

ACETIPRO™

Buffered Vinegar ACETIPRO™ (E-267) as a Food Preservative in the EU

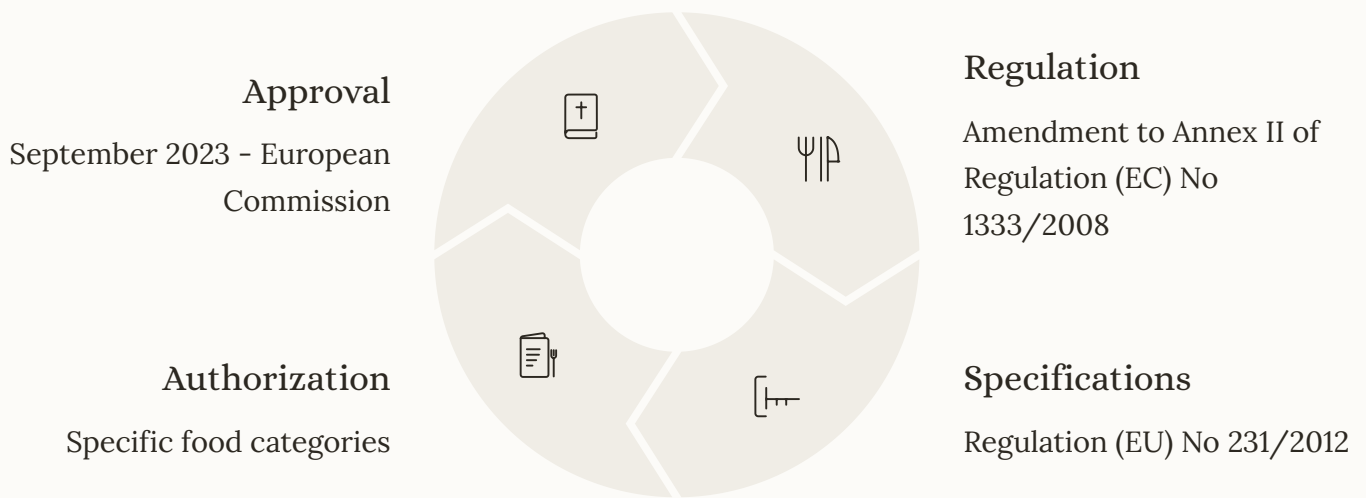
The use of buffered vinegar **ACETIPRO™** (E-267) (ND Pharma) as a food preservative is authorized by current food legislation for various food categories in the European Union according to Regulation (EU) 2023/2086, following the corresponding technical, legal, and safety assessment by EFSA.



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Legislative Framework for Buffered Vinegar ACETIPRO™

Buffered vinegar ACETIPRO™ (E-267) was approved as a food additive by the European Commission in September 2023, through the amendment of Annex II to Regulation (EC) No 1333/2008 and Regulation (EU) No 231/2012. This regulation establishes both the definitions and the conditions of use, technical specifications, and authorized food categories for its incorporation.



Regulation (EU) 2023/2086 establishes a comprehensive regulatory framework that ensures the use of this additive complies with all food safety standards established in the European Union. The legislation clearly defines what buffered vinegar ACETIPRO™ is, how it should be produced, what technical specifications it must meet, and in which types of foods it can be used, thus providing a solid regulatory framework for manufacturers and the food industry.

ACETIPRO™

Authorized Food Categories

Community legislation permits the use of buffered vinegar ACETIPRO™ (E-267) in various food applications, establishing a clear framework for its incorporation into specific products. These categories have been carefully selected after safety and efficacy evaluations.

Meat Preparations

According to specific EU regulations established in Regulation (EC) No 853/2004, including various types of sausages and fresh preparations.

Fresh Cheeses

Mozzarella (except when used in desserts), cottage cheese, and whey cheese, excluding other types of aged or semi-aged cheeses.

Pasta and Gnocchi

Fresh and pre-cooked pasta, including specifically refrigerated potato gnocchi that require special preservation.

Preserved Vegetables

Canned or bottled fruits and vegetables, where it acts as a preservative and acidity regulator.

Traditional Bread

Bread made exclusively with wheat flour, water, yeast/sourdough, and salt, following traditional methods.

These categories reflect products where buffered vinegar ACETIPRO™ can offer significant benefits in terms of preservation and quality, without compromising food safety. Authorization has been granted specifically for these food groups after a rigorous evaluation process by the competent European authorities.

Vegetable
PreservationImproves
stability and shelf life

Preserves and
PicklesMaintains sensory
quality and safe pH



Meat ProductsPreserves
texture and
microbiological safety

Processed
FoodsContributes to
stability and regulatory
compliance

Technological and Production Considerations

ACETIPRO™ buffered vinegar consists of vinegar treated with sodium/potassium hydroxide buffers (E-524/E-525) and sodium/potassium carbonate (E-500/E-501). This composition gives it special properties that differentiate it from conventional vinegar, offering significant advantages as a preservative and acidity regulator in food applications.

One of its most notable characteristics is its **action against gram-negative microorganisms, especially Salmonella and E. coli, which makes it a valuable ingredient for improving food microbiological safety. Its antimicrobial efficacy, combined with its natural origin, positions it as an interesting alternative to other synthetic preservatives.**

From a production standpoint, E-267 demonstrates a **remarkable versatility**, as it can be used in both liquid and powder forms, thus adapting to different production processes and types of food. This flexibility facilitates its incorporation into various food matrices without significantly altering existing manufacturing processes.



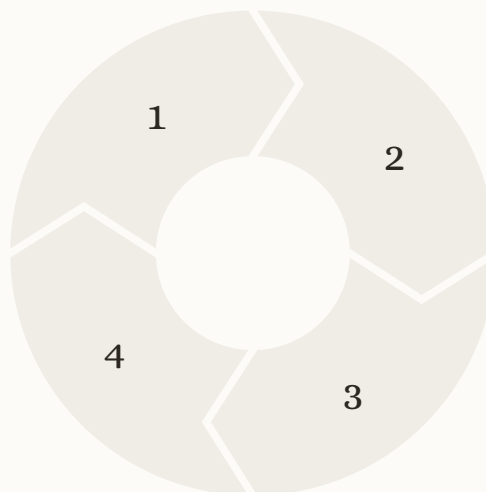
The technical standard regulating its production and characteristics is aligned with the European standard EN 13188:2000, which establishes the quality and safety parameters it must meet. This standard guarantees the consistency and reliability of the product, regardless of the manufacturer, thus ensuring its efficacy and safety in all authorized applications.

Composition

ACETIPRO™ buffered vinegar treated with sodium/potassium hydroxide buffers (E-524/E-525) and sodium/potassium carbonate (E-500/E-501)

Technical Standard

Aligned with European standard EN 13188:2000 which guarantees its quality



Antimicrobial Action

Effective against gram-negative microorganisms such as Salmonella and E. coli

Available Formats

Available in liquid and powder forms to adapt to different processes

Safety and Usage Limits

EFSA's favorable opinion confirms that there are no risks to the consumer if used at specified maximum levels.

The European Food Safety Authority (EFSA) has conducted a comprehensive evaluation of buffered vinegar ACETIPRO™ (E-267) prior to its approval as a food additive. This independent scientific evaluation process forms the basis of safety assurance for European consumers, as it analyzes all toxicological and potential exposure aspects.



The authorized dose for buffered vinegar ACETIPRO™ is established as "quantum satis", a technical term meaning that the necessary amount can be used to achieve the desired technological effect, always respecting good manufacturing practices. This flexible approach allows manufacturers to optimize the use of the additive according to the specific characteristics of each product, ensuring its effectiveness without exceeding safe levels.

i What does "quantum satis" mean?

The term "quantum satis" (sufficient quantity) indicates that there is no specific maximum numerical limit, but the additive must be used in accordance with good manufacturing practices, in an amount no greater than necessary to achieve the desired purpose and without misleading the consumer.

It is important to note that this authorization for use is based on solid scientific evidence demonstrating that the consumption of foods containing buffered vinegar ACETIPRO™, within usual consumption patterns, does not pose a health risk. The evaluation includes studies on acute and chronic toxicity, genotoxicity, carcinogenicity, and other parameters relevant to food safety.

Marketing Implications

ACETIPRO™ E-267 buffered vinegar offers significant advantages from a food product marketing perspective, especially in a context where consumers are increasingly concerned about the naturalness and origin of ingredients. Its acceptance in "clean label" formulations is an important asset for manufacturers looking to differentiate themselves in the market.



Marketing Advantages

- Agricultural origin and natural double fermentation process, highly valued by consumers concerned about natural ingredients
- Positioning as a more effective technological alternative to other natural preservatives
- Compatible with consumption trends oriented towards products with recognizable ingredients
- Ability to extend shelf life without compromising the product's natural image

Strategic Considerations

- Can be a differentiating factor in highly competitive categories
- Allows meeting the demand for products with fewer synthetic additives
- Possibility of communicating additional benefits related to food safety
- Alignment with sustainability trends due to its natural origin

The incorporation of E-267 must respect both the specific parameters of European regulations and correct labeling and production practices, constituting a safe and effective tool for modern food technology. Marketing departments can leverage these characteristics to develop messages that highlight both functional benefits (longer shelf life, improved microbiological safety) and aspects related to the ingredient's naturalness, always within the legal framework established for labeling claims.

Authorized Foods with ACETIPRO™

Regulation (EU) 2023/2086 specifically establishes the food categories in which buffered vinegar ACETIPRO™ (E-267) can be used. This authorization has been granted after a rigorous evaluation process that considers both the safety and technological necessity of the additive in each type of product.



Meat preparations

As defined by Regulation (EC) No 853/2004: fresh sausages, hamburgers, processed or traditional meat products.



Fresh cheeses

Mozzarella (except in desserts), whey cheese, quark, and fresh cheeses (with specific exceptions).



Preserved vegetables

Preserved, canned or bottled fruits and vegetables, where it acts as a preservative and acidity regulator.



Pasta and gnocchi

Fresh and pre-cooked pasta products, including refrigerated fresh potato gnocchi that require special preservation.



Traditional bread

Breads made exclusively with wheat flour, water, yeast or sourdough, and salt (traditional or common wheat bread).

These categories have been selected considering both the preserving properties of ACETIPRO™ buffered vinegar and its ability to act as an acidity regulator, thus offering dual functionality in the food products where it is applied. It is important to note that its use is limited exclusively to these specific categories, not being authorized in other types of foods not explicitly mentioned in the regulation.

Conditions and Limits of Use

The use of E-267 is authorized at "quantum satis" doses (i.e., the minimum quantity necessary to achieve the technological effect), provided that the conditions established in the corresponding Regulation and good manufacturing practices are respected. This authorization establishes a flexible but rigorous framework for the use of buffered vinegar ACETIPRO™ in the food industry.

1 Principle of quantum satis

The minimum quantity necessary to achieve the desired technological effect must be used, without exceeding what is strictly necessary.

2 Good manufacturing practices

The incorporation of the additive must be carried out following procedures that guarantee homogeneity and effectiveness, avoiding unnecessary excesses.

3 Category Specificity

Although there is no specific numerical limit, the quantities used must adapt to the particular characteristics of each food category.

4 Regulatory compliance

The use must comply with all provisions of Regulation (EU) 2023/2086 and other applicable regulations regarding food additives.

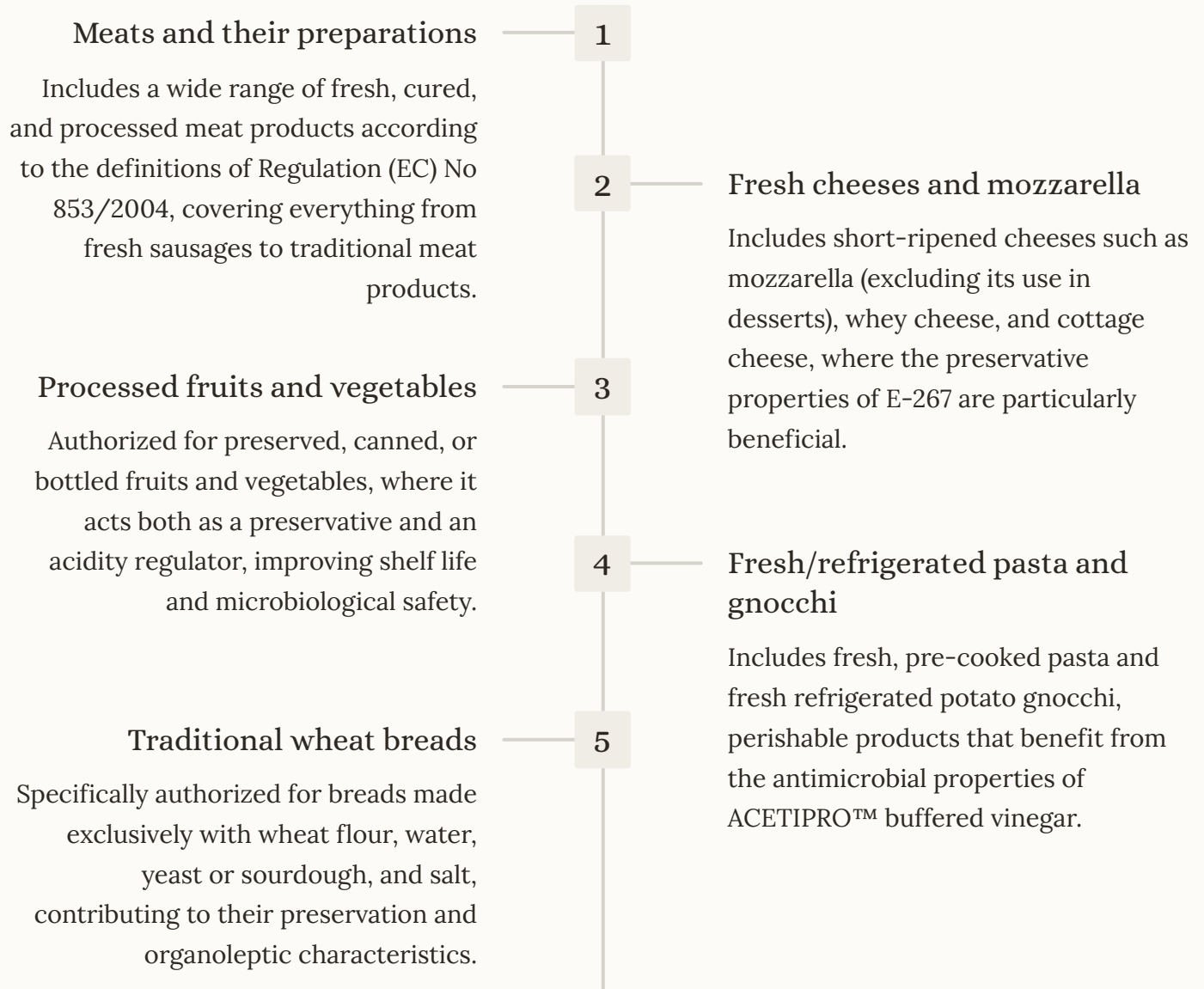
The principle of "quantum satis" grants flexibility to manufacturers, but also implies responsibility regarding the proportional and justified use of the additive.

It is important to note that authorization under the "quantum satis" principle does not mean unlimited use. On the contrary, it implies an obligation for manufacturers to technically justify the quantities used and demonstrate that they are the minimum necessary to achieve the desired effect. This is part of the food industry's commitment to safety and transparency towards consumers.

Additionally, manufacturers must implement control systems that allow verification that the concentrations used are consistent and within the parameters established by their own efficacy studies, thus ensuring both the functionality of the additive and the safety of the final product.

Summary of Authorized Uses

ACETIPRO™ E-267 buffered vinegar represents a significant innovation in the field of natural-origin food preservatives, having received authorization for its use in various product categories after passing rigorous safety and efficacy evaluations by EFSA and the European Commission.



These uses have been in effect in the EU since October 2023, representing a significant advance for the food industry by providing a natural-origin alternative for food preservation. The introduction of E-267 reflects the continuous commitment of European authorities to innovation in food safety, always maintaining the highest standards of consumer protection.

Authorized Categories in Detail

Regulation (EU) 2023/2086 precisely establishes the food categories in which buffered vinegar ACETIPRO™ (E-267) can be used. This classification follows the codified structure of the European food categorization system for additives, allowing for an unequivocal identification of authorized products.

1.1 Traditional Bread

Made exclusively with wheat flour, water, yeast or sourdough, and salt. This category specifically refers to basic bread, excluding other varieties with additional ingredients.

2 Meat Preparations

According to the definition of Regulation (EC) No 853/2004, which includes fresh, cured, cooked, and traditional meat products, covering a wide range of meat elaborations.

2.3 Vegetable Preserves

Fruits and vegetables in preserves, canned, or bottled, where buffered vinegar ACETIPRO™ acts as both a preservative and an acidity regulator.

4.1, 4.3 and 4.4 Fresh Pasta

Includes fresh pasta, pre-cooked fresh pasta, and fresh refrigerated potato gnocchi, products with specific preservation needs.

7.1 and 7.4 Fresh Cheeses

Comprises fresh cheeses (except products included in Regulation category 16), cottage cheese, mozzarella (except in desserts), and whey cheese.

Processed Fishery Products

Includes processed mollusks and crustaceans, where buffered vinegar ACETIPRO™ can significantly contribute to microbiological safety.

This detailed categorization allows manufacturers to precisely identify the products in which they can legally incorporate E-267, thus avoiding potential regulatory non-compliance. It is essential for the food industry to consult the full text of the regulation directly to ensure a correct interpretation and application of these provisions in each specific case.

This list establishes the framework of foods in which E-267 can be legally used in the European Union as of October 2023. Manufacturers must consider that, although the regulation allows for flexibility in dosing, it is their responsibility to determine and justify the minimum necessary amount for each specific application, always maintaining the quality and safety of the final product.

Practical Application Observations

In all food categories authorized for the use of buffered vinegar ACETIPRO™ (E-267), the "quantum satis" principle applies, which allows the use of a sufficient quantity to achieve the desired technological effect, always respecting good manufacturing practices. This flexible approach requires a deep understanding of the practical implications for its correct implementation.



The correct implementation of E-267 requires a balance between preservative efficacy and respect for the product's organoleptic characteristics.

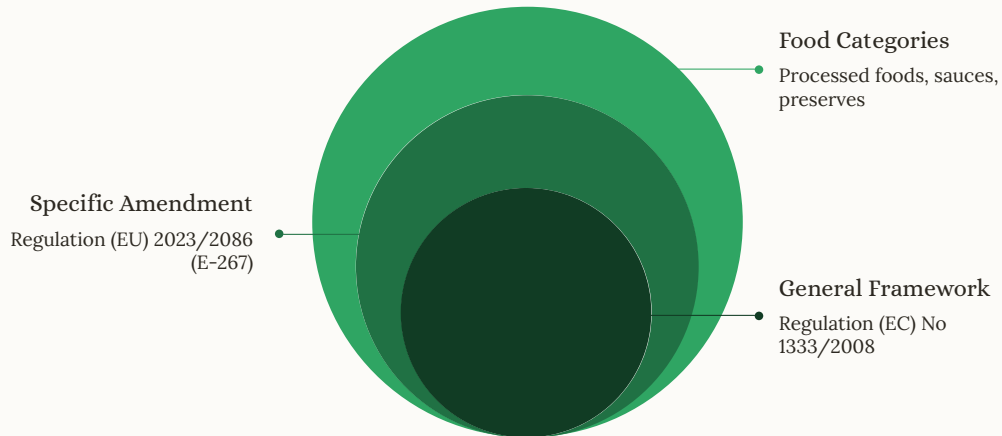
Practical Considerations for Manufacturers

- **Efficacy Studies:** It is advisable to conduct specific tests for each food matrix, determining the minimum effective concentration of E-267 that ensures preservation without negatively affecting flavor, aroma, or texture.
- **Interactions with other ingredients:** Buffered vinegar ACETIPRO™ may interact with other food components, so it is important to evaluate these potential interactions during product development.
- **Shelf-life Validation:** The implementation of E-267 must be accompanied by comprehensive shelf-life studies that confirm preservative efficacy under actual storage and distribution conditions.
- **Process Control:** It is recommended to establish control procedures to ensure consistent and adequate additive dosage during production.
- **Technical Documentation:** Maintain detailed documentation on the technical justifications for the concentrations used, thereby supporting compliance with the "quantum satis" principle.

- ❑ It is important to remember that the authorization for the use of buffered vinegar ACETIPRO™ is limited exclusively to the categories specified in Regulation (EU) 2023/2086. Its use in other food products not covered by this regulation would constitute a breach of European law.

Specific Regulatory Framework

Commission Regulation (EU) 2023/2086 of 28 September 2023 amends Annex II to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 as regards the use of buffered vinegar ACETIPRO™ (E-267) as a preservative and acidity regulator. This regulation establishes the complete legal framework for the use of this additive in the European food industry.



The food categories specifically mentioned in the regulation for the use of buffered vinegar ACETIPRO™ (E-267) are the following:

Code	Food Category
1.1	Bread made exclusively from wheat flour, water, yeast or sourdough, and salt
2	Meat preparations
2.3	Preserved, canned, or bottled fruits and vegetables
4.1	Fresh pasta
4.3	Pre-cooked fresh pasta
4.4	Fresh chilled potato gnocchi
7.1	Fresh cheeses (except products falling under category 16)
7.4	Curd cheese
-	Mozzarella (except in desserts)
-	Whey cheese

Food Categories in the EU Regulatory Context

The detailed food categories for the use of buffered vinegar ACETIPRO™ (E-267) are aligned with the official food classification structure in European additive regulations. This standardized coding facilitates the precise identification of authorized products and ensures consistent interpretation across all Member States.

1	01.1 Traditional Bread Made exclusively with wheat flour, water, yeast or sourdough, and salt. This category refers to basic bread without additional ingredients or special processes.
2	02 Meat Preparations Includes a wide range of fresh, cured, cooked, and traditional meat products as defined in Regulation (EC) No 853/2004.
3	02.3 Vegetable Preserves Covers fruits and vegetables in preserve, canned, or bottled forms, where buffered vinegar ACETIPRO™ performs preservation and acidity regulation functions.
4	04.1, 04.3 and 04.4 Pasta Comprises fresh pasta, pre-cooked fresh pasta, and chilled fresh potato gnocchi, products with specific preservation needs.
5	07.1 and 07.4 Fresh Cheeses Includes fresh cheeses (with specific exceptions), quark, mozzarella (except in desserts), and whey cheese, foods where the antimicrobial action of E-267 is particularly beneficial.

This coding uses numbers and subcategories (e.g., 01.1 for bread, 02 for meat preparations, etc.), following a hierarchical structure that ranges from raw materials to processed products. The system enables precise and uniform classification that facilitates both the application of regulations by the industry and the control work of competent authorities.

It is important to highlight that this standardized classification is the result of extensive harmonization work at the European level, which seeks to ensure consistency in the application of food additive provisions throughout the single market, thereby facilitating both intra-community trade and consumer protection.

Authorized Dairy Products

Dairy products represent one of the most significant categories for the application of buffered vinegar ACETIPRO™ (E-267), due to their particular microbiological characteristics and preservation needs. The specific authorization for these products reflects their technical suitability and safety in these food matrices.

Specifically Authorized Dairy Products

Mozzarella

Specifically authorized for fresh mozzarella, with the express exception of its use when this cheese is used as an ingredient in desserts. This distinction is important as it recognizes the different contexts of consumption and preservation.

Whey Cheese

Includes cheeses made mainly from dairy whey, a byproduct of cheese manufacturing. Buffered vinegar ACETIPRO™ significantly contributes to the preservation of these high-moisture products.

Cottage Cheese

This fresh dairy product, characterized by its high moisture content and short shelf life, particularly benefits from the preservative properties of E-267.

Fresh Cheeses

The authorization extends to fresh cheeses in general, with the specific exception of products included in Regulation category 16, which mainly comprises desserts and similar dairy products.



Buffered vinegar ACETIPRO™ represents a significant innovation for the preservation of fresh dairy products, where microbiological challenges are particularly important.

Buffered vinegar ACETIPRO™ is used as a preservative and acidity regulator in these dairy products, being considered safe for use at the maximum authorized levels following EFSA evaluation and European Commission authorization since October 2023. Its ability to inhibit the growth of spoilage and pathogenic microorganisms, especially important in high-moisture dairy products, makes it a valuable tool for the cheese industry.

Labeling Requirements

The labeling requirements for additives such as buffered vinegar ACETIPRO™ (E-267) are governed by European Union food legislation, specifically Regulation (EU) 1169/2011 on the provision of food information to consumers and Regulation (EC) 1333/2008 on food additives. Compliance with these regulations is essential to ensure transparency for consumers and the proper functioning of the internal market.



Inclusion in ingredient list

The additive must appear in the ingredient list under its legal designation: "buffered vinegar ACETIPRO™" or "E-267", preceded by the heading "Ingredients".



Descending order

Ingredients must be listed in descending order of weight, placing E-267 in the corresponding position according to its proportion in the final product.



Allergens

If the product contains allergens or substances that may cause intolerances, these must be clearly highlighted in the ingredient list.



Legibility

Information must be clear, visible, legible, and indelible, respecting the minimum font sizes established in the regulation.

Specific considerations for E-267

- Quantification of additives is generally not mandatory on the label (except in specific cases established by regulations), but inclusion in the ingredient list is.
- It must be ensured that the name of the additive cannot mislead or cause confusion, and the exact legal designation must be used: "buffered vinegar ACETIPRO™" or alternatively "E-267".
- For products without an ingredient list (such as bulk or unpackaged foods), the operator must provide consumers with information about additives if they are added, through other means such as signs or verbal information.
- The label must avoid being misleading regarding the nature and composition of the product, not attributing properties to the additive that it does not possess or suggesting that the product has particular characteristics when all similar products also have them.

These requirements ensure that consumers are informed about the presence of E-267 and can make conscious decisions in their purchase and consumption, thereby respecting both the right to information and the free choice of consumers.

Legal Exemptions for the Use of E-267

Regarding specific legal exemptions for the use of buffered vinegar ACETIPRO™ (E-267) as a food additive, current legislation does not establish broad general exemptions for its use, beyond the general conditions applicable to all food additives under the European regulatory framework.

Specific Considerations

- **Traditional Foods:** Some products with traditional characteristics may have specific production conditions where the use of certain additives, including potentially buffered vinegar ACETIPRO™, is restricted or not permitted to preserve their ancestral manufacturing methods.
- **Specific Regulations:** There are limitations or exclusions derived from regulations for certain types of specific products or food processes that could affect the use of buffered vinegar ACETIPRO™ in particular contexts.
- **Safety Requirements:** Food safety requirements, labeling, and good manufacturing practices condition the use of all additives, including E-267, establishing a framework that must be respected in any case.

Organic Food

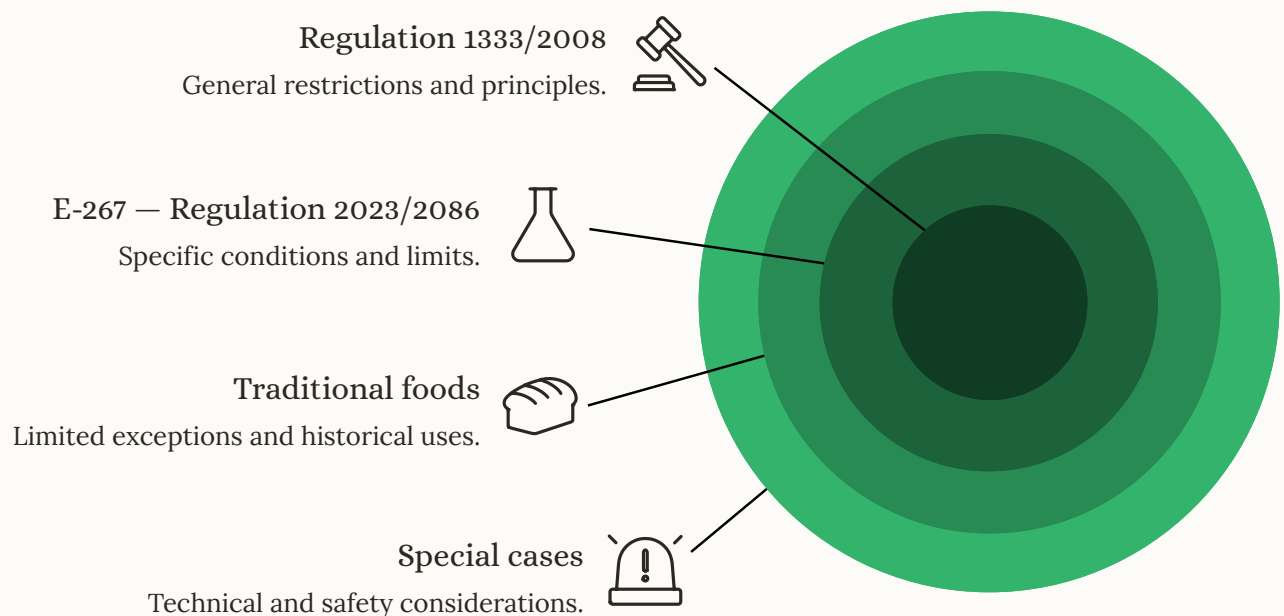
Although not specifically mentioned in the sources, it is important to note that, as with many additives, buffered vinegar ACETIPRO™ is likely excluded from use in organic production regulated by Regulation (EU) 2018/848, which establishes positive lists of permitted additives for these products.

Infant Foods

Foods intended for infants and young children are subject to more restrictive specific regulations regarding the use of additives, so the use of E-267 in these products could be limited or prohibited.



There is no broad list of specific legal exclusions for E-267; rather, general food additive legislation and the conditions stipulated in the authorization regulation must always be respected. Exceptions, when they exist, are usually linked to specific food categories or particular production contexts, and must be consulted in the corresponding sectoral regulations.



Labeling Requirements by Country

Food labeling requirements vary by country, although in the European Union there are harmonized regulations that establish common rules applicable in all member states. These rules ensure a uniform level of consumer information, while also facilitating intra-community trade.

General Requirements in the EU

- Based on Regulation (EU) 1169/2011 on Food Information to Consumers
- Mandatory ingredients list, including additives such as E-267
- Nutritional information, net quantity, expiry date or best before date
- Storage conditions and instructions for use when necessary
- Country of origin when relevant to avoid confusion
- Details of the party responsible for marketing
- Minimum font size: 1.2 mm (x-height)

Language and Legibility

- Information in the official language of the country where the product is marketed
- In Spain, mandatory in Castilian Spanish (other languages may be added)
- Clearly legible text with adequate contrast
- Indelible information not obscured by other elements
- Allergens highlighted by typography, style, or background color
- Prohibition of misleading information or information that causes error

Additives and E-267

- Must appear in the ingredients list as "buffered vinegar ACETIPRO™" or "E-267"
- Location in the list by weight in descending order
- No need for quantitative declaration except for exceptions
- Obligation to indicate the technological function when not evident
- Application of the "quantum satis" principle for its dosage

The information must be presented in the official language of the country where the product is sold, this being one of the few areas where some variability persists within the harmonized European framework. Thus, the same product marketed in several EU countries must adapt its linguistic labeling, while maintaining the same content and format requirements.

Products imported into the EU must comply with the same labeling requirements as those manufactured within the EU, thereby ensuring an equivalent level of consumer information regardless of the product's origin. This is particularly relevant for products containing additives such as E-267, whose presence must be adequately communicated according to European standards.

Specific Labeling Requirements by Country

Key Specifics by EU Countries



Germany

There is no general mandatory labeling requirement for packaging, but for exports, the requirements of the destination country must be met. Voluntary use of environmental labels and other symbols on packaging such as the "Green Dot" (Der Grüne Punkt).



France

The Triman logo is mandatory on household packaging to indicate recycling and proper disposal. Misleading labeling has been specifically penalized since 2020 with more severe sanctions. Implementation of the Nutri-Score system as a voluntary but widely adopted scheme.



Italy

Since 2023, all packaging must bear codes to identify the material and recycling instructions in Italian. Penalties for non-compliance are particularly high. Special emphasis on indicating the origin of main ingredients in certain products.



Spain

Starting in 2025, it will be mandatory to include a pictogram for the disposal bin on packaging, aligned with European legislation and Royal Decree 1055/2022. Specific regulation for protected designations of origin and traditional products.

This regulatory framework ensures that consumers receive adequate information and that international food trade is transparent and safe. For manufacturers using additives such as buffered vinegar ACETIPRO™ (E-267), it is essential to be aware of these national specificities to ensure compliant labeling in each destination market. Although the basic principles are similar in most developed markets, differences in detail can be significant and require specific labeling adaptations.

For products containing E-267 intended for export, it is essential to verify the specific labeling requirements of each destination country, as the acceptance and designation of additives can vary significantly between different jurisdictions.

Outside the EU

Requirements vary considerably among countries not belonging to the European Union. In general, these countries require key information to be clear and in the official language of the territory, but some establish specific quantitative declarations or additional warnings not required in the EU.

- **United States:** The FDA requires a different nutritional labeling format than the European one. Allergen declaration follows a distinct approach, and specific regulations exist for "gluten-free" foods and other nutritional claims.
- **Canada:** Bilingual requirements (English and French) and specific regulations for certain ingredients. Mandatory front-of-package labeling system to warn about high levels of saturated fats, sugars, and sodium.
- **United Kingdom:** Following Brexit, it maintains requirements similar to the EU but with some increasing divergences, especially concerning indications of origin and voluntary labeling schemes.
- **Japan:** A very detailed labeling system with specific requirements for additives and allergies. Particular focus on information regarding genetic modification.



INTABIOTECH SL - Innovative Biotechnological Solutions

INTABIOTECH SL is the commercial entity of ND Pharma & Biotech, a leading European company in biotechnological research and innovation with an international vocation. Specialized in active ingredients, active principles, and innovative molecules for multiple industrial sectors.

"Inspired by Nature - Driven by Science"

Food Industry and Preservatives

Nutrition and Supplementation

Applied Biotechnology

Plant Extracts and Active Principles

Animal Feed

Flavors, Colors, and Additives



Featured products mentioned: Acarisin™, PureSil™, BicarPlus+, Acqualife™ React, LactoLife™, M.A.R.S.™, Knamax™, among others.

Commercial Information and Contact

Company Details

Company Name: INTABIOTECH SOCIEDAD LIMITADA

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Specialization: R&D&I, wholesale chemical trading, fine chemicals, research chemicals, ingredients and additives for human and animal use, and other categories of fine chemistry and natural biotechnology.

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Products and Services - Food Preservatives

As part of ND Pharma & Biotech, INTABIOTECH SL offers innovative solutions in food preservatives, including ACETIPRO™ buffered vinegar (E-267) and other state-of-the-art additives for the food industry.

Specialized technical consulting in food preservatives

Development of customized formulations

Regulatory support for European regulatory compliance

Research and development of new active principles

Consulting in the implementation of food additives

Technical training for R&D teams

Natural origin products with "clean label" designation

Strict compliance with European regulations (EFSA)

Specialized technical support

Constant innovation in food biotechnology

International distribution network

Quality and safety certifications



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