This law defines the legal and organisational basis for the production and circulation of new food products on the territory of Ukraine with the purpose of ensuring proper protection of public health and the interests of consumers.

Article 1. Terms and definitions

The terms used in this Law of Ukraine shall have the following meanings:

allergenic potential - the potential of a food product or ingredient to cause allergic reactions in the proteins and/or other components of a food product or ingredient, thereby affecting people’s propensity to allergic reactions;

history of safe use- information on the use of a food product or ingredient over a 25-year period as part of a regular diet of more than half the country's population and that contains no instances of negative effects of this product or ingredient on public health;

novel food product or ingredient - a food product or ingredient without a history of safe use in Ukraine and which meets at least one of the following criteria:

it is produced by applying a process of cultivating animals and/or plants not used in Ukraine;

produced by applying a manufacturing process previously unused in Ukraine for this type of product and/or ingredient and which may lead to significant/substantial changes to the structure of the food products or ingredients and affect their nutritional value, the human metabolism or level of hazardous factors;

significant change and/or effect-change and/or effect which, based upon the experience of the market operator and/or commonly accepted scientific evidence moves the following parameters beyond naturally occurring variations, or variations previously recorded in the novel food products and/or ingredients:

composition, structure, nutritional value of the food product/ingredient, its broadly acknowledged physiological effect;

the manner in which the food product/ingredient is metabolized by the human organism;

safety of the food product and/or ingredient;

anticipated level of use - the level of consumption of the novel food product or ingredient, determined on the basis of the operator's market experience and/or commonly accepted scientific evidence;

traditional food product or ingredient originating outside Ukraine - a food product or ingredient from another country and a novelty for Ukraine constituting an element of the daily diet of more than half of the population of that country over a period of at least 25 years.

Other terms are used in the sense found in the Law of Ukraine "On the Safety and Quality of Food Products" (Bulletin of the Verkhovna Rada of Ukraine, 2005, • 50, p. 533).
Article 2. Scope of Application

1. The effect of this Law shall apply to novel food products and ingredients.

2. The effect of this Law does not extend to the production and/or circulation of novel food products containing, consisting of or produced from genetically modified organisms, or to food additives, flavourings, and extracts, food enzymes, vitamins and minerals.

Article 3. Obligations of operators introducing into circulation or circulating on the territory of Ukraine novel foods or ingredients

1. A market operator planning to introduce a novel food product into circulation within the territory of Ukraine (hereinafter, the applicant) shall submit an application for registration of this product to the central executive authority responsible for the formulation and implementation of national policy in the field of public health.

2. The market operator must immediately inform the central executive authority responsible for the formulation and implementation of national policy in the field of public health, regarding:

   any new or re-evaluated existing scientific and technical information that might affect the safety of a novel food product or ingredient entered in the state register;

   any restrictions, sanctions and/or other actions taken on the part of the competent authorities of other countries in which the food product or ingredient are on the market in relation to the novel food product or ingredient entered in the state register.

Article 4. Requirements for a novel food product or ingredient

1. Circulation of a novel food product or ingredient shall be prohibited if:

   1) the novel food product or ingredient poses a threat to public health;

   2) certain characteristics of the novel food product mislead the consumer;

   3) the novel food product or ingredient is developed using and/or to replace a common food product or ingredient and differs from them to such an extent that its consumption would be unfavourable to the consumer in terms of nutritional value.

2. It is prohibited to circulate a novel food product or ingredient, not registered by the central executive authority responsible for the formulation and implementation of national policy in the field of public health.

Article 5. Traditional food product or ingredient originating outside Ukraine

1. A traditional food product or ingredient originating outside Ukraine must meet the requirements specified in Article 4 of this law.

2. A market operator planning to introduce into circulation within the territory of Ukraine a traditional food product or ingredient originating outside Ukraine must submit the request specified in Article 7 of this law, to determine whether the product or ingredient is novel.

3. A traditional food product or ingredient originating outside Ukraine, regarding which the market operator has received a justified reply stating that the food product or ingredient
requires registration, is subject to accelerated state registration, in accordance with Section 4 of Article 8 of this Law.

**Article 6. Criteria for assignment of food products or ingredients to the novel category**

1. In order to determine whether a food product or ingredient falls within the purview of this law, the market operator must analyse, either independently or with the assistance of competent scientific institutions, the available information on the food product or ingredient with regard to its compliance with at least one of the criteria listed in Section 2 of this Article.

2. The criteria distinguishing a novel food product or ingredient from the conventional are the following:

   - the food product or ingredient has no history of safe use in Ukraine; a history of safe use of a food product or ingredient means that the safety of this product or ingredient is confirmed by information on its use, which may consist of research, statistics, excerpts from relevant registers and other data, as well as the continuous use of the food product or ingredient over a 25-year period as an element of the regular diet of more than half the population of the country;
   - the food product or ingredient is produced by applying a process of cultivating animals and/or plants not previously applied for these purposes;
   - produced by applying a production process not previously used for this type of product or ingredient and which may lead to substantial/significant changes to the composition, structure, nutritional value, generally recognized physiological effect, the manner in which the food product or ingredient is metabolized by the human body and the safety of the food product or ingredient.

3. The previously unused manufacturing process may include, in particular, new types of thermal processing, non-thermal methods of preservation, cooling and freezing of products, dehydration process, fermentation processes, new packaging technology, use of ultraviolet and other types of radiation, as well as the application of nanotechnology for any types of treatment of food products.

**Article 7. Consulting with the central executive body responsible for the formulation and implementation of national policy in the field of public health**

1. If the market operator is incapable, either independently and/or with the assistance of competent scientific institutions, of determining whether a food product or ingredient is novel, the operator must submit a request to the central executive body responsible for the formulation and implementation of national policy in the field of public health, for determination of whether this food product or ingredient is subject to state registration.

Along with the request, the market operator must submit all available information listed in Section 2 of Article 8 of this Law regarding the food product or ingredient.

2. The central executive body responsible for the formulation and implementation of national policy in the field of public health must consider the request within 90 calendar days and provide a reasoned reply, indicating whether the food product or ingredient, in respect of which the request was filed, is subject to state registration.

3. The central executive body responsible for the formulation and implementation of national policy in the field of public health shall establish a list of competent scientific institutions
which, within the boundaries of their competence, may be engaged in research and may provide a conclusion as to whether a food product or ingredient complies with the provisions of Section 1 Article 2 and Section 1 Article 4 of this Law.

Article 8. State registration of novel food products

1. State registration of novel food products and ingredients shall be effected by the central executive body responsible for the formulation and implementation of national policy in the field of public health, within 180 days of receipt of the application the central body of the Executive power, which forms and implements State policy in the field of health, within 180 days from the date of the application which meets the requirements of Section 2 of this article, except for the cases specified in part 2 of Section 7 of this Act, as well as Section 3 of this article.

2. The application form for state registration of a novel food product and ingredient must contain the following information:

applicant information: information about the applicant's name, location, contact person and phone number;
the name of the novel food product or ingredient;
a description of the food product or ingredient, including information about:
the process of production, packaging and storage, which must contain a description of each process, allowing for differentiation of the novel production process from the existing process used to produce conventional food products or ingredients; predict the possibility of the manufacturing process changing the chemical, physical and/or biological properties of the product and the basic nutrients, toxicological and microbiological properties of the final product;
the composition, nutritional and energy value, use and preparation of the novel food product or ingredient;
the microbiological and toxicological characteristics of the food product or ingredient;
the allergenic potential of the novel food product or ingredient, confirmed by laboratory research;
the common food product or ingredient, if the novel food product or ingredient was developed on its basis and/or for its replacement;
the registration, circulation, use of the novel food product in other countries, if this novel (for Ukraine) food product or ingredient has a history of safe use in other countries;
the anticipated level of consumption of the novel food product or ingredient;
the possible consequences of use of the novel food product or ingredient in excessive (maximum) quantities, confirmed by research findings;
the possible consequences of the use of the novel food product or ingredient by groups of the population requiring a special dietary intake;
In the event that any other information is available, which may affect the safety assessment and/or is of vital significance for the assessment of a novel food product or ingredient, it must be included with the application.

If the applicant refuses to submit all of the information listed in Section 2 of this Article, he/she must provide a sufficient reason for such a decision.

In the event of incompleteness and/or inaccuracy of the information, the central executive body responsible for the formulation and implementation of national policy in the field of public health, must suspend consideration of the application until it receives the necessary information, and must inform the applicant of the incompleteness and/or inaccuracy of the information within 5 days of the moment of discovery.

3. A novel (for Ukraine) food product or ingredient entered in the register of novel food products or ingredients in other countries, with the exception of the European Union, is subject to accelerated registration, in accordance with Section 4 of this Article.

Subject to accelerated registration are novel food products or ingredients, in respect of which was submitted the request specified in Section 1 Article 7 of this Law, and in respect of which the central executive body responsible for the formulation and implementation of national policy in the field of public health has provided a reasoned reply regarding the necessity of state registration.

4. Accelerated registration of a novel food product takes place by means of consideration of the application and information on the use, registration and circulation of the product in other countries.

The decision on accelerated registration of a novel food product or ingredient shall be made within 90 days of the date of filing of the application.

5. If the central executive body responsible for the formulation and implementation of national policy in the field of public health, the applicant, scientific institution or any other interested party engaged upon the emergence of new or reassessment of existing information, has sufficient grounds to believe that the use of the novel food product or ingredient may pose a threat to public health or the environment, the central executive body responsible for the formulation and implementation of national policy in the field of public health must suspend or prevent the sale of this novel food product or ingredient without delay, in order to examine the new information and take a decision on this issue.

If, as a result of discovery of the new information specified in Section 5, Paragraph 1 of this Article, the central executive body responsible for the formulation and implementation of national policy in the field of public health makes a decision to prohibit the further sale of the novel food product or ingredient, it must delete the novel food or ingredient from the state register, by amending the register and informing the applicant, providing a detailed explanation for its decision.

6. The applicant may appeal the decision of the central executive body responsible for the formulation and implementation of national policy in the field of public health in court.

7. After state registration and entry of the novel food product or ingredient in the state register, any market operator shall be entitled to produce and circulate this food product or ingredient, subject to the provisions of the law on the protection of intellectual property rights.
Article 9. The state register of novel food products and ingredients and its maintenance

1. The state register of novel food products and ingredients (hereinafter - the state register) includes at least all of the novel food products and ingredients recognised by the European Union as safe for human consumption, with the exception of traditional Ukrainian food products. Entry in the state register of novel food products and ingredients recognized by the European Union as safe for human consumption does not depend on the approval or any other action with respect to the creation and/or maintenance of the state register on the part of the central executive body responsible for the formulation and implementation of national policy in the field of public health. The central executive body responsible for the formulation and implementation of national policy in the field of public health shall be entitled to amend the register:

upon its own initiative;
upon a petition from market operators or associations thereof;
upon a petition from the Ukrainian National Commission for the Codex Alimentarius;
in cases set forth in the second paragraph of Article 8 Part 5 of this Law.

2. The central executive body responsible for the formulation and implementation of national policy in the field of public health shall provide unimpeded, free and permanent access to all persons interested in the state register on its own Internet website.

3. The format of the state register must provide the following information on novel food products or ingredients: name, if necessary, conditions of use and the specific labelling conditions specified in Article 10 of this Law.

Article 10. Labelling of novel food products

1. Labelling of novel food products shall be in accordance with the provisions of the Law of Ukraine "On the Safety and Quality of Food Products", as well as with Section 2 of this Article.

2. A novel food product must be labelled in such a way that the consumer may clearly distinguish it from other food products and know:

the properties distinguishing the novel food product or ingredient from existing food products, with the particular properties being composition, nutritional value and means of use;
where appropriate, the properties of the novel food product absent in existing food products and which have an impact on public health or specific categories of the populace;
where appropriate, the proposed means of use.

Article 11. Confidentiality.

1. The central executive body responsible for the formulation and implementation of national policy in the field of public health must ensure the confidentiality of the information provided by the applicant, and constituting a trade secret in the instances set forth in Section 1 Article 7, Parts 2, 3 and 5 of Article 8 of this Law, with the exception of cases provided by law.
The applicant must indicate on the application form which information must be deemed confidential, with the approval of the central executive body responsible for the formulation and implementation of national policy in the field of public health.

2. At the request of the applicant, the information specified in Section 2 Article 8 of this Law, with regard to the results of its own development and research, provided for the completeness of the application, may not be used for the benefit of other applicants over a 5-year period from the date of entry of the novel food product or ingredient in the state register without the permission of the applicant.

Article 12. State control of novel food products

State control of novel foods is within the purview of the central executive body responsible for the formulation and implementation of national policy in the field of public health, in accordance with the Law of Ukraine "On the Safety and Quality of Food Products".

Article 13. Final provisions

1. This law shall come into effect two years from its publication date.

2. To establish that:

1) sale on the market of novel foods or ingredients, the labelling of which meets the requirements of the Law of Ukraine "On the Safety and Quality of Food Products" regarding labelling regulations for food products, on the rules of food labels, shall be carried out before the end of such goods to the operators of the market;

2) foods that are in circulation on legal grounds to the effective date of this Law may be in circulation for two years from the date of the effective date of this law.

3) To bring into compliance with the norms of this Law and other laws and regulations applicable, to the extent that they do not contravene this Law.

4. Law of Ukraine "On the Safety and Quality of Food Products" (Bulletin of the Verkhovna Rada of Ukraine, 2005, • 50, p. 533):

in Article 1, the term "novel food product" shall be revised as below: "novel food product or ingredient - a food product or ingredient without a history of safe use in Ukraine and which meets at least one of the following criteria:

it is produced by applying a process of cultivating animals and/or plants not used in Ukraine;

produced by applying a manufacturing process not previously used in Ukraine for this type of product and/or ingredient and which may lead to significant/substantial changes to the structure of the food products or ingredients and affect their nutritional value, the human metabolism or level of hazardous factors;

Article 37 of the Law of Ukraine to be deleted;

throughout the text of the Law, the words "new food product" can be replaced with the words "novel food product" where appropriate.

5. The central executive body responsible for the formulation and implementation of national policy in the field of public health shall approve within one year of the publication of this Law the form of the state register of novel foods and ingredients.