product in the repair of the gastric mucosa was added to certain foods in order to prevent the patients from being satiated by a single food from a sensory point of view. The resulting food products were organoleptically and physico-chemically analyzed. Results: The new food is sustainable and has versatile uses. It can be hydrated with water, non-carbonated drinks, mixed with cottage cheese, or with fruit puree and oatmeal. It is stable under normal storage conditions and microbiologically safe. Conclusions: Through its versatile use, the new food product for special nutritional conditions represents a worldwide novelty. Through the development of forestry for the cultivation of white or black mulberry (*Morus alba* and *Morus nigra*), the raising of silkworms (*Bombyx mori*), the processing of fibroin to obtain natural silk and the processing of sericin resulting as a residue in the textile industry, the new food product developed actively contribute to the global economy II.

Keywords: food; gastric mucosa repair; sericin; lactoferrin; inulin; sodium bicarbonate; sustainable; global economy II



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1. Introduction

The New Global Economy is represented by a number of major features, such as the use of green energy, reducing the carbon footprint in all industrial and civil areas, as well as finding alternative food resources. Added to this is the rapid development of artificial intelligence in all economic sectors (agriculture, horticulture, animal husbandry, the food industry, pharmaceuticals, hospitals, the automotive and aircraft construction industries, and other industries-textiles, footwear, etc.), which has led and will lead to the loss of jobs and the decrease in people's quality of life, due to stress. Other causes that can increase the negative effects of stress are pandemics, such as the one caused by the SARS-CoV-2 (COVID-19) virus, and lifestyle changes.

Recent research [1] has shown that the COVID-19 pandemic has negatively affected the entire world economy, much more than the economic crisis of 2008. Although after

its end, the world economy began to grow slowly, the geo-political conditions due to the context of the war in Ukraine started to change the global economic poles, towards China and India [2]. As presented by Ungureanu AV [3], regardless of the economic sector, an important part of the technological profile of the new global economy is driven by innovation and the entrepreneurial initiative that is at the heart of innovative business strategies. In Asian countries, such as China, Korea, India, and Vietnam, silk production is the largest in the world. This has great economic value [4]. In order to provide the raw material (fibroin) for obtaining silk, a very large number of *Bombyx mori* cocoons and a very large amount of mulberry leaves (*Morus alba*) as food for silkworms were required. Like any agricultural crop, including *Morus alba*, it requires specific agro-pedo-climatic conditions, such as soil composition, temperature, and rainfall. The white mulberry (*Morus alba*) grows well in temperate or subtropical regions of Asia, Africa, Europe, and North America, on light, loose, sufficiently moist soils. It also withstands beaten soils. Withstands transient flooding.

Due to the fact that the root is pivoting-trailing, the white mulberry (*Morus alba*) pulls its salts from the soil from certain depths, depending on the age, and has a long life (100 years [5]), in addition to the production of leaves needed as food for *Bombyx mori*, the white mulberry (*Morus alba*) culture contributes to the prevention of landslides (land). Mulberry wood (*Morus alba* and *Morus nigra*) is hard, resistant, and durable and processes and polishes well, being a particularly important material in the fields of the economy such as carpentry, handicrafts, office furniture, and musical instruments [5]. The fruits of the two varieties of mulberry (*Morus alba* and *Morus nigra*) are used in the food industry or in biotherapy.

In addition to these exceptional benefits, mulberry leaves (*Morus folium*) produce oxygen necessary for humans and animals, which leads to the possibility of establishing protection zones for localities or silvosteppe (intermediate vegetation zone between a steppe and a deciduous forest), but they are also used in the food of silkworms. The tender leaves (*Morus folium*) are picked without the petiole in the months of May–June and can be dried in the shade in a thin layer. Silkworms can be fed on tender leaves (*Morus folium*) of *Morus alba* and *Morus nigra*, and old leaves only of *Morus alba* [5].

The authors Matran IM et al. showed [6] the structure and processing method of the threads secreted by the silkworm gland in the textile industry and the importance of processing the sericin that results as a residue from this industry.

Currently, both in Romania and in other countries from the European Union (EU), as well as non-EU countries, functional foods are analyzed by manufacturers only regarding allergies. Currently, in the EU, nutravigilance is regulated by law and implemented in France, Italy, Belgium, Slovenia, the Czech Republic, and Ireland. In these countries, risk assessments are carried out at the post-sale stage of food and food supplements. In France, the following are analyzed and monitored: food supplements (food supplements containing melatonin, food supplements containing spirulina, food supplements for pregnant women, food supplements for athletes, food supplements containing red rice yeast, food supplements containing p-synephrine), energy drinks, nutrient concentrates, plants or other substances in measured doses, foods or fortified drinks: foods supplemented with vitamins, minerals or other substances, amino acids or plant extracts, such as so-called energy drinks, vitamin D-enriched milk, certain nutrient-enriched vegetarian products, new foods and new ingredients: foods that were not consumed in Europe before 1997 or that were produced from new sources, with new substances or technologies, such as guar gum, noni juice, fruit pulp dehydrated baobab, products intended for food for specific categories of the population: preparations for infants, products for patients suffering from metabolic disorders or malnutrition, etc.

In Italy, natural products, herbal products, preparations from traditional Chinese or Ayurvedic medicine, dietary supplements, vitamins and probiotics, homeopathic medicines, medicinal preparations, or galenic masters are monitored. In Belgium, authorized food supplements are monitored.

Considering the recent research of sericin in the pharmaceutical and biomedical field, such as tissue engineering, wound healing, drug administration, and cosmetics [7], in this paper, we present the research of a sustainable food product with a special nutritional purpose in the vision of nutrigenetics, developed in Romania, as an adjuvant in the repair of the gastric mucosa. Another objective was to evaluate the versatility of usage of this new product, to prevent the appearance of sensory boredom (saturation) in adult patients, in the form of a single mono dose per day.

2. Materials and Methods

2.1. The Materials Used in the Research—Development of the New Food

2.1.1. Raw Materials and Food Ingredients

The materials used in the research and development of the new food are the following: inulin, lactoferrin, sericin, and sodium bicarbonate. The choice of raw materials was made based on the assessment of the state of knowledge using the PubMed and ResearchGate databases.

In order to be able to achieve the traceability of the finished product and the raw materials used, all related information (name of the product), batch/batch, manufacturing company, or importing company was recorded.

The information necessary to achieve the traceability of the finished product and the raw materials used (inulin, lactoferrin, sericin, and sodium bicarbonate) in the research and development of the new adjuvant food in the repair of the gastric mucosa is presented in Table 1.

Table 1. Traceability of the finished product (the new adjuvant food product in the repair of the gastric mucosa) and of the raw materials used.

Name of the Raw Material	Identification Data	Manufacturer/Importer Company
Inulin	Batch: RHBGD1BGD1	Adams Vision SRL, Targu Mures
Lactoferrin 1	Batch: 107CLXP	Frisland Campina/KUK Romania ¹
Sericin	Batch: S1911251	Sollice Biotech, France
Sodium bicarbonate	Batch: A 02L 05	Dr. Oetker, Romania

¹ Lactoferrin is a newly authorized food ingredient in the European Union (EU) [8].

2.1.2. The Equipment Used

The equipment used was:

- Electronic balance with two decimal places, the brand “Digital Scale”, capacity 500 g/0.01 g;
- pH-meter (0–14 pH), brand Adwa, manufacturer Adwa kft Romania;
- Electronic probe type thermometer, brand Checktemp, manufacturer Hanna Instruments Romania;
- Electronic refractometer (0–85% Brix), model HI 96801, manufacturer Hanna Romania;
- Magnetic stirrer, model Nachita, model no. 690/1, maximum capacity 2000 mL, Romania;
- Berzelius glasses with various volumes were used to carry out the experimental samples, Romania.

2.2. Methods

The sensory characteristics and physicochemical quality (Brix (refractometric soluble dry matter and pH)) of all the previously mentioned raw materials were analyzed. In addition, the stability of the finished product was checked under normal storage conditions (temperature between 20 to 25 °C, relative air humidity maximum 75%, and protection from direct sunlight or sources of frost).

Table 2 shows the methods and references that were applied for the sensory analysis and the physicochemical parameters (refractometric soluble dry substance (Brix) and pH) for the raw materials used in this research.

Table 2. The methods and references that were applied for the sensory analysis and the physicochemical parameters (refractometric soluble dry substance (Brix) and pH) for the raw materials used.

Name of the Raw Material	Analysis Method	Analyzed Parameters	Reference
Inulin	5% solution	Sensory Physicochemical	The quality document from the supplier
Lactoferrin	2% solution	Sensory Physicochemical	The quality document from the supplier
Sericin	10% solution	Sensory Physicochemical	The quality document from the supplier

Tests such as acidity, product oxidation state, antioxidant activity, color measurement, protein content, fiber content, and carbohydrate content were not performed in this research. These will be carried out within a financing project to be submitted.

The other raw materials used (inulin, sericin, and sodium bicarbonate) were purchased from suppliers or local stores. When determining the amount of lactoferrin that must be added to the new adjuvant food in the repair of the gastric mucosa, the following aspects were taken into account: the maximum dose allowed per day, according to the Decision to place lactoferrin on the EU market as a new food ingredient [8], the goal is for the new food to be in the form of a single mono dose per day, and for the patients to be adults. According to this legislative regulation, in food products for special medical purposes, lactoferrin can be added at a maximum of 3 g/day. The preparation of this new adjuvant product in the repair of the gastric mucosa is shown in Figure 1.

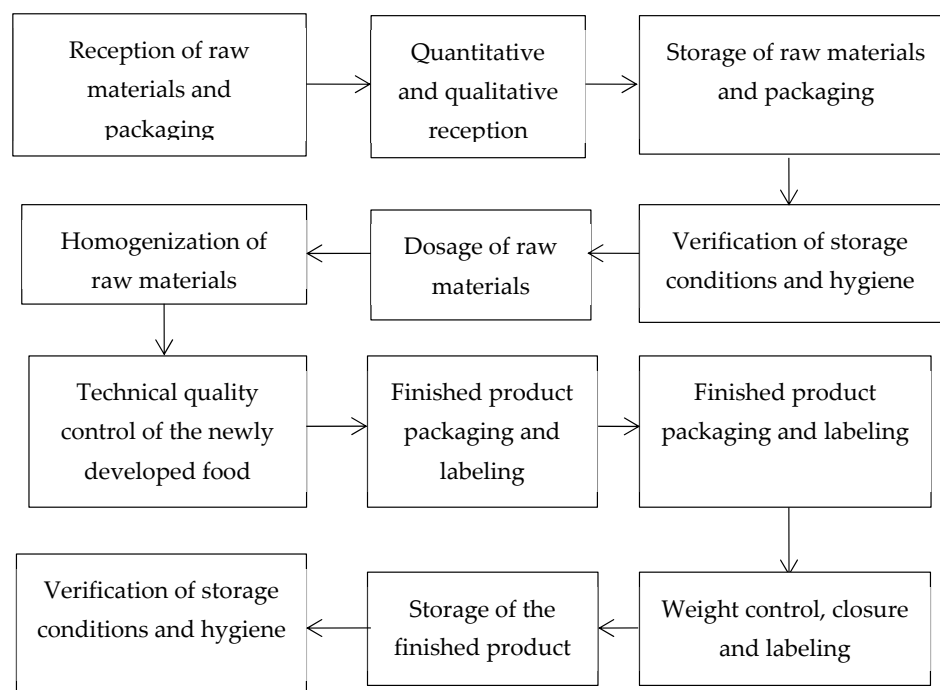


Figure 1. The preparation of the new adjuvant food in the repair of the gastric mucosa.

In the case of the quantitative and qualitative reception of raw materials and packaging, depending on the degree of non-conformity (minor or major), the treatment of the non-conforming product can re-submit a statement of findings or Non-conformity Sheet, including resolution of the complaint to the supplier or scrapping (destruction). The packaging is stored in different spaces compared to the raw materials. If the storage conditions (storage method, temperature, and relative air humidity) and hygiene conditions are

non-compliant (both for raw materials, packaging, and the finished product), they will be remedied as soon as possible. Likewise, in the case of weight control, closing and labeling of packages with the finished product, and the adjuvant food used in the repair of the gastric mucosa.

To check the shelf life of the finished product (of the final recipe), a sample was analyzed microbiologically, at an accredited external laboratory, within the National Sanitary Veterinary and Food Safety Authority, Sanitary-Veterinary and Food Safety Directorate Mures, Romania, subordinated to the Ministry of Agriculture and Rural Development and the Government of Romania (Table 3). These analyses were carried out for the freshly prepared product, and will be repeated every 6 months, for 12 months, to verify whether, under normal storage conditions of the final product, microbiological changes have occurred or not.

When designing the adjuvant food in the repair of the gastric mucosa, from the point of view of sustainability, we considered that its manufacture, storage, and transport should not require special temperature conditions in order to prevent the use of related resources (e.g., gas, water).

Table 3. The analysis methods for the microbiological analysis related to the finished product applied by the accredited external laboratory within the National Sanitary Veterinary and Food Safety Authority, Sanitary-Veterinary and Food Safety Directorate Mures, Romania.

The Analyzed Parameters	Analysis Method
Beta glucose-positive <i>Escherichia coli</i>	SR ISO 16649-2:2007 * (RA *)
<i>Enterobacteriaceae</i>	SR EN ISO 21528-2/2017 * (RA)
<i>Staphylococcus coagulase-positive</i>	SR EN ISO 6888-1:2021 * (RA)
Yeasts and molds	SR ISO 21527-2:2009 * (RA)

* SR ISO 16649-2:2007—Romanian standard: Microbiology of food and feed. Horizontal method for the enumeration of beta-glucuronidase positive *Escherichia coli*, RA—RENAR accredited (Accreditation Association from Romania), SR EN ISO 21528-2/2017—Microbiology of the food chain—Horizontal method for the detection and enumeration of *Enterobacteriaceae*—Part 2: Colony-count technique, Microbiology of the food chain. Horizontal method for counting coagulase-positive staphylococci (*Staphylococcus aureus* and other species). Part 1: Method using Baird-Parker agar medium, Microbiology of food and animal foodstuff—Horizontal method for the enumeration of yeasts and molds—Part 2: Colony count technique in products with water activity less than or equal to 0.95 (ISO 21527-2:2008).

In addition to the sensory, physicochemical, and microbiological analyses, the finished product (new adjuvant food product in the repair of the gastric mucosa) was tested in simulated gastric fluid and physiological serum to analyze and verify its dissolution. The simulated gastric liquid formula was 7 mL concentrated HCl (36–37%), 2 mg NaCl, and the difference to 1000 mL distilled water. In both solutions, the newly developed food product completely dissolves. From the point of view of versatile uses, the following variants were made: the new product and cottage cheese, the newly developed food and non-carbonated drink, and the new product, mashed bananas, and oatmeal. The choice of versatile uses of a food for special nutritional conditions, thus designed, must be made in accordance with the European in force.

Following the tests (Brix and pH), technological tests in terms of processing and versatile use by patients, and also microbiological analyses, the final recipe was registered at the State Office for Inventions and Trademarks in Romania in order to obtain the Patent of Invention. Invention Patent Application registration number A/00589/07.11.2022.

For the validation of the laboratory model, on a reduced or increased scale, as appropriate, with the reproduction by the similarity of the real operating conditions (TRL 5) [9,10] and the following TRLs (6–9) [9,10], the control points (CP) were also analyzed and critical control points (CCPs).

3. Results

The other raw materials used (inulin, sericin, and sodium bicarbonate) were purchased from suppliers or local stores. When determining the amount of lactoferrin that must be added to the new adjuvant food product in the repair of the gastric mucosa, the following aspects were taken into account: the maximum dose allowed per day, according to the Decision to place lactoferrin on the EU market as a new food ingredient [8], the goal is for the new food to be in the form of a single mono dose per day, and for the patients to be adults. According to this legislative regulation, in food products for special medical purposes, lactoferrin can be added at a maximum of 3 g/day. In the case of the quantitative and qualitative reception of raw materials and packaging, depending on the degree of non-conformity (minor or major), the treatment of the non-conforming product can re-submit a statement of findings or Non-conformity Sheet, including resolution of the complaint to the supplier or scrapping (destruction).

The packaging is stored in different spaces compared to the raw materials. If the storage conditions (storage method, temperature, and relative air humidity) and hygiene conditions are non-compliant (both for raw materials, packaging, and the finished product), they will be remedied as soon as possible. Likewise, in the case of weight control, closing and labeling of packages with the finished product, the adjuvant food can be used in the repair of the gastric mucosa.

The results of sensory and physicochemical analyses (Brix and pH) of the raw materials used (inulin, lactoferrin, and sericin) can be followed in Tables 4–6. Sodium bicarbonate was not analyzed for taste nor for physicochemical parameters, because it is an additive food and has consistent quality, as well as conforming to the product specifications of each manufacturer or supplier.

Table 4. Results of sensory and physicochemical analyses (Brix and pH) of the inulin compound.

Name of the Raw Material	Sensory Characteristics	Physico-Chemical Analyses ¹
Inulin	Fine powder, free of clumps and free of foreign particles Color: White, homogeneous Smell/Taste: Pleasant, specific	Brix: 4.73 (4.73, 4.72, 4.74) pH ² : 6.61 (6.61, 6.62, 6.62)

¹ The values of the results of the physicochemical analyses represent the arithmetic mean of three consecutive determinations at the reference temperature of 20 °C. ² The pH of inulin was analyzed on 5% solution.

Table 5. Results of sensory and physicochemical analyses (Brix and pH) of the lactoferrin compound.

Name of the Raw Material	Sensory Characteristics	Physico-Chemical Analyses
Lactoferrin	Fine powder, free of clumps and free of foreign particles Color: Light pink, homogeneous Smell/Taste: Pleasant, specific	Brix: 2.43, 2.42, 2.44 pH ¹ : 6.23, 6.24, 6.22

¹ The pH of lactoferrin was analyzed on a 2% solution, according to the applicable legislative regulation.

Table 6. The results of sensory and physicochemical analyses (Brix and pH) of the sericin.

Name of the Raw Material	Sensory Characteristics	Physico-Chemical Analyses ¹
Sericin	Fine powder, free of clumps and free of foreign particles Color: Light yellow, homogeneous Smell/Taste: Pleasant, specific	Brix: 11.70, 11.60, 11.80 pH ¹ : 5.45, 5.44, 5.46

¹ The pH of sericin was analyzed on a 10% solution, according to the product specification/quality certificate received from the supplier.

Sericin and lactoferrin have anti-inflammatory action on several interleukins (e.g., IL-1, IL-4, IL-5, IL-6, IL-8, IL-10, IL-13, IL-17, IL-31); these leading to humoral and eosinophil inflammation, mucosal damage and the production of adaptive cellular inflammation—tumor necrosis factor-alpha (TNF- α) and interferon-gamma (IFN- γ), cytotoxic T lymphocytes (CTLA-8) and activated CD4+ T cells, and more specifically, CD4+CD45RO+ T cells, and CD19 and CD56 cells. Sodium bicarbonate has a systemic, rapid antacid action.

Table 7 shows the recipe for the new product. This recipe is protected at State Office for Inventions and Trademarks, and we are about to receive the Patent of the Invention.

Table 7. The recipe of the new adjuvant food product in the repair of the gastric mucosa.

Ingredient	Quantity, g
Inulin	10
Lactoferrin	3
Sericin	9
Sodium bicarbonate	6
Total ingredients	28 ¹

¹ This is the amount of a single dose that can be consumed in one day.

Figure 2 shows the new adjuvant food product developed by us.

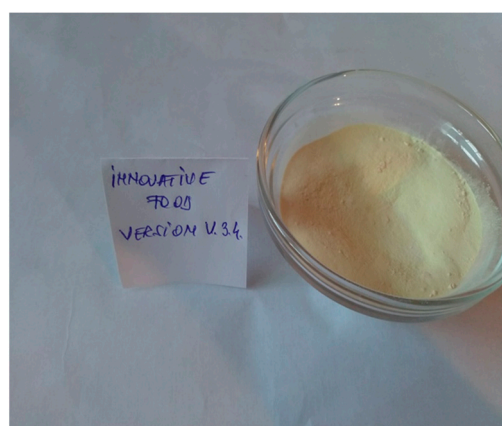


Figure 2. The newly developed food is adjuvant in the repair of the gastric mucosa. Version V 3.4. represents the notation during research.

Physicochemical analyses for the new food product can be found in Table 8 and Figure 3. Hydration was carried out with 100 mL of water at a temperature of 20–25 °C.

Table 8. Physicochemical analyses for the new food.

The Moment of Analysis	Brix	pH
Immediately after moisturizing	22.30, 22.10, 22.30	7.41, 7.42, 7.42
After 5 h of hydration	22.60, 22.50, 22.70	7.8, 7.7, 7.9

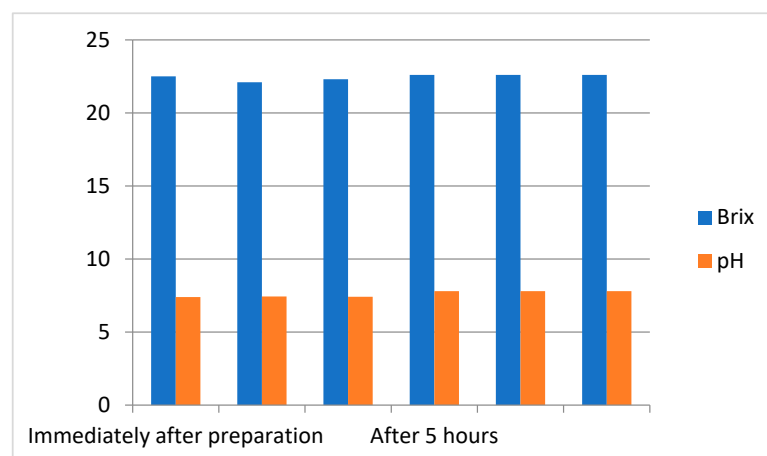


Figure 3. Changes in the physicochemical parameters of the newly developed food.

Under normal storage conditions (temperature between 20 and 25 °C, relative air humidity maximum 75%, and protection from direct sunlight or sources of frost), the adjuvant food was stable and does not form agglomerations or crystals.

In order to establish the validity period of the new product, microbiological analyses were carried out at the Mures Sanitary-Veterinary and Food Safety Laboratory. The results obtained are presented in Table 9.

Table 9. Results of the microbiological analyses carried out for the newly developed product after it has been prepared.

Analyzed Parameters	Result, ufc/g ¹
<i>Escherichia coli</i> beta-glucuronidase positive	<10
<i>Enterobacteriaceae</i>	<10
<i>Coagulase-positive staphylococci</i>	<10
Yeasts and molds	<10

¹ Analysis bulletin no. 21964 of 10 October 2022.

In addition to the sensory, physicochemical, and microbiological analyses, the finished product (the new adjuvant food in the repair of the gastric mucosa) was tested in simulated gastric fluid and physiological serum, to analyze and verify its dissolution. The simulated gastric liquid formula is: 7 mL concentrated HCl (36–37%), 2 mg NaCl and the difference to 1000 mL, distilled water. In both solutions, the newly developed food completely dissolves.

From the point of view of versatile uses, the following variants were made: the new product and cottage cheese (Figures 4 and 5), the newly developed food, non-carbonated drink (Figures 6 and 7 and Table 10), and the new food, banana puree, and oat flour (Figures 8 and 9 and Table 11).



Figure 4. The newly developed food is mixed with cottage cheese, raspberry jam with inulin, and no preservatives. The leaves in the picture are mint leaves (*Mentha piperita*). It was added for chromotherapy (color) and aroma diversification.

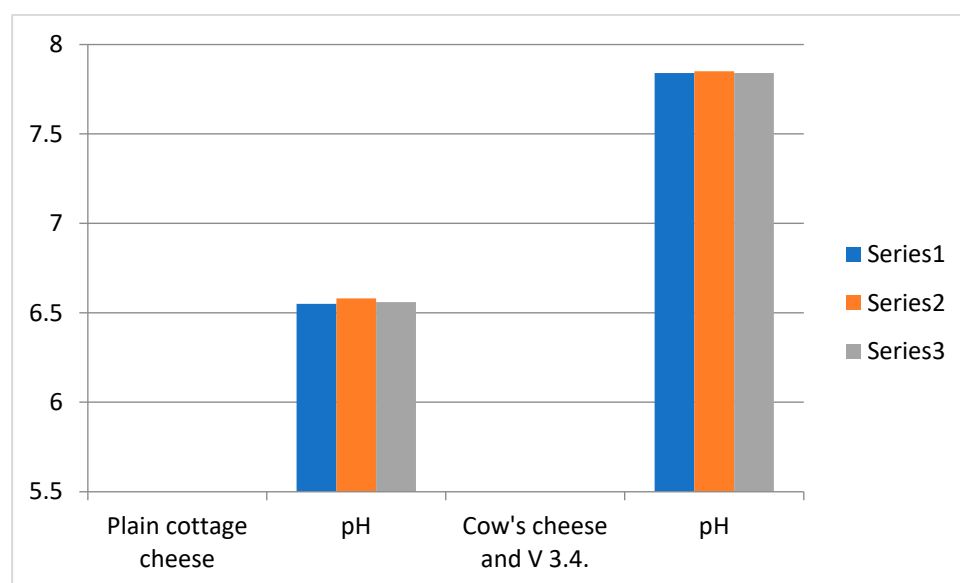


Figure 5. Comparative analysis of the pH of cottage cheese and cottage cheese mixture and the newly developed food. Series 1..3 represent the three values measured for the PH of Plain cottage chesse and cow's cheese and V 3.4.

Table 10. The results of the physicochemical analyses of the non-carbonated drink used and the new food developed, hydrated with this drink.

Food	Brix	pH
Non-carbonated drink	5.25; 5.2; 5.3	4.04; 4.04; 4.04
The newly developed food, hydrated with the non-carbonated drink	26.4; 26.4; 26.35	8.01; 8.02; 8.0

Table 11. The results of the physicochemical analyses of the newly developed food mixed with mashed bananas and oat flour.

Food ¹	Brix	pH
Mashed bananas	18.8; 19.3; 19.8	6.48; 6.45; 6.46;
The new mixed food with mashed bananas and oat flour	39.96; 39.95; 40.5	8.18; 8.16; 8.17 ¹

¹ For oat flour, we were unable to analyze refractometric soluble dry matter (Brix) and pH.

The finished product (mixture) has a lower viscosity compared to cottage cheese. The consistency of the final product is optimal for the enteral nutrition of small children and patients with dysphagia or certain dental pathologies. It is ideal for dietary/functional desserts or regular foods. Lactoferrin and sodium bicarbonate are authorized in the EU, for the food category: food for special medical purposes, cheese-based products, cakes, and pastries.

This product (mixture of cottage cheese and V.3.4) can also be used as a dessert in the hospital for patients with dysphagia. The sensory characteristics of the finished product are a creamy appearance, a golden/light yellow color, with a specific smell and taste of fresh cow's cheese. The product was kept cold until the 2nd day. In the case of the cow's cheese and the mixture with the new product, the refractometer soluble dry matter (Brix) could not be determined due to air entrapped in the products.

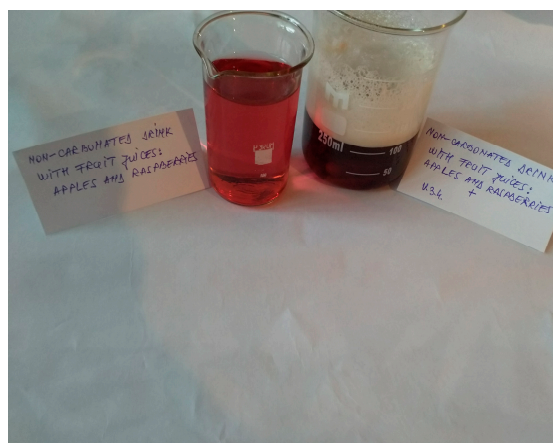


Figure 6. The appearance and color of the used non-carbonated drink and of this drink with the new adjuvant food in the repair of the gastric mucosa developed.

The color of the liquid changed due to the change in pH (basicity). It is a normal property of natural dyes. The foam of the mixture is due to lactoferrin which has a foaming capacity. It is not stable and decreases rapidly.

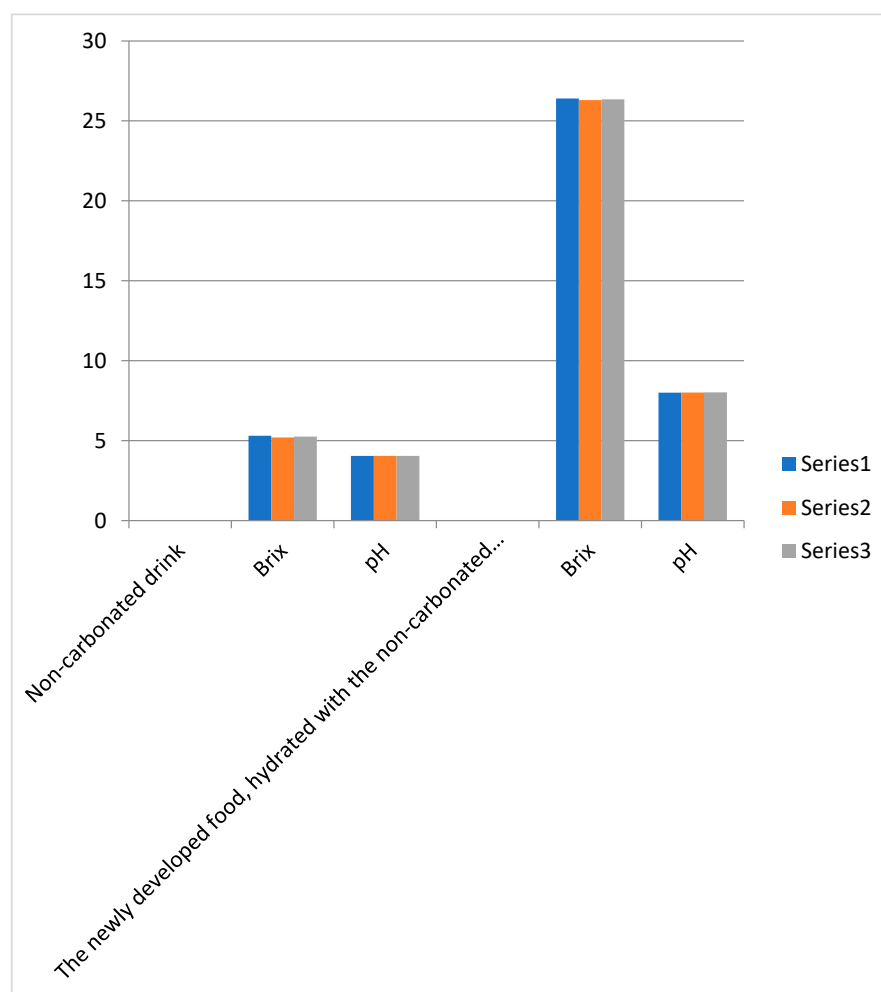


Figure 7. Variation of refractometric soluble dry matter and pH in the still drink and the newly developed food product hydrated with the same still drink. Series 1..3 represent the three measured values for the PH and Brix of the still drink and the newly developed food hydrated with the still drink.

The increase in refractometric dry matter (Brix) value in the newly developed food hydrated with the non-carbonated beverage is explained by the sugar content of the added beverage as well as the chemical reactions occurring between the two foods. This information is useful for health professionals (doctors, pharmacists, and dieticians) to know what to recommend to patients who have associated pathologies, including diabetes. The increase in pH is due to the composition of the newly developed food, in particular sodium bicarbonate.

The identification data related to the cottage cheese and strawberry jam with inulin used are as follows: cottage cheese, Romanian Ibanesti brand, and 32% fat. For this pod, the batch was not mentioned because the cheese was loose. For the strawberry jam with inulin, the identification data are as follows: Ver-mondo brand, produced in the EU for Lidl Discount SRL, Romania, expiration date 2 May 2025, lot 122 B3. For the “Ciao” brand non-carbonated drink: batch 204023 RS D and expiring date 4 February 2023. This drink contains fruit juices (apples and raspberries), with sugar and sweeteners: water, sugar and/or glucose-fructose syrup, fruit juices (4%) obtained from concentrated apple juice (3%) and raspberries (1%), acidity correctors: citric acid, sodium citrates, black carrot concentrate for color, vitamin C, flavor, sweeteners: Cyclamates and Saccharins.

The mixture consisting of the newly developed food, mashed bananas, and oat flour, as well as the results of the physicochemical analysis are presented in Figure 8 and Table 9.



Figure 8. The new food developed in a mixture of mashed bananas and oat flour.

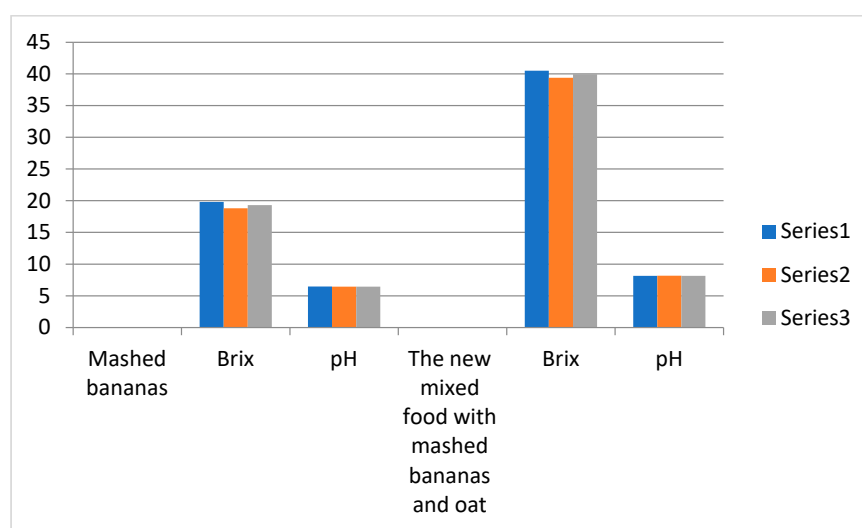


Figure 9. Variation of pH and Refractometric Soluble Dry Matter (Brix) for Banana Mash and the Newly Developed Food Mashed Banana and Oat flour Blend.

Dietary dessert was obtained from 100 g of mashed bananas, 28 g of the new food, and 70 g of oat flour.

Regarding the elements for achieving the traceability of the raw materials (bananas, new food, and oat flour): The bananas were purchased from the grocery store. These were bulk, without identification data for traceability, printers on the receipt from the cash register. The puree was prepared by hand from bananas. Oatmeal was obtained in the laboratory from ground oat flakes. The identification data for the oat flakes used are *Sanovita* brand. Made in Germany. Packaged and distributed by S.C. Sano Vita SRL. OF: 7 March 2023, their 124 2.

4. Discussion

Our research concerns a new adjuvant food for the repair of gastric mucosa used in medicine and pharmacy. Before the research and development of the new food, the state of knowledge was checked for the products sold in other countries and the existing invention patents worldwide. The results of this check can be followed in the lines below:

Alternative products marketed in other European or non-European countries are:

- “GI Repair Powder | 168g”, manufacturer Vital Nutrients [11], with zinc composition and patented blend (L-glutamine powder, N-acetyl glucosamine, slippery elm bark powder, MSM (OptiMSM®), NF rutin, lactoferrin, aloe vera leaf inner fillet extract, xylitol. According to the manufacturer’s recommendations, taking this formula helps support gastrointestinal health and intestinal lining cells. This supplement contains nutrients, including amino acids with botanicals and a stable probiotic. There are no mentions of verification of effectiveness in vitro or in vivo, and it contains ingredients that may cause adverse reactions and may interact with certain drugs and alter their clearance, and adversely affect drug treatment. In this sense, I exemplify aloe vera. It can cause gastrointestinal disturbances, arrhythmias, nephropathy, and edema and can interact with antidiabetic drugs, which can lead to hypoglycemia. Zinc may cause adverse effects such as nausea, vomiting, metallic taste, and sideroblastic anemia and may interact with quinolones or tetracycline and lead to decreased antibiotic absorption [12].
- MSM is the abbreviation for methylsulfonylmethane. Adverse effects observed may include bloating, constipation, indigestion, headache, fatigue, or insomnia. The most notable adverse effect recorded for this ingredient was an acute episode of bilateral iridocorneal angle closure, [13] leading to the need/recommendation to include a warning to this effect, and the product label “GI Repair Powder” does not present this information. Among the side effects of slippery elm, I mention the possibility of allergic reactions and contact dermatitis [11]. In addition, according to the label, the product “GI Repair Powder” contains many allergens (fish, shellfish, lobster, crab, and/or shrimp) and lactoferrin and is not evaluated by the FDA (Food and Drug Administration).
- Patent US20160228490 [14]—“Methods and composition for treating mucosal tissue disorders”, refers to pharmaceutical compositions containing glutathione, ascorbate, and bicarbonate with or without thiocyanate and methods of using them to treat diseases and disorders in mucosal tissue. The disadvantage of this patent is that the number of patients with gastrointestinal pathologies, including those who refuse drug treatments and are adherents of alternative treatments such as food and/or food supplements, is constantly increasing, which means that the segment of patients who buy drugs is decreasing;
- A patented composition (US20190125820 [15])—“Powder for regulating intestinal flora and protecting gastric mucosa, preparation method and use thereof”, has as ingredients: xylooligosaccharide, isomalto-oligosaccharide, mannitol, inulin, *Codonopsis* root, *Hypericum erinaceus* fruit extract, *Dioscorea opposita* rhizomes, *Sclerotium poria*, *Semina dolichos*, *Pericarpicerum amicum*, *Corpizum* fruit and *Heridium erinaceus* fruit. Experimental data show that the powder described in the present disclosure has the function of ameliorating gastric mucosal injury by reducing the acute ethanol-induced gastric mucosal injury effectively and has the function of regulating the gastric mucosa.

Therefore, the powder could be used to prepare a healthcare product that has the function of regulating the gastrointestinal tract and protecting the gastric mucosa. The disadvantages of this patent are represented by the multiple drug interactions it can cause, such as *Codonopsis* can slow blood clotting. Taking *Codonopsis* with medicines that slow and clot blood could increase the risk of bruising and bleeding. Another drug that may interact with this ingredient in the proprietary product is a cancer drug called Abiraterone. The interaction between *Codonopsis* and this medicine may reduce the effectiveness of Abiraterone in the treatment of cancer. In the case of people who have conditions that can be aggravated by estrogen, this patented composition containing *Codonopsis* should not be used/consumed because it contains rhizomes of *Dioscorea opposita* [16].

Phytotherapeutic products manufactured in Romania, or manufactured in other countries and marketed in our country, are:

- Reglacid—Hofigal, 60 capsules with the composition for one capsule: contains powder from 60.00 mg of sea buckthorn fruit (*Hippophae fructus*), 50.00 mg of the bird's-eye cuticle, 60.00 mg of chamomile flower (*Chamomillae flos*), 52.00 mg St. John's wort (*Hyperici herba*), 52.00 mg amaranth (*Amaranthus caudatus herba*), 1.2 mg thyme volatile oil (*Thymi vulgaris aetheroleum*), 0.8 mg lavender volatile oil (*Lavandulae aetheroleum*) and excipients (lactose, polyvinylpyrrolidone K30, magnesium carbonate, talc, magnesium stearate) up to 400.00 mg. Action: The product was intended to supplement the diet for its properties: antiseptic and anti-inflammatory in the gastrointestinal tract; to improve the symptoms of some gastrointestinal conditions and to reduce the risk of complications and evolution towards more severe forms; the product regulates gastric acidity, improves digestion, protects the gastrointestinal mucosa and stimulates its regeneration; depurative, slightly laxative and diuretic. There is no mention of verification of effectiveness in a clinical trial. Administration: 1–2 capsules three times a day or two tablets two times a day, 10–15 min before meals depending on the stage and nature of the digestive disease or on the recommendation of the doctor who evaluates the dose and the rate of administration. Storage conditions: at room temperature (15–25 °C), protected from moisture and light, in the original packaging. Manufacturer: Hofigal, Romania.
- Gastracid D100, 63 chewable tablets—Fares with the composition: clay, chamomile flowers (*Matricariae flos*), soft extract of chamomile flowers (*Matricariae flos*), soft extract of licorice root (*Liquiritiae radix*), tincture of propolis, calami rhizomes (*Calami rhizoma*), fennel essential oil (*Foeniculi aetheroleum*), mint essential oil (*Menthae aetheroleum*), excipients (bulking agent: cellulose, starch, anti-caking agent: talc). Action: Gastracid tablets (clay, chamomile flowers, soft extract of chamomile flowers, soft extract of licorice root, propolis tincture, rhizomes of oleander, fennel essential oil, peppermint essential oil) help to neutralize gastric acid with reduction of discomfort and unpleasant sensations from the gastroesophageal level; protects the lining of the stomach and esophagus and promotes healthy digestion. There is no mention of verification of effectiveness in a clinical trial. Administration: Take one tablet three times a day 30 min before meals or as needed. Manufacturer: Fares, Romania.
- Healthy Stomach (Ulcerofit) 7 Fares with the composition/capsule: calendula flowers (*Calendulae flos*) 40 mg, plantain leaves (*Plantaginis folium*) 40 mg, mugwort grass (*Myelalis muralis herba*) 40 mg, St. John's wort (*Hyperici herba*) 40 mg, hyssop (*Hyssopi herba*) 20 mg, licorice root (*Liquiritiae radix*) 20 mg. Action: This product acts synergistically through several mechanisms. It reduces the inflammation of the gastric mucosa through faradiol present in marigolds, active substances from plantain and robber grass (chlorogenic acid, neo chlorogenic, apigenin), glycyrrhizic acid from licorice root, amentoflavone from St. John's wort and essential oil from hyssop. They favor the healing of mucosal erosions and increase the secretion of mucus with a gastric protective role through carotenoids, mucilages, chlorogenic and neochlorogenic acid from the composition of calendula and plantain. Thieves' grass is a traditional remedy

used to heal ulcers. Added to these are the antispasmodic and stomach pain-soothing action due to the active principles of sedum grass, calendula, and licorice root. Clinical studies: Following the study carried out at the III Cluj-Napoca Medical Clinic, it became evident that Stomac Sănătos is an effective preparation in the treatment of peptic diseases (gastritis and erosive duodenitis, duodenal ulcers). Administration: Children between 6–14 years: one capsule three times a day; Adults: two capsules three times a day. The administration is done 15 min before the main meals. The duration of a cure is 4–6 weeks, according to the doctor's recommendation. Manufacturer: Fares, Romania.

Although worldwide there are invention patents for foods containing sericin, lactoferrin, inulin, and sodium bicarbonate, worldwide there is no food designed like the new food developed by us, an adjuvant in rapping the gastric mucosa with versatile use.

Existing patents are for healthy consumer (personal) foods and do not have versatile applicability. Examples of patented foods for healthy consumers are JP2000184868—Water for food and drink [17], CN107048419—Sericin drink [18], JP2000312568—Hardly digestive additive for food and beverage, and auxiliary health product [19], CN107034102—Sericin wine [20], EP2025246—Multi-component dessert product [21], RU0002640872—Cream and vegetable spread with inulin [22], RU0002623739—Method of processing inulin-containing raw material with obtaining food inulin powder and method of obtaining ultra-pure inulin [23], CN1875748—Application method of lactoferrin in food [24], CN114431296—Preparation method of liquid dairy product and liquid dairy product [25].

The mixture/cream cheese with the new food developed by us has lower viscosity compared to cow's cheese. The consistency of the finished product is optimal for enteral feeding of young children and patients who have dysphagia. This food can be prepared at home, in Hotel Restaurant Canteen units, or in hospital kitchens. The finished product is ideal for dietary/functional desserts or regular foods. Lactoferrin and sodium bicarbonate are authorized in the European Union for the food categories: dairy-based food intended for young children (ready-to-eat), food for special medical purposes, cheese-based products, cakes, and pastries.

For children or to diversify the taste, any type of jam can be added. For the sensory (organoleptic) analysis, I added strawberry jam with inulin (without sugar).

The large variation in Brix related to the mixture resulting from the hydration of the new food with the non-carbonated drink is explained by the reactions that took place between the ingredients of the new food subject to the invention and the ingredients of the non-carbonated drink (water, sugar and/or glucose-fructose syrup, fruit juices (4%) obtained from concentrated apple (3%) and raspberry (1%) juices, acidity correctors: citric acid, sodium citrates, black carrot concentrate for color, vitamin C, sweeteners: cyclamate and saccharin). This drink was purchased commercially and was chosen as a possibility to hydrate the new food subject to the invention to diversify the taste.

The newly developed food is natural and easy to be administered. It does not contain preservatives, gluten, or other synthetic substances. It was presented in the form of a powder without foreign particles, with pleasant sensory characteristics specific to the ingredients, also was microbiologically safe and was stored in clean, sanitized, and disinfected spaces, away from heat sources and the direct action of the sun's rays, with a maximum temperature of 25 °C and a relative air humidity of 75%. The product was transported in clean, sanitized means of transport at a maximum temperature of 25 °C. It does not pollute the environment, and as a result, no special precautions are required for the disposal of residues. The food can be administered once a day, after meals, or when needed.

By applying the invention, the following advantages are obtained:

- Synergistic effect both on the oral cavity and on the stomach and large intestine [26];
- It has a systemic action to quickly reduce acidity, both in the oral cavity and in the stomach, thanks to sodium bicarbonate [26];
- Stimulates remineralization of tooth enamel, thanks to sodium bicarbonate which increases the pH in the oral cavity [26];

- Stimulates the absorption of minerals and including calcium, thanks to sodium bicarbonate [26];
- Prevents/treats constipation, including that caused by an adverse reaction by drugs (e.g., opiates or other drugs), thanks to sericin and lactoferrin [27];
- It is prebiotic and improves the intestinal microflora and the gut-brain connection, thanks to inulin [28];
- It is natural and easy to administer;
- It has versatile uses, being able to be used for food preparation, including by patients at home, or in hospital kitchens, for patients suffering from gastroesophageal reflux disease, gastritis, ulcers, constipation, or dysphagia;
- Does not contain preservatives, gluten, or other synthetic substances (e.g., preservatives);
- Does not require special storage conditions (e.g., refrigeration/freezing);
- The ingredients used do not show adverse reactions or interactions with over-the-counter medicines;
- It can also be consumed by people who have diabetes because it has a low glycemic index;
- Reduces the level of plasma lipids, reducing the risk of atherosclerosis due to inulin [29,30];
- Prevents cancer, thanks to lactoferrin, sericin, inulin, and sodium bicarbonate [30];
- Regulates the immune system thanks to sericin, inulin, and lactoferrin [30,31];
- Is an alternative to drugs such as proton inhibitors, which have numerous side effects and contraindications [30]. It does not precipitate in an aqueous environment due to the ratio of the components;
- It has anti-Gram + and anti-Gram negative—antibacterial, also antiviral actions thanks to sericin and lactoferrin [30];
- It has an anti-inflammatory effect, reducing pro-inflammatory cytokines, tumor necrosis factor-alpha (TNF- α), and interferon-gamma (IFN- γ), thanks to sericin and lactoferrin [31]

Currently, there are no proprietary foods for the repair of gastric mucosa, patented and with versatile applications.

Because dental erosions are a common symptom of gastroesophageal reflux disease, it is necessary to address this extraesophageal manifestation of this disease. According to the state of the art presented previously, no product/supplement acts on the protection of the improvement of the intestinal microflora and of the gut-brain axis and does not prevent/treat constipation, which can result in the appearance of gastroesophageal reflux and gastric acidity, with the appearance other complications (e.g., ulcer) [10,12].

From the point of view of nutravigilance, the label of the new food must contain information about possible allergens (lactoferrin), and health professionals must inform patients how this food should be consumed, including from the point of view of possible drug interactions. We recommend that their administration be done at an interval of one hour after the ingestion of the new food. As possible unwanted but harmless side effects, we mention flatulence or abdominal bloating, in sensitive patients, due to inulin. Another possible adverse reaction is an increased frequency of defecation (laxative effect) [3].

The research of the new adjuvant food in the repair of gastric mucosa represents industrial research. Future research directions are the preclinical evaluation of the efficacy of the new food in Wistar rats and randomized double-blind versus placebo clinical evaluation.

Regarding the Technology Maturity Level (TRL), for this research was 4. This grade 4 is defined as TRL 4 validation under laboratory conditions of the components and/or the assembly/system. Its description is: The main components of the technology are integrated to establish the functionality of the assembly. This approach may have a relatively low degree of fidelity compared to the real system. For example, separate components are integrated into the laboratory, and tests are carried out in a range of operating conditions. Deliverables include test results for the component assembly, highlighting proximity (or differences) to expected functionality and performance. TRL 4–6 is the bridge between scientific research and engineering/practical application. TRL 4 is the first step in determining whether the assembly of individual components is functioning properly as a system.

The lab system will most likely be a mix of existing (more general purpose) equipment and components that require handling, calibration, alignment, etc., specific to become functional [9,10].

In our case, the deliverables that validated TRL 4, in laboratory conditions of our final recipe, the analyses, the technological samples on various applications/foods, the photos taken of the foods that contain the food developed by us, and the bulletin as well, were carried out of analyses received from the Mures Sanitary-Veterinary and Food Safety Laboratory.

5. Conclusions

Through its versatile use, the new food product for a special nutritional state represents a sustainable worldwide novelty. Due to the development of forestry for the cultivation of white or black mulberry (*Morus alba* and *Morus nigra*), the development of their wood processing, the raising of silkworms (*Bombyx mori*), the processing of fibroin to obtain natural silk and the processing of sericin resulting as a residue in the textile industry, the new food actively contribute to the global economy II.

6. Patents

The work reported in this manuscript is intellectually protected by patent application number A/00589/07.11.2022.

Author Contributions: Conceptualization, I.M.M.; methodology, I.M.M.; M.T. and D.-L.M. software; validation, M.T., D.-L.M. and D.C.; formal analysis, I.M.M.; investigation, D.C.R.; resources, I.M.M., M.T., D.-L.M. and D.C.; data cleaning, M.T.; writing—original preparation of the project, R.V. and D.C.R.; writing, M.T.; visualization, D.-L.M. and D.C.; supervision, I.M.M.; project management, I.M.M. All authors have read and agreed to the published version of the manuscript.

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