

# ***THE LAW OF UKRAINE***

## **On Introducing Amendments to Certain Legislative Acts of Ukraine**

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The Supreme Rada of Ukraine ***resolves***:

To introduce amendments to the following Legislative Acts of Ukraine:

1. In the Code of Administrative Offences of Ukraine (*Vidomosti Verkhovnoyi Rady URSR*, 1984, Annex to # 51, p. 1122):

1) Add Article 188<sup>20</sup> reading:

“Article 188<sup>20</sup>. Non-execution of lawful requirements (regulations, rules, orders) of bodies and officials of the State Sanitary-Epidemiological Service and of the State Veterinary Medicine

Non-execution of regulations, rules, or orders of bodies and officials of the State Sanitary-Epidemiological Service and of the State Veterinary Medicine decreeing the destruction of food products, food additives, aromatizers, dietetic additives, and auxiliary products used in processing foodstuffs deemed dangerous for human or animal consumption or other uses, -

Shall entail the confiscation of such objects”;

2) Supplement Part one of Article 221, after ciphers “188<sup>19</sup>”, with ciphers “188<sup>20</sup>”;

3) Supplement Part two of Article 277, after ciphers “185<sup>10</sup>”, with ciphers “188<sup>20</sup>”.

2. Article 18 of the Law of Ukraine ***On External Economic Activity*** (*Vidomosti Verkhovnoyi Rady Ukrayiny*, 1991, # 29, p. 377) shall read:

“Article 18. Procedure for determination and use of technical, pharmacological, sanitary, phytosanitary, veterinary, and ecological standards and requirements

Goods imported into Ukraine must conform with requirements set in accordance with sanitary, veterinary-sanitary, and phytosanitary measures and technical regulations in conformance with Ukrainian law”.

3. In the Law of Ukraine ***On Assuring Sanitary and Epidemiological Safety of Population*** (*Vidomosti Verkhovnoyi Rady Ukrayiny*, 1994, # 27, p. 218; 2002, # 29, p. 190):

1) Supplement Article 1 with the following paragraphs reading:

“State sanitary-epidemiological expert examination of the safety of food products: a professional activity performed by bodies, institutions, and establishments of State Sanitary-Epidemiological Service aimed at preventing, bringing to a minimum, and eliminating possible harmful impact on human health of a food product consisting in assessing the existing risk, defining appropriate sanitary measures and / or technical

regulations in respect of production and / or putting into circulation of food products and in conducting inspection (extended control measures) to verify the conformance with such measures and regulations of the sample of a food product, auxiliary means and materials used in manufacture and circulation of food products as made available by producer or supplier, as well as of new processes and technological equipment;

The conclusion of State sanitary-epidemiological expert examination on safety of food products: a document drawn up to an established form where on the basis of risk analysis results and inspection (extended control measures) results of the performed verification of the sample of a food product, auxiliary means and materials used in manufacture and circulation of food products as made available by producer or supplier, of manufacturing processes and technological equipment used in production thereof, a schedule of sanitary measures and technical regulations is set forth which must be observed by producer and supplier to assure safety of the food product concerned;

Target objects of sanitary measures: food products including those intended for special dietary use; functional food products; and food additives, aromatizers, dietetic additives, and auxiliary products used in processing foodstuffs, auxiliary means and materials used in manufacture and circulation of food products;

Risk: a possibility and probable scale of impact of negative influence of target objects of sanitary measures during a certain period of time;

Risk analysis: a process consisting of three interrelated components: risk assessment, risk management and risk notification;

Risk assessment: a scientifically sound process that includes identification and description of hazard, assessment of impact, and definition of risk;

Risk management: a process of selecting alternative solutions on the basis of risk assessment results and, where necessary, of selecting and introducing appropriate means of management (control) including regulatory measures;

Risk notification: mutual exchange of information on risk between risk assessment experts, persons who perform risk management, interested trade partners, and other interested parties;

Sanitary food product safety measure (hereinafter “sanitary measure”): application of any laws, regulations, requirements, and procedures aimed at protecting human life and health from hazards inherent in consumption of food additives, contaminants, toxic agents or pathogenic organisms in food products that are subject to control by sanitary service, and food products that are subject to control by veterinary service, the observance of which is mandatory. Sanitary measures include, inter alia, the obligatory parameters of end product safety; processing and manufacturing technologies; procedures for expert examination, inspection, certification, and approval; provisions related to appropriate statistical methodologies; procedures for sampling and risk assessment methods; requirements in respect of packing and labeling that directly affect food products safety;

Technical regulation: a legal-normative document approved by a central executive authority on matters of technical regulation and consumer policies which defines product characteristics or related processes and fabrication methods including the relevant administrative provisions that are mandatory. Technical regulation does not

contain food product safety requirements established in accordance with sanitary measures, and it may include or indicate requirements in respect of terminology, designation, packing, marking, or labeling in relation to a product, process or method of fabrication;

Border inspection stations: facilities (objects) located at State Border crossing points including those placed on motor roads, at railway stations, airports, seaports and river ports where the appropriate control (inspection) is performed of imported and exported goods containing target objects of sanitary measures, that are moved across the State Border of Ukraine;

Food product: any substance or product (raw including agricultural raw materials, unprocessed, half-processed or processed) intended for human consumption. Food products include beverages, chewing gum and any other substance, in particular, water deliberately added to a food product during fabrication, preparation or processing;

Food additive: any substance not considered to be a food product or component thereof but added to a food product for technological purposes in the process of fabrication and which becomes, as a result, an integral part of the product (the term does not apply to contaminants, pesticides or substances added to food products to improve their nutritive properties);

Aromatizers: aromatic substances, aromatic compounds, technological aromatizers, smoking aromatizers and blends thereof;

Dietetic additives: vitaminous, vitaminous-mineral or herb additives, individual or blended in the form of pills, tablets, and powders consumed orally with food or added to food within physiological norms for the purpose of additional, as compared to normal diet, intake of such substances; dietetic additives also contain or include various substances or mixtures of substances including proteins, carbohydrates, aminoacids, eatable oils and extracts of vegetable and animal materials that are considered necessary or beneficial for nutrition and general health of humans;

Auxiliary products used in processing foodstuffs: any material except for materials of which food processing machinery and equipment are made, which are not consumed but only used in fabrication or processing of a food product or components thereof for a certain production purpose, resulting in presence of residues or derivative substances in the end product;

Auxiliary means and materials used in manufacture and circulation of food products: materials or substances including machinery and equipment, packing items (containers) that come into contact with food products and thus may affect safety thereof”;

2) In Part two of Article 13 delete the words “food products and food additives”;

3) Part seven of Article 14 shall read:

“List of institutions, organizations, and establishments assigned the authority to perform tests of products to verify the compliance with safety requirements in respect of health and life of population, shall be compiled by the Chief Sanitary Inspector of Ukraine”;

4) Article 17 shall read:

“Article 17. Food product requirements

Requirements in respect of safety and certification of food products, food additives, aromatizers, dietetic additives, and auxiliary products used in processing foodstuffs, as well as auxiliary means and materials used in manufacture and circulation of food products shall be established by the Law of Ukraine ***On Safety and Quality of Food Products***;

5) Complement Part two of Article 29 with words “border inspection stations”;

6) Paragraph “a” in Part one of Article 40 shall read:

“a) approves state sanitary norms, regulations for the use of hazardous factors, maximum permissible concentrations, maximum limits of residues in food products and levels tentatively presumed safe of chemical and biological active agents in objects and artifacts, in water, air, and soil, and establishes norms of radiation safety and admissible levels of impact on humans of other physical factors”;

7) In Part one of Article 42:

Delete words “food products” in paragraphs “b” and “e”;

Add to this Part paragraph “ж” reading:

“ж) ban on production or circulation, as well as withdrawal from circulation of food products, food additives, aromatizers, dietetic additives, auxiliary products used in processing foodstuffs, and auxiliary means and materials used in manufacture and circulation of food products, on grounds and in accordance with the procedure established by Laws of Ukraine on safety and quality of food products and on withdrawal from circulation, reprocessing, recycling, destruction or subsequent use of substandard and hazardous products”.

4. In the Law of Ukraine ***On Pesticides and Agricultural Chemicals*** (*Vidomosti Verkhovnoyi Rady Ukrayiny*, 1995, # 14, p. 91; 2004, # 26, p. 362):

1) In Article 17:

Delete words “and also sale of food products” in paragraph five of Part one;

Add new Part to this Article reading:

“In case of contamination of food products with residue of pesticides and agricultural chemicals in amounts exceeding set limits, the right to impose ban on processing and sales of such food products shall be assigned to specially authorized executive bodies in the field of health protection and agricultural policy according to their competence”;

2) The title of Chapter V shall read:

“ Agricultural Raw Materials Safety Requirements”;

3) Article 18 shall read:

“ Article 18. Agricultural raw materials safety requirements

Agricultural raw materials must conform with sanitary requirements in respect of residue of pesticides and agricultural chemicals.

Decisions on further utilization of agricultural raw materials not in conformance with such requirements shall be taken by bodies of the State Sanitary-Epidemiological Service and of the State Veterinary Medicine according to their competence.

Agricultural raw materials that are not fit for use, shall be subject to withdrawal, recycling, or destruction according to the procedure established by the Cabinet of Ministers of Ukraine”;

4) Delete Article 19.

5. Delete Article 4 of the Law of Ukraine ***On State Regulation of Imports of Agricultural Products*** (Vidomosti Verkhovnoyi Rady Ukrayiny, 1997, # 44, p. 281; 1998, # 10, p. 31; 2005, # 4, p. 91).

6. In the Law of Ukraine ***On Protection of Population from Infectious Diseases*** (Vidomosti Verkhovnoyi Rady Ukrayiny, 2000, # 29, p. 228):

1) In paragraph 24 of Article 1, in Part one of Article 11, in the first sentence of Part four and in the second sentence of Part seven of Article 28 replace the words “food raw materials” with words “agricultural raw materials”;

2) In paragraph four of Article 4 delete the words “hygiene and sanitary, sanitary-epidemiological and veterinary rules and norms” and “over the quality and safety of food products and foodstuffs at all stages of fabrication, storage, and sale”;

3) Paragraph nine of Article 6 shall read:

“shall determine admissible levels of contamination with microorganisms and other biological agents causing infectious diseases in food products, water, soil, and other objects of human habitation environment”;

4) Part one of Article 18 shall read:

“Rights and duties of enterprises, institutions, and organizations, irrespective of the form of ownership, in the field of protection of population from infectious diseases shall include the prevention of contamination of food products, potable water, open water bodies and soil with causative agents of infectious diseases; the maintenance of the required sanitary state of the territory of localities, population rest places, recreation areas etc.”;

5) In Article 28:

Delete words “or put in jeopardy human life and health” in the first sentence of Part four;

Delete words “or poisoning” in paragraph four of Part six;

6) Delete paragraph five in Article 30.