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Quality Control and Substantiation of Health-Related Claims for Processed Berry Products Entering the U.S. Market

Tomash Roman

Pharmacist, Founder, Tomash LLC, Fargo, North Dakota, USA.
ORCID: https://orcid.org/0009-0009-4024-6033

Abstract

Processed berry products often reach the United States with labels, dossiers, and sales practices shaped by foreign rules, where a product may be registered as a functional food and sold in recommended courses. This review examines quality control and the substantiation of health-related claims as part of the evidentiary chain for such products. The study combined an analysis of U.S. food law, a review of literature on anthocyanin bioaccessibility, bioavailability, and clinical effects of Vaccinium berries, and a retrospective audit of dealer records on whole-berry pastes handled by a Ukrainian community pharmacy business from 2012 to 2021. The audit showed that two type-level sanitary conclusions, a dealer agreement, and fifty-eight receiving invoices confirmed product identity and recurring supply, yet none of these documents identified a lot. The regulatory analysis showed that a whole-fruit puree meets the definition of juice in 21 CFR 120.1, which shifts the import route to Juice HACCP and exempts shipments from a compliant processor from the Foreign Supplier Verification Program. Four evidence levels above a base level of identity and composition were linked to permissible U.S. claim classes and supporting documents. The resulting matrix helps importers plan lot testing and label review before the first shipment.

Keywords: *Processed Berry Products, Health Claims, Claim Substantiation, Evidence Hierarchy, Bioaccessibility, Food Import Compliance, Juice HACCP, Quality Control.*

INTRODUCTION

Small importers bring processed berry products from Eastern Europe to the United States, and each product carries a history written under another legal system. A bilberry paste registered in Ukraine as a functional food product, sold through pharmacies and offered to buyers in recommended courses, arrives in a market where functional food has no legal status and where every statement about health falls into a class defined by statute and regulation [1, 2]. The gap between the two systems becomes visible at the moment of import, when a label, a dossier, and a set of sales habits meet requirements that were never part of their design.

U.S. law separates foods from drugs by intended use. A product offered to cure, mitigate, treat, or prevent disease falls under the drug definition in section 201 of the Federal Food, Drug, and Cosmetic Act, whatever its composition and however it is manufactured [1]. Food labels may carry nutrient content claims, health claims that the Food and Drug Administration, FDA, has authorized or allowed in qualified form, and structure/function claims that derive from nutritive value [2]. Advertising beyond the label answers to the Federal Trade Commission, FTC, which expects competent and reliable scientific evidence and, for health benefits, randomized controlled trials on the product or on an essentially equivalent formulation [3]. A berry producer that wants to say anything about health needs a document behind each word, and the strength of that document sets the ceiling for the strength of the word.

The scientific literature on berries looks generous at first reading. Reviews trace anthocyanins from the oral cavity through the stomach and small intestine to their transformation by colonic microbiota [4], and an expert roundtable on blueberries reported associations with cardiovascular, glycemic, cognitive, and gut outcomes [5]. Bilberry, the species used in the pastes reviewed here, presents a less comfortable picture. Its traditional indications for vision, diabetes, and circulation rest on contradictory trials, and some of these trace back to claims that have been repeated without verification since the twentieth century [6]. For a product made from bilberry, borrowing the evidence

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gathered on blueberry would mix two species, two matrices, and two bodies of data.

Quality problems compound the evidentiary ones. A market survey of eleven bilberry-containing dietary supplements found that four did not meet their specifications and that two had been adulterated with waste extracts from black rice production [7]. A statement about anthocyanin content is meaningful only when the lot in question has a verified botanical identity and a measured composition. Quality control and claim substantiation thus belong to one evidentiary chain, and a break in any link voids the statement printed on the label, however solid the literature behind it may look.

European experience shows how unsettled the boundary between food and medicine remains for botanical products. Court practice on botanical health claims in the European Union leaves a gray area between the two categories and gives the notion of a claim a scope wide enough to cover indirect suggestions of benefit [8]. The European Food Safety Authority's preference for randomized trials has drawn criticism as a methodological monism that sets aside mechanistic and essentiality evidence [9]. These debates also bear on U.S. imports, since an exporter trained under one regime tends to carry its vocabulary into the next.

General frameworks for the review of claims exist, yet no scheme that links each level of evidence for a processed berry product to a permissible U.S. claim class and the supporting document was found in the reviewed literature. Importers bear the practical cost of this gap. They decide on lot testing, label wording, and the regulatory route before the first shipment, often working from a dossier assembled for a different market.

The review grows out of first-hand pharmacy practice. From 2012, a family-run community pharmacy business in Ukraine distributed whole-berry pastes under a dealer agreement, and direct work as a pharmacy manager and as an authorized person for the quality of medicinal products shaped the reading of the documents analyzed here. The same product line is now being prepared for import into the United States.

The aim of this review is to connect quality control and the substantiation of health-related claims for processed berry products entering the U.S. market. The first task is to describe the control points along the chain from raw material through the lot to import. The second task is to audit a documentary record covering the years from 2012 to 2021 against U.S. requirements. The third task is to build a classification of evidence levels and a matrix linking each level to a permissible claim and a supporting document.

MATERIALS AND METHODS

The study combined a narrative review of U.S. regulatory texts, a review of peer-reviewed literature, and a retrospective documentary case analysis, and the results of these three components served as input for an evidence classification. Such a design suits a question that sits at the intersection of food law, food science, and pharmaceutical practice, where no single body of literature covers the entire chain from a berry field to a sentence on a label.

Regulatory analysis relied on primary texts in their electronic versions, current as of September 2026. The set comprised the definitions of the Federal Food, Drug, and Cosmetic Act [1], the labeling rules of 21 CFR Part 101 [2], the Juice HACCP regulation in 21 CFR Part 120 [10], the Foreign Supplier Verification Program, FSVP, in 21 CFR Part 1, Subpart L [11], the preventive controls rule in 21 CFR Part 117 [12], the regulations on thermally processed low-acid foods and on acidified foods in 21 CFR Parts 113 and 114 [13, 14], the tolerances for pesticide residues in 40 CFR Part 180 [15], the FDA guidance levels for radionuclides in imported foods [16] and the FTC guidance on health products [3].

Each provision was read for three attributes: the link of the chain it governs, the party it obliges, and the document it expects as proof of compliance. Provisions without a documentary consequence for a berry paste, such as the rules for seafood or for infant formula, were set aside. This reading turned a body of regulation into a list of documents that could then be compared with the documents in the case.

The literature search covered PubMed, Google Scholar, the Directory of Open Access Journals, and eLIBRARY.RU for publications from 2021 to 2026. Search strings combined the terms anthocyanin, bilberry, blueberry, bioaccessibility, bioavailability, health claim, substantiation, radiocesium, and heat-resistant molds. Earlier primary studies of hydrothermodynamic processing, abbreviated HTD, were considered because the reviewed product line relies on this process. Inclusion required a peer-reviewed article or an academic thesis with a stated method and relevance to at least one link of the chain from raw material to claim. Retracted publications were excluded, and one review of hydrodynamic cavitation in liquid foods was removed on this ground during screening.

The documentary case covered whole-berry pastes marketed under the LiQberry trademark and handled by a family-run community pharmacy business in central Ukraine. The record comprised dealer agreement No. 2 of February 13, 2012, with two appendices, two conclusions of the state sanitary and epidemiological expertise issued in 2011 and 2012 for the technical specifications of the product, fifty-eight receiving invoices dated from 2012 to 2021, and one hundred two operations recorded in the accounting system as internal receipt, which documented transfers to Pharmacy No. 2. Scanned originals and accounting exports were read in full, and their contents were transcribed into a structured table before coding.

Each document was coded by the object it certifies, whether a product type, a lot, or a commercial transaction, and each code was then matched with the U.S. requirement that relies on a document of that kind. A document that certifies a type can support a statement about a specification, a lot document can support a statement about the contents of a container, and a transaction document can support neither of them. Names of private persons and supplier details were excluded from the analysis.

The evidence classification followed the sequence used in biopharmaceutics to separate what is present in a dosage form from what is released, what reaches the circulation, and what influences a clinical outcome. Applied to food, this sequence gives four levels: analytical availability, bioaccessibility, bioavailability, and clinical efficacy. A baseline of identity and composition was placed beneath them because every higher claim presupposes that the product is what its label says it is. Each level was then matched with the claim categories recognized in U.S. law and with the type of document that each category requires.

The design sets limits on every conclusion. The manufacturer has not confirmed that serial production follows the process described in the published studies, so technological data are treated as properties of the studied process. Requirements for raw material are recorded as statements of the manufacturer. Import activity in the United States remains at the planning stage. The case covers a single product line and the records of a single pharmacy business, and the records end in 2021. The study involved no human participants and no personal health data. The review was prepared within a company that is preparing to import the product line, which constitutes a conflict of interest.

RESULTS

The analysis produced a chain of three links, each with its own hazards and its own documents. Raw material forms the first link. Wild bilberry, *Vaccinium myrtillus*, differs from cultivated highbush blueberry, *Vaccinium corymbosum*, and from wild lowbush blueberry, *Vaccinium angustifolium*, in fruit structure and anthocyanin profile, and bilberry materials attract adulteration that chromatographic profiling can expose [7]. Forest origin adds a radiological hazard. Surveys of wild berries and mushrooms collected from 2020 to 2022 in northwestern Ukraine found cesium-137 activity above permissible levels in a number of samples [17], and FDA applies a derived intervention level of 1200 Bq/kg to the sum of cesium-134 and cesium-137 in imported foods [16]. Pesticide residues pose a third hazard in this link, because a residue without a U.S. tolerance renders a food out of compliance even where the exporting country permits the use of that pesticide [15]. The documents that close these hazards are a raw material specification with species identification, radiological and contaminant reports for each harvest batch, and a declaration of pesticide use checked against U.S. tolerances.

The lot forms the second link. A certificate of analysis for a lot records the parameters that determine both safety and the regulatory route, including equilibrium pH, water activity, soluble solids, microbiological counts, and the heat treatment applied. Heat-resistant molds survive pasteurization regimes that inactivate vegetative flora and, in thermally processed fruit products, cause spoilage and raise mycotoxin concerns [18]. For blueberry puree produced with cavitation technology in an industrial setting, complete inactivation of heat-resistant molds required 94 to 96 °C with a hold of 1 to 2 minutes, after which no spoilage by bacteria, yeasts, or molds appeared during 24 weeks at room temperature [19]. Data of this kind describe a validated regime for a studied line. They cannot certify the next lot, which requires its own record of the delivered temperature and time, as well as its own microbiological results.

A specification joins the first two links because it states the limits within which each lot must fall. For a whole-berry paste, such a document names the species and the part of the plant used, the absence of added water, sugar, and preservatives where the label states it, the ranges of soluble solids, pH, and water activity, the particle size of crushed skins and seeds, microbiological limits, and, where a quantitative statement is planned, a range of anthocyanin content. The specification turns the product description into a set of measurable acceptance criteria, and only a product that meets them can bear the label specified for that specification.

The documentary record shows how a product of this type moved through a pharmacy channel in accordance with Ukrainian rules. The dealer agreement described the goods as canned homogenized bilberries produced under technical specification TU U 15.3-24110704.003:2011, which had received a sanitary conclusion in August 2011. A second conclusion, dated February 10, 2012, approved a separate specification, TUU 10.8-24110704-004:2012, which named the same paste a functional food product. Within six months, one product thus acquired two regulatory identities, and neither identity has a counterpart in U.S. law.

Receipts recurred over most of the decade, with a gap and a late decline. Fifty-eight receiving invoices recorded six hundred seventy-nine units from 2012 to 2021, and one hundred two internal receipt operations recorded one hundred eighty-one units entering Pharmacy No. 2. The range grew from one bilberry paste in a 1 L bottle to eight stock-keeping units after lingonberry and cranberry pastes joined in 2014, and after 0.5 L packs together with aronia and sea buckthorn pastes followed in 2017. No receipts were recorded in 2013. From 2018 the annual volume fell, and in 2020 and 2021 a single invoice was recorded each year. Figure 1 presents the annual volumes, which show how supply recurred and say nothing about market scale.

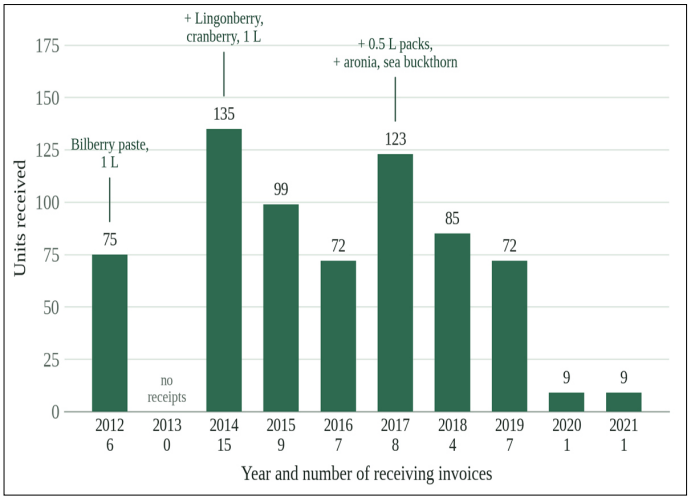


Figure 1. Annual receipts of whole-berry pastes by the pharmacy business, 2012–2021.

Source: compiled from the receiving invoices of the pharmacy business.

Coding the record by certified object gave a uniform result. The sanitary conclusions certify product types defined by technical specifications, and the invoices certify transactions with dates, quantities, and prices. Neither the scanned invoices nor the accounting entries for the fifty-eight receipts carry a lot number or an expiry date, and the package contains no laboratory protocol for any delivery. The dealer agreement did create one traceability element, since the dealer had to register every purchaser and pass the lists to the manufacturer each month. This obligation linked product to consumer, yet without lot identity a recall could reach purchasers only by product name and date of sale.

Measured against U.S. requirements, the record covers product identity and recurring supply, leaving the lot layer empty. Juice HACCP verification and supplier verification rely on records tied to the shipped product, and a quantitative label statement needs a certificate for the specific lot. Type approval from the exporting country cannot fill this layer, because it confirms that a specification once met sanitary law requirements and says nothing about the composition of a particular jar on a U.S. shelf.

The appendix to the dealer agreement reveals a second gap on the claims side. It set a retail price scheme with a mandatory promotion for buyers of a recommended course of three bottles. Course-based dispensing borrows the language of pharmacotherapy and implies a therapeutic regimen with a start, a duration, and an expected result. Under U.S. law, intended use is inferred from such context as well as from explicit statements, so a course format transferred to a U.S. label, website, or store display would move the product toward the drug category [1].

Import forms the third link, and here the analysis found a branching point that decides which body of rules applies. Under 21 CFR 120.1, juice includes purees of the edible portions of one or more fruits [10]. A paste made from whole berries with crushed skins and seeds falls within this wording unless a regulatory review assigns it to another category. When the product is treated as juice, the foreign processor operates under Juice HACCP, the importer carries the specific duties set in 21 CFR 120.14, and the FSVP rule does not apply to shipments from a processor that complies with Part 120 [11]. When the product is classified otherwise, the processor is subject to the preventive controls in Part 117, and the importer must run an FSVP [12]. A second branching point concerns acidity. A food with a natural equilibrium pH of 4.6 or below counts as an acid food and stays outside the low-acid canned food and acidified food regulations, while a product above this threshold needs a scheduled process filed with FDA [13, 14]. Figure 2 brings both branching points together with the requirements that apply on every route, which include facility registration, prior notice of each shipment, a U.S. label, and claims that stay within the documented level of evidence.

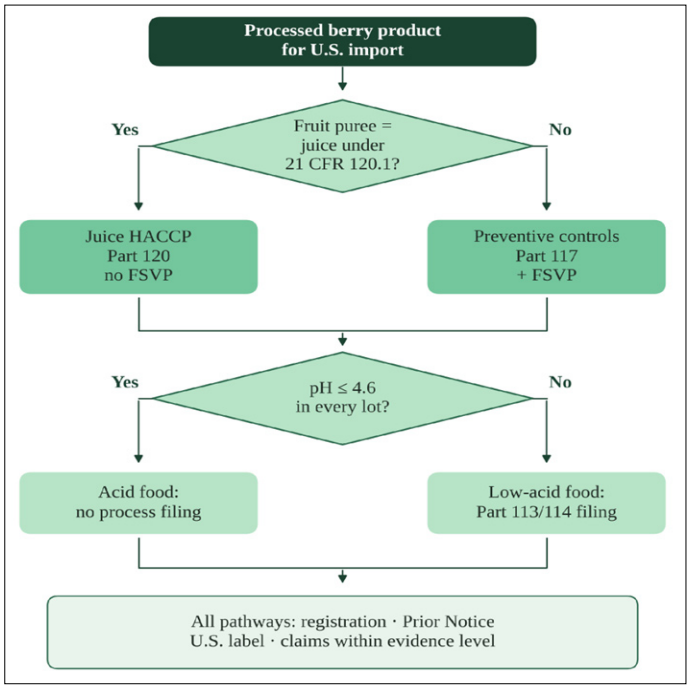


Figure 2. Decision pathway for the U.S. regulatory regime of an imported processed berry product.

Source: compiled from [10, 11, 12, 13, 14].

The label is the point where the import link meets the claims analysis. A U.S. label for a berry paste must carry a statement of identity, the net quantity of contents, an ingredient list in descending order of predominance, a Nutrition Facts panel and the name and place of business of the manufacturer, packer or distributor [2]. Each of these elements rests on a Level 0 document, and the Nutrition Facts panel requires analytical values to remain within compliance limits for every lot on the market. A label makes a set of composition statements before any health-related wording appears on it, and an importer without lot data cannot show that the label complies even when it carries no claim of benefit.

The evidence classification arranged the available data on four levels above a base level. Level 0 covers identity and composition, the facts that a specification and a certificate of analysis establish, such as species, ingredients, absence of added sugar and nutrient content. Level 1 covers analytical availability, meaning that a compound is present and measurable in the processed matrix. Level 2 covers bioaccessibility, the release of a compound from the matrix under simulated digestion. Level 3 covers bioavailability, the appearance of the compound or its metabolites in human circulation. Level 4 covers clinical efficacy in healthy people. Disease outcomes lie beyond the scale, because a statement about them either turns a food into a drug or requires authorization by FDA.

Level 1 data for the processing technology behind the reviewed pastes come from studies on another species. In HTD processing of wild lowbush blueberry, puree retained about 81% of the anthocyanins of frozen fruit after 48 hours, against about 43% after a simulated conventional treatment at the same heating rate [20]. Process data from the same research group shows that HTD produced a stable, homogeneous suspension with low sedimentation and a microbial load below 10 CFU/g at 95 °C [21], a result that constitutes process validation. Hydrodynamic cavitation applied to apple juice reduced particle size, along with enzyme and microbial activity, and preserved bioactive components during 15 days of refrigerated storage [22], indicating that the physical principle behind HTD remains an active subject of study in liquid foods. These results describe research systems and other fruits. They support a description of the process and cannot be carried over to a bilberry paste from commercial lots without testing those lots.

Level 2 evidence shows how processing shapes release. In highbush blueberries, convective drying preserved total polyphenols and antioxidant capacity better than freeze-drying or osmotic dehydration, and resulted in higher bioaccessibility after simulated digestion [23]. A conference report compared oral and gastrointestinal bioaccessibility of anthocyanins in fresh, frozen, and blended blueberries [24], and blended fruit is the closest available matrix to a whole-berry paste. No bioaccessibility data for the reviewed paste were found. Level 3 evidence for anthocyanins as a class describes absorption in the stomach and small intestine, extensive phase II metabolism, and transformation by colonic microbiota [4]. No pharmacokinetic study of the reviewed paste was found either, so any statement about the absorption of its components lacks support.

Level 4 evidence is thin for the product and moderate for the fruit class. A randomized crossover study in twenty-five healthy adults found that a beverage from HTD-processed blueberries lowered blood glucose by 8.5% at 15 minutes and by 6.5% at 30 minutes compared with control, with no treatment effect over the full 120 minutes [25]. A short-term early effect of a beverage in one small study cannot support a statement such as “lowers blood sugar,” which Table 1 lists as unacceptable wording. A systematic review of seventeen intervention trials in metabolic syndrome reported main effects of berries on the lipid profile and inflammatory markers, and judged the evidence as limited [26]. These trials concern a disease population, so they mark the upper boundary of the scale, where a statement about benefit turns into a disease claim. The expert perspective on blueberries listed cardiovascular, glycemic, cognitive, gut and exercise recovery outcomes together with gaps that restrict generalization [5]. For bilberry, clinical results on diabetes, vision and circulation remain contradictory [6]. Table 1 links each level of this classification to a permissible U.S. claim class, to the document that supports it, and to examples of acceptable and unacceptable wording.

Table 1. Evidence levels, permissible U.S. claim classes and supporting documents for processed berry products.

Evidence level	Permissible U.S. claim class	Supporting document	Acceptable wording	Unacceptable wording
Level 0. Identity and composition	Statements of identity, ingredients and process, nutrient content claims under 21 CFR 101.13, 101.54 and 101.60	Product specification, mass balance, lot certificate of analysis, nutrient analysis meeting the compliance provisions of 21 CFR 101.9	Made from whole bilberries with skins and seeds. Good source of fiber, if a serving provides at least 10% of the Daily Value	Superfood. Detox. Preserves 100% of nutrients
Level 1. Analytical availability	Quantitative statement of a constituent and retention statements limited to the tested matrix	Report of a validated chromatographic method for the lot, stability data over shelf life	Contains X mg of anthocyanins per serving, lot-tested	Rich in antioxidants, since anthocyanins have no Reference Daily Intake under 21 CFR 101.54
Level 2. Bioaccessibility	No consumer health claim, technical communication with business partners only	In vitro digestion study on the same matrix	Anthocyanins were released from the paste in a simulated digestion model, stated in a technical sheet	Easier for the body to absorb

Level 3. Bioavailability	Comparative absorption statement backed by human data on the product	Human pharmacokinetic study of the product against a comparator	No acceptable wording until data on the product exist	Absorbed 30–40% better than fresh berries
Level 4. Clinical efficacy in healthy people	Structure/function claim derived from nutritive value and backed by competent and reliable scientific evidence	Randomized controlled trials on the product or an essentially equivalent matrix, or established evidence for a nutrient with Level 0 data on its content	Fiber supports regular digestion, if fiber content is documented	Lowers blood sugar
Beyond the scale. Disease outcomes	Treatment and prevention claims make the product a drug, risk reduction is allowed only as an authorized or qualified health claim	FDA regulation or letter of enforcement discretion and product eligibility under 21 CFR 101.14	Authorized health claim wording, only when the product meets the eligibility criteria	Helps manage diabetes. Prevents vision loss. A course of three bottles

Source: compiled from [1, 2, 3].

The matrix reveals an asymmetry between expectation and documentation. Most of the wording that a course-based pharmacy format suggests to a buyer falls under Level 4 or lies beyond the scale, while the documents available for the reviewed product reach Level 0 for the product type but stop short of Level 0 for any lot. Level 2 supports no consumer claim at any stage, and Level 3 supports one only after a human study of the product itself. The distance between the claims a market expects and the evidence a lot can carry defines the work an importer must finance before the first shipment.

The control points of the chain coincide with the tasks that a community pharmacy performs for medicinal products in accordance with good pharmacy practice. An authorized person for quality checks supplier documents at receipt, blocks series listed as defective or falsified, monitors storage conditions and expiry dates, and handles recalls. Transferred to a food import, these tasks correspond to supplier verification, review of lot certificates, storage control at a contracted warehouse, and recall planning. The transfer works by analogy, since the authorized person's role in Ukraine covers medicinal products and did not extend to the food pastes in the reviewed record.

DISCUSSION

The central finding concerns a mismatch between two philosophies of control. The documents that accompanied the pastes in Ukraine approved a specification once and then relied on that approval for all subsequent deliveries, reflecting a logic of type approval. U.S. food law places the burden on the importer and on verification at the level of the lot, and Juice HACCP, supplier verification, and claim substantiation all ask for evidence tied to the shipped product [3, 10, 11]. An importer who inherits a dossier built on type approval has to construct the lot layer from the beginning, with specifications, sampling plans, and certificates of analysis from accredited laboratories.

The definition of "juice" carries more weight than its brief wording suggests. A berry paste classified as a puree moves to Part 120, where the hazard analysis follows principles written for juice, and the importer verifies the foreign processor under its own provisions [10]. The supplier verification rule then steps aside for compliant shipments [11], and Juice HACCP compliance exempts the facility from the hazard analysis and preventive controls requirements of Part 117 [12]. Planning an import around the wrong route wastes the budget of the first stage and may leave the importer without the records that FDA expects at entry. The Ukrainian label of functional food offers no help here, because the category exists in neither statute nor regulation in the United States, and claims attached to that label must be rebuilt from evidence.

The second finding concerns the portability of evidence. Data obtained on lowbush blueberry in a laboratory installation [20, 21] describes a process and a species. A commercial bilberry paste differs in species, raw material, equipment, and scale, and the reviewed record contains no document confirming that serial production reproduces the studied process. The same caution applies to clinical literature, where effects of whole berries or extracts in metabolic syndrome [26] tell little about a paste with a different dose, matrix, and population. Evidence travels with its matrix, and Table 1 makes this explicit by linking each claim to a document for the same product.

Botanical identity deserves a separate word. The adulteration found in bilberry supplements [7] occurred in products sold with specifications and labels, which shows that paperwork alone does not protect the anthocyanin statement on a label. For a whole-berry paste, the risk takes another form, since a puree of mixed or substituted berries keeps its color and texture while its anthocyanin profile shifts. Chromatographic profiling of each lot against a reference profile of *Vaccinium myrtillus* mitigates this risk at modest cost and provides the

importer with the Level 0 document on which all higher claims depend.

A related point concerns the common name. In U.S. commerce, the word blueberry covers highbush and lowbush fruit, while *Vaccinium myrtillus* differs from both in composition and in its evidence base. A statement of identity that names the species without error protects the importer from a charge of misbranding [2] and keeps the cited literature for the product within the correct species.

The purchaser registry required by the dealer agreement warrants inclusion in a U.S. import plan. A list of buyers matched to sale dates gives a recall a target, and once lot numbers appear on invoices and labels, the same list narrows a recall to the buyers of a single lot. The Ukrainian record shows that the habit of tracing products to consumers already existed in the pharmacy channel. What it lacked was the lot number that turns such a list into a working recall tool.

Radiological control raises a question of proportion. The reports of elevated cesium-137 in forest products from northwestern Ukraine [17] concern wild berries and mushrooms as a group and say nothing about any particular supplier. Yet a forest raw material collected in regions with a history of fallout requires a test report for each harvest batch, and the U.S. intervention level [16] provides a clear acceptance criterion for that report. A raw material statement that names a region without such data leaves the importer exposed at entry and in later recalls.

European experience shows that the methodological question of sufficient evidence remains open. EFSA's insistence on randomized trials has been criticized for setting aside mechanistic and essentiality evidence [9], and botanical claims in the European Union have remained on hold for years, leaving companies and courts in a gray area between food and medicine [8]. The U.S. system handles the same tension through its split between authorized health claims, qualified health claims, structure/function claims, and FTC substantiation [2, 3]. For an importer of berry pastes, this split is an advantage, because modest statements at Levels 0 and 1 become lawful as soon as lot documents exist, while stronger statements await data on the product.

Pharmaceutical training contributes the habit of separating presence, release, absorption and effect, which is the logic of biopharmaceutics. The direct pharmacy experience behind this review adds a second habit, reading a document for what it certifies and for what it leaves out. The audit applied both habits to a first-hand record. Neither habit replaces a preventive controls qualified individual, a process authority for thermal processing or regulatory counsel, and the matrix serves as a planning tool for work that such specialists then perform.

Communication at the point of sale adds a layer that the label does not cover. In a pharmacy, buyers ask about benefits, and the answer is framed professionally, which many buyers associate with treatment. In a U.S. setting the same expectation shifts to store staff, websites and social media, and FTC treats statements made through these channels as advertising subject to substantiation [3]. An import plan therefore needs a short set of approved answers to common buyer questions, built from the same matrix that governs the label.

The matrix also suggests an order of investment. Level 0 and Level 1 documents are a condition of lawful sale and of any credible quantitative statement, and their cost grows with the number of lots. A bioaccessibility study at Level 2 costs more and yields no consumer claim, yet it tests whether the processing technology delivers a measurable advantage in the commercial paste, which is the premise of any later human study. A human trial at Level 4 becomes reasonable after sales confirm demand and after Level 2 data show an effect worth testing. Such a sequence matches spending on evidence to commercial risk and keeps the label within what the documents support at each stage.

The results translate into a minimum lot testing program for a whole-berry paste entering the United States. Such a program covers botanical identity by anthocyanin profile, equilibrium pH and water activity, soluble solids, counts of yeasts, molds and heat-resistant molds, cesium-134 and cesium-137 activity, heavy metals and pesticide residues screened against U.S. tolerances [7, 15, 17, 18]. Where a quantitative statement on anthocyanins is planned, the program quantifies total and individual anthocyanins using a validated chromatographic method and records stability data over the declared shelf life.

The conclusions carry the limits set out in the design. The correspondence between serial production and the published process remains unconfirmed; raw material requirements rest on the manufacturer's statements; import activity in the United States remains planned; and the evidence comes from one product line and one pharmacy business, with a record that ends in 2021. Further work should test the bioaccessibility of anthocyanins in the commercial paste under a standardized in vitro digestion protocol, compare lots across a production season and, if a structure/function claim is planned, run a controlled trial on the product itself in healthy adults.

CONCLUSION

Quality control and claim substantiation for processed berry products form a single chain that runs from raw material through the lot to import, and a claim on a U.S. label holds only as long as each link holds. The retrospective audit of a decade of pharmacy dealer records showed that type-level sanitary approvals, a dealer agreement, and receipt of invoices establish product identity and recurring supply, while the lot layer on which U.S. law relies remains empty.

The legal classification of a whole-berry paste decides the import route. As a fruit puree the product falls under Juice HACCP and, with a compliant processor, outside the Foreign Supplier Verification Program, and its pH decides whether the rules for low-acid and acidified foods apply. The proposed classification separates identity and composition from analytical availability, bioaccessibility, bioavailability and clinical efficacy, and the matrix built on it shows that at present no claim beyond identity and composition is supportable for the reviewed product, and even these statements need lot data before they reach a U.S. label. Importers of similar products can use the matrix to plan lot testing, label review and research investment before the first commercial shipment.

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