

Draft

On Amendment of the Law of Ukraine

«On Providing Sanitary and Epidemic Safety of the Population»

The Supreme Rada of Ukraine hereby decrees:

- I. to introduce the following amendments to the Law of Ukraine ‘On Providing Sanitary and Epidemic Safety of the Population’ (the Bulletin of the Supreme Rada, 1994, No.27, Art. 218; 1997, No.6 Art. 49; 1997, No.31, Art. 199; 1998 No10, Art. 36; 1999; No.34, Art. 274; 2000, No.5, Art. 34):

1. to present Article 1 in the following wording:

In this Law terms shall be used in the following meanings:

- sanitary and epidemic safety of the population encompass conditions of health of the population and conditions of the environment that ensure parameters of diseases to stay within the levels set for a given territory and a given contingent of population, provision of conditions favorable to functioning and keeping impact of harmful contributors on the environment within the limits stipulated in the sanitary legislation;
- human environment (hereafter referred as ‘environment’) is a combination of factors and events of the (both natural and man made) environment that determines conditions of living, nutrition, labor, recreation, training, etc.;
- factors of human environment – biological (viral, bacterial, parasitical, genetically modified materials, products of biotechnologies, etc), chemical (organic and non-organic, natural and synthetic), physical (noise, vibration, ultrasonic, infrasonic, thermal, ionizing, non-ionizing and other irradiation), social (nutrition, water supply, living conditions, working conditions, training, recreation, etc.) and other factors of human environment that have or may have impact on human health and/or conditions of health for future generations;
- harmful impact on human health – impact of factors of human environment that may endanger life, health and functioning of the population or may endanger life or health of future generations;
- safe conditions for the population – the conditions of human environment that exclude dangerous impact of its factors on the population;
- favorable conditions of functioning of the population – the conditions of the environment that exclude any harmful impact of its factors on human health (non-harmful factors) and that enable regeneration of damaged functions of the human body;
- sanitary and epidemic situation – condition of human environment characteristic for certain territory and certain time and its influence on the health of population;
- state sanitary and epidemic requirements including state hygienic requirements, epidemiological parameters, anti-epidemic requirements - maximum or minimum permissible quantitative and/or qualitative parameters set by experiments that characterize this or that factor of human environment on the basis of medical criteria (parameters) of its safety for the population and future generations and for the conditions of health of the population and

impact on its health in regard of incidence and propagation of diseases, physical development, immune system, etc.;

- state hygienic and anti-epidemic rules and norms (hereafter referred as 'sanitary norms') – mandatory legislative acts that stipulate medical requirements in regard of safety of human environment (medical criteria of safety of environmental factors, their parameters and maximum permissible levels) including sanitary (sanitary and epidemiological) rules and norms; anti-epidemic rules and norms; sanitary and epidemiological norms that ensure protection of life and health of the population and future generations and prevent occurrence and propagation of diseases among the population;
- state enforcement of sanitary and epidemiological norms – activities of the central body of the executive branch of power in charge of health protection that is authorized to conduct sanitary and epidemiological control and also of enterprises, institutions and organizations (hereafter referred as 'bodies') of the sanitary and epidemiological service of Ukraine involved in drafting, introduction, implementation and enforcement of the adopted sanitary norms;
- health and life safety requirements – the requirements developed on the basis of organizational, administrative, engineering, technical, medical, ecological, veterinary and other methodological criteria and parameters with the view to protect health and life of the population. The present Law considers health and life safety requirements (medical requirements) as those developed on the basis of medical science and represented through medical criteria, parameters, etc.;
- dangerous factor - any chemical, physical, biological component, substance, material or product which effects or under certain conditions can have negative influence on the health of people;
- sanitary and anti-epidemic (prophylactic) measures (hereafter referred as 'sanitary measures') – a set of organizational, administrative, engineering, technical, medical, ecological, veterinary and other measures directed at elimination or diminishing of harmful influence of the factors of human environment on the population, at prevention of occurrence and propagation of infectious diseases and mass non-infectious diseases including intoxication and at their liquidation;
- state sanitary and epidemiological expertise – activities of the bodies and institutions of the state sanitary and epidemiological service directed at insurance of adherence to sanitary norms. For instances when these norms are absent, the expertise shall determine potential harmful impact on human health and give substantiation of medical criteria of safety, their parameters and maximum permissible levels, content, concentration, etc. for the items under expertise;
- conclusion of the state sanitary and epidemiological expertise – a standard document that contains description of the item of examination, a conclusion (positive or negative) on compliance of the item to the requirements of sanitary regulations (sanitary norms). These requirements (safety criteria, parameters, maximum permissible levels, etc.) to the item under examination should be transparent and mandatory to the customer –owner of the item under examination;
- subjects of the state sanitary and epidemiological expertise – any activity, technology, production, raw material, regulation, design, technical, methodological documentation, etc. that may directly or indirectly affect human health and are connected with necessity to adhere to the requirement of sanitary regulations;

- mass non-infectious diseases including intoxication – diseases induced by physical and/or chemical and/or social factors of human environment;

2. to present Article 2 in the following wording:

“Article 2. Ukrainian Legislation on Provision of Sanitary and Epidemiological Safety of the population

Ukrainian legislation on provision of sanitary and epidemiological safety of the population (sanitary legislation) is based on the Constitution of Ukraine, on main legislative acts of Ukraine that govern health protection and it consists of the present law, other legislative acts, decrees of the Cabinet of Ministers of Ukraine, the central executive body in the field of health protection and sanitary norms”.

3. In the paragraph of the first part of the Article 6 the word ‘state’ should be excluded after the words ‘to receive from the bodies’ and the words ‘and regional’ should be excluded after the word ‘local’

4. Article 7:

- in the fourth paragraph of the first part the word ‘hygienic’ should be substituted for the word ‘epidemiological’;
- in the seventh paragraph of the first part the word ‘institutions’ should be excluded;
- in the second part the words ‘sanitary and epidemiological’ should be followed by the word ‘(prophylactic)’

5. In Article 8 after the words ‘officials of the state executive power’ the words ‘state’ and ‘and regional’ should be omitted and the words ‘can be appealed’ should be followed by the words ‘pursuant to standing legislation’ and the words ‘within one month period to the respective main state sanitary doctor or in court’ should be excluded.

6. The title of Part III should start with ‘State regulation and...’

7. Article 10:

- in the first part the word ‘hygienic’ should be substituted by the word ‘epidemiological’
- in the second part the word ‘hygienic’ should be substituted by the word ‘epidemiological’

8. In Article 11:

- in the title of the Article the word ‘hygienic’ should be substituted by the word ‘epidemiological’;
- in the first part the word ‘hygienic’ should be substituted by the word ‘epidemiological’;

9. In Article 12:

- in the title of the Article the word ‘hygienic’ should be substituted by the word ‘epidemiological’;

- in the first part the word 'hygienic' should be substituted by the word 'epidemiological and the words 'examination divisions' should be substituted by the word 'bodies';
- in the second, third, fourth, fifth and sixth parts the word 'hygienic' should be substituted by the word 'epidemiological.

10. In Article 14:

- in the second part the word 'hygienic' should be substituted by the word 'epidemiological;
- in the fourth part the word 'organs' should be excluded;
- in the sixth part the words 'agencies, organizations and' should be excluded.

11. In Article 16:

- in the first part the words 'substantiating that such products are not dangerous to health of the population of Ukraine' should be substituted by the words 'the owner of the products or agent authorized by him should provide a positive conclusion of the sanitary and epidemiological expertise for these products';
- parts two and three to be excluded;
- the first part should be followed by the second part with the following wording: 'Liabilities to fulfil requirements of the sanitary legislation that governs import of products to Ukraine, guarantees to adhere to the sanitary norms and/or requirements of the state sanitary and epidemiological expertise should be obligatory included into agreements (contracts) for shipment of every batch of these products.'

12. In Article 17:

- in the third part the word 'hygienic' should be substituted by the word 'epidemiological.

13. In Articles 18 and 20:

- in the first parts of the articles the words 'state' and 'and regional' should be excluded;
- in the second part of Article 20 the word 'agencies' should be substituted by the word 'institutions'

14. In part four of Article 21 - the words 'state' and 'and regional' should be excluded.

15. In Article 22:

- in the first part the words 'state' and 'and regional' should be excluded;
- in the third part the words 'state' and 'and regional' should be excluded.

16. In Article 24:

in the first part the words 'state' and 'and regional' should be excluded.

17. Article 25:

in the first part the words 'state' and 'and regional' should be excluded.

18. In the third part of Article 28 – the words 'Ministry of Healthcare' should be substituted by the words 'using procedures stipulated in the standing legislation'.

19. Article 30 should be attached with the first and the sixth parts with the following wording:

- 'The State Extraordinary Anti-Epidemic Commission shall be set up under the Cabinet of Ministers of Ukraine in order to conduct current control, management and co-ordination of the activities of enterprises, institutions, organizations and citizens directed at prevention and liquidation of mass diseases or intoxication of the population.
- The State Extraordinary Anti-Epidemic Commission under the Cabinet of Ministers of Ukraine shall be headed by the Vice-Prime Minister of Ukraine.
- The composition of the State Extraordinary Anti-Epidemic Commission under the Cabinet of Ministers of Ukraine shall be approved by the Cabinet of Ministers of Ukraine.
- The Chief Sanitary Doctor of Ukraine and his deputies are included into the State Extraordinary Anti-Epidemic Commission under the Cabinet of Ministers of Ukraine as a deputy chairman and members of the Commission.
- The State Extraordinary Anti-Epidemic Commissions under the Cabinet of Ministers of Ukraine shall be set up in the Autonomous republic of Crimea and in oblasts, cities and rayons.
- Provisions of the State Extraordinary Anti-Epidemic Commissions under the Cabinet of Ministers of Ukraine shall be adopted by the Cabinet of Ministers of Ukraine'.
- Due to introduction of this amendment Parts 1, 2 and 3 shall be Parts 7, 8, and 9.
- in Parts 7 and 8 the words 'state' and 'and regional' should be excluded.

20. In the title of Section IV the words 'The State Sanitary and Epidemiological Service' should be followed by the word 'of Ukraine'.

21. In Article 31:

- in the title of Article 31 the words 'The State Sanitary and Epidemiological Service' should be followed by the word 'of Ukraine'
- part 1 should be substituted by the following wording:

'The State Sanitary and Epidemiological Service of Ukraine consists of:

- a central executive body in charge of healthcare;
- divisions of the sanitary and epidemiological control of the Ministry of Healthcare of Ukraine;
- relevant agencies and divisions of the Ministry of Defense of Ukraine, the Ministry of Interior of Ukraine, the State Committee of Ukraine for Border Protection, the State Penitentiary Department of Ukraine, the State Treatment and Recreation department, the state Security Service of Ukraine;
- scientific institutions of the State Sanitary and Epidemiological Service of Ukraine';
- the first part should be attached with the second part with the following wording:

'The chief sanitary doctors, their deputies and the officers of the State Sanitary and Epidemiological Service of Ukraine authorized to conduct the State Sanitary and Epidemiological Supervision are the officers of the State Sanitary and Epidemiological Service of Ukraine';

- in the second part the word 'state' should be excluded after the words 'central executive body';

- in Parts 3 and 5 the words 'Institutions and' should be excluded;
- in Part 4 the word 'institutions' should be excluded
- Part 5 should be attached with Part 7 of the following wording:

'Institutions and bodies of the State Sanitary and Epidemiological Service of Ukraine have independent balance sheets, bank accounts, forms, letterheads and stamps'.

- in Part 6 the words 'institutions and' should be excluded and the words 'Provisions of the State Sanitary and Epidemiological Supervision of Ukraine' should be attached with the words 'Provisions of the State Sanitary and Epidemiological Service of Ukraine'
- due to the above Parts 2, 3, 4, 5, 6 should be shifted to be Parts 3, 4, 5, 6 and 8.

22. In Article 32:

- Part 2 should be attached by part 3 of the following wording:

'The Chief Sanitary Doctor of Ukraine has one first deputy and four deputies. The first deputy and the deputies of the Chief sanitary Doctor of Ukraine are nominated to and dismissed from their offices by the Cabinet of Ministers of Ukraine on the request of the Chief Sanitary Doctor of Ukraine. The Chief Sanitary Doctor of Ukraine and his deputies have their forms and stamps';

- Part 5 should be followed by Part 7 with the following wording:

'Deputy Chief Sanitary Doctors of the Autonomous Republic of Crimea, oblasts, cities of Kiev and Sebastopol, of certain means of transportation are nominated to and dismissed from their offices by the Chief sanitary Doctor of Ukraine';

- In Part 6 the words 'rayon departments' should be followed by the words 'in agreement with the Chief State Sanitary Doctor of Ukraine';
- In Part 7 the words 'means of transportation should be followed by the words 'in agreement with the Chief State Sanitary Doctor of Ukraine';
- Part 8 should be attached by Part 11 with the following wording:

'Chief State Sanitary Doctors of the Autonomous Republic of Crimea, of the Central Sanitary and Epidemiological Station of the Ministry of Healthcare of Ukraine, of oblasts, of cities of Kiev and Sebastopol, of corresponding means of transportation, of rayons, municipalities are contracted according to Procedures adopted by the Cabinet of Ministers of Ukraine'.

- In Parts 9 and 10 the words 'the National Guard of Ukraine' should be excluded after the words 'the state committee for National Border Control' which should be attached with the words 'The State Penitentiary Department of Ukraine, the State Treatment and Recreation Department';
- Part 11 should be attached with Part 15 of the following wording:

'The Chief State Sanitary Doctors have forms and stamps and they are in charge of corresponding bodies of the State Sanitary and Epidemiological Service of Ukraine';

- Part 12 should be followed by part 17 of the following wording:

'The Board of the State Sanitary and Epidemiological Service of Ukraine shall be set up to solve pressing issues of provision of sanitary and epidemiological protection of the population of Ukraine and to manage activities of State Sanitary and Epidemiological Service of Ukraine. The Board shall be headed by the Chief State Sanitary Doctor of Ukraine. The Provisions of the State Sanitary and Epidemiological Service of Ukraine and staff requirements shall be adopted by the cabinet of Ministers of Ukraine. The Boards of the State Sanitary and Epidemiological Service of the Autonomous Republic of

Crimea, of oblasts, cities of Kiev and Sebastopol of air and railway transportation shall also be set up. The Boards shall be headed by corresponding Chief State Sanitary Doctors. Provisions and staff requirements of these Boards are adopted by the Chief State sanitary doctor of Ukraine. At the meetings of the Boards of the State Sanitary and Epidemiological Service of Ukraine reports and explanations concerning enforcement of requirements of the sanitary legislation delivered by the senior officials from the ministries and other central bodies of executive power, by other public agencies, supervisory bodies, enterprises, institutions and organizations their associations and other official representatives.

- in view of above amendments Parts, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 are shifted to be Parts 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, correspondingly.

23. In Article 33:

- in paragraph 8 the word 'hygienic' should be substituted for the word 'epidemiological'.

24. In Article 34:

- In Parts 1 and 2 words 'institutions' should be excluded.

25. In Article 35:

- in the title the words 'financial support' should be followed by the words 'and assets';
- in Part 1 the word 'institutions' should be excluded, the words 'budget of the Ministry of Health Protection of Ukraine, budgets of the Crimean Autonomous Republic, oblasts' budgets and budgets of cities of Kyiv and Sevastopol as well as from non-budgetary (*off budget*) funds' should be substituted by the words 'funds from the national budget of Ukraine and other sources stipulated in the legislation.';
- Part 1 should be attached with Part 2 with the following wording:
'Bodies of the State Sanitary and Epidemiological Service may receive off-budget funds as donations and proceeds from contracted services.';
- in Part 2 the words 'the National Guard of Ukraine' should be excluded after the words 'the state committee for National Border Control' which should be attached with the words 'The State Penitentiary Department of Ukraine, the State Treatment and Recreation Department'
- Part 2 should be attached by Part 4 with the following wording:
'Premises, buildings, equipment, means of transportation and other assets used by bodies and departments of the State Sanitary and Epidemiological Service of Ukraine that conduct the State Sanitary and Epidemiological Supervision are held in public property and are transferred in full possession of the said agencies according to procedures stipulated in Ukrainian legislation. Plots of land under buildings of the State Sanitary and Epidemiological Service of Ukraine are transferred to the said agencies according to procedures stipulated in Ukrainian legislation.';
- Part 3 should be excluded;
- due to the above amendments Part 2 is shifted to be Part 3.

26. In Article 36:

- Part1 should be presented in the following wording:

‘Training of officers for the State Sanitary and Epidemiological Service of Ukraine is conducted by medical educational institutions according to corresponding levels of accreditation. Training requirements are defined by the Ministry of Healthcare of Ukraine.’;

- in Part 2 the words ‘sanitary and hygienic’ should be substituted by the words ‘scientific’.

27. In Article 37:

- In Parts 1 and 3 the words ‘executive power’ should be preceded by the word ‘state’;
- In Part 2 and 3 the word ‘institutions’ should be excluded;
- In Part 3 the words ‘and regional’ should be excluded.

28. In Article 38:

- in Part 8 the words ‘the National Guard of Ukraine’ should be excluded after the words ‘the state committee for National Border Control’ which should be attached with the words ‘The State Penitentiary Department of Ukraine, the State Treatment and Recreation Department’

29. In Article 39:

- to exclude the word ‘institutions’ in Part 1;
- in Part 2, paragraph 2 the words ‘state’ and ‘and regional’ should be excluded;
- in Part 2, paragraph 5 the word ‘hygienic’ should be substituted for the words ‘epidemiological’;
- in Part 3 the words ‘bodies institutions and’ should be excluded.

30. In Article 40:

- in Part 1, b after the words ‘activities of bodies’ and ‘local’ the words ‘state’ and ‘and regional’ should be excluded correspondingly;
- in Part 1, p the words ‘organizations and establishments’ should be excluded;
- Part 1, q should be excluded.
-

31. In Article 41:

- in Part 1, a the words ‘state’ and ‘and regional’ should be excluded;
- in Part 1 f, k the word ‘hygienic’ should be substituted for the words ‘epidemiological’;
- in Parts 2 and 5 the words ‘the National Guard of Ukraine’ should be excluded after the words ‘the state committee for National Border Control’ which should be attached with the words ‘The State Penitentiary Department of Ukraine, the State Treatment and Recreation Department’;
- in Part 3 the words ‘bodies, institutions and’ should be excluded;
- in Part 4 the words ‘institutions’ and ‘divisions’ should be excluded.

32. In Article 42:

- in Part 1, b the word ‘hygienic’ should be substituted for the word ‘epidemiological’;
- in Parts 2 and 3 the words ‘bodies, institutions and’ should be excluded

33. In Article 43:

- in Part 1, b the words 'the National Guard of Ukraine' should be excluded after the words 'the state committee for National Border Control' which should be attached with the words 'The State Penitentiary Department of Ukraine, the State Treatment and Recreation Department'.

34. In Article 47:

- in Part 2, 1 and 9 the words 'the National Guard of Ukraine' should be excluded after the words 'the state committee for National Border Control' which should be attached with the words 'The State Penitentiary Department of Ukraine, the State Treatment and Recreation Department';
- Part 7 should be changed for the following wording:
'Set off of the fines is conducted according to the standing legislation.'

II. Final Provisions

The present Law comes into effect after the day it published.

Until the Ukrainian legislation is harmonized with the present law the standing regulations shall be enforced when they do not contradict the present Law.

Within 6 months after this law comes into effect the Cabinet of Ministers of Ukraine is obligated to:

- submit proposals to the Supreme Rada concerning harmonization of the Ukrainian legislation with the present Law;
- harmonize regulations adopted by the Cabinet of Ministers with the present Law;
- to provide adoption of regulations necessary for enforcement of the present Law;
- to ensure revision and annulment of the regulations that are in contradiction with the present Law.