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Ihor Chernychenko
Doctor of Medical Sciences, Professor
SI "Marzieiev Institute for Public Health of the National Academy of Medical Sciences of Ukraine"
02094, 50 Hetman Pavlo Polubotok Str., Kyiv, Ukraine
https://orcid.org/0000-0002-4784-4628

Olha Lytvychenko
Doctor of Biological Sciences
SI "Marzieiev Institute for Public Health of the National Academy of Medical Sciences of Ukraine"
02094, 50 Hetman Pavlo Polubotok Str., Kyiv, Ukraine
https://orcid.org/0000-0003-2039-3318

Diana Hlavachek*
Master's Degree, Research Fellow
SI "Marzieiev Institute for Public Health of the National Academy of Medical Sciences of Ukraine"
02094, 50 Hetman Pavlo Polubotok Str., Kyiv, Ukraine
https://orcid.org/0000-0002-0512-6927

Serhii Harkavyi
Doctor of Medical Sciences, Professor
Bogomolets National Medical University
01601, 13 T. Shevchenko Blvd., Kyiv, Ukraine
https://orcid.org/0000-0001-7344-1980

Vitalii Babii
Doctor of Medical Sciences, Professor
SI "Marzieiev Institute for Public Health of the National Academy of Medical Sciences of Ukraine"
02094, 50 Hetman Pavlo Polubotok Str., Kyiv, Ukraine
https://orcid.org/0000-0003-2519-1440

Olena Kondratenko
PhD in Biological Sciences
SI "Marzieiev Institute for Public Health of the National Academy of Medical Sciences of Ukraine"
02094, 50 Hetman Pavlo Polubotok Str., Kyiv, Ukraine
https://orcid.org/0000-0002-9504-7228

Substantiation of medical and sanitary standards for permissible levels of carcinogenic substances in ambient air in populated areas, taking into account the experience of EU countries

Abstract

Relevance. Ukraine's integration into the European Union requires the harmonisation of national legislation with European standards. One of the priority areas is the improvement of the system of medical and sanitary standards for hazardous substances in ambient air. Unlike the EU Member States and the United States, where the regulation of carcinogens is based on a risk-oriented approach that allows for an acceptable level of risk and the periodic revision of limits, the maximum permissible concentrations (MPCs) of carcinogens in Ukraine have traditionally been established on the basis of toxicological experiments without mandatory subsequent review.

Aim. To analyse the compliance of the current Ukrainian medical and sanitary (hygienic) standards for carcinogenic substances in the ambient air of populated areas with international standards.

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*Corresponding author (*glavachek@gmail.com*)

Materials and methods. The Ukrainian regulatory framework governing carcinogenic substances in ambient air, EU legislation and directives, US standards, and the recommendations of the International Agency for Research on Cancer were examined.
Results. A comparative assessment of the current Ukrainian standards for carcinogenic substances was carried out to determine their compliance with internationally accepted carcinogenic risk levels (1×10^{-4}) and reference concentrations. Hygienic standards for 45 substances with established carcinogenic potential were analysed. It was found that the current standards for 34 substances do not comply with international requirements. An improved system of standards is proposed, incorporating annual average concentrations for the assessment of chronic exposure and daily average concentrations for the assessment of acute exposure.
Conclusions. The need to harmonise the Ukrainian system of medical and sanitary regulation of carcinogens with international standards has been demonstrated. The introduction of a risk-oriented approach based on an acceptable risk level (1×10^{-4}), the differentiation of standards according to averaging periods (annual average and daily average concentrations), and the regular revision of the regulatory framework in accordance with current toxicological and epidemiological evidence are scientifically substantiated.
Keywords: acceptable risk; system of permissible level indicators; daily average and annual average concentrations; prevention of adverse effects on human health and the environment.

INTRODUCTION

As Ukraine continues its process of state-building, it has chosen the path of European integration and, in doing so, has undertaken to align its legislation with the laws, standards, and practices of the European Union. Despite the considerable resources devoted to countering Russian aggression, the development of preventive medicine continues, with one of its key priorities being the improvement of the Ukrainian system of medical and sanitary standards governing permissible levels of hazardous substances in ambient air and their effects on the environment, in accordance with international best practice [1-3]. An important contribution to the harmonisation of Ukrainian sanitary legislation with European legislation was made by Law of Ukraine No. 2573-IX [4]. Further progress in this area has been facilitated by the introduction of the risk-based approach into sanitary and hygienic practice [5-6]. In particular, I.O. Chernychenko *et al.* [7-8], in previous studies, analysed the compliance of hygienic standards for carcinogenic substances with international standards and identified differences in the criteria and principles underlying hygienic standard-setting in Ukraine compared with those applied in the EU and the United States.

In the United States and EU countries, including France, the United Kingdom, and Germany, the strategy for preventing the adverse effects of carcinogens on human health and the environment follows a stepwise approach. When a hazardous substance is detected in industrial emissions and poses a potential risk of environmental contamination, the primary objective is to eliminate the substance from the production process or replace it with a less hazardous alternative. Only where such measures are not feasible is the issue of establishing hygienic standards for the substance considered, followed by the periodic review and revision of its maximum permissible concentration (MPC) in the light of newly available scientific evidence. In Ukraine, by contrast, once a compound is identified in the air environment, the immediate focus is on establishing a regulatory standard, without any mandatory requirement for the subsequent review of the approved value. Furthermore, the criteria used to establish maximum permissible concentrations of chemical substances differ substantially. In the EU and the United States, separate exposure limits are established for carcinogens and, where appropriate, mutagens [9-11], based on an acceptable level of risk associated with exposure to the hazardous substance. These health-based limits are derived as threshold exposure concentrations. Internationally, the recommended exposure limit for carcinogens in the ambient air of populated areas has traditionally been based on an acceptable lifetime excess cancer risk of one additional case per 10,000 exposed individuals (1×10^{-4}).

In addition to carcinogenic risk assessment, EU countries also apply the concept of a reference concentration (RfC), which is broadly comparable to the Ukrainian daily average concentration but specifically addresses adverse non-carcinogenic effects on human health. In Ukraine, however, the derivation of MPCs for carcinogenic compounds is based primarily on data from acute and subacute laboratory toxicological studies used to establish dose-response relationships for toxic effects, supplemented, where possible, by published evidence concerning other biological effects, including mutagenicity. It is assumed that lifelong exposure to carcinogens at concentrations equal to the MPC should not result in any adverse effects on either human health or the health of future generations. Once established, these MPC values are, in practice, rarely subject to revision. Given these methodological differences in the derivation of permissible concentrations for carcinogenic substances, the aim of the present study was to evaluate the extent to which the current Ukrainian hygienic standards for carcinogenic substances in ambient air are consistent with their international counterparts.

MATERIALS AND METHODS

A systematic analysis was conducted of the regulatory framework governing carcinogenic substances in the ambient air of populated areas in Ukraine and its compliance with the requirements adopted in the European Union and the United States. Analytical and bibliometric methods were employed to evaluate current methodological approaches to the establishment of hazard assessment criteria for carcinogenic substances, as well as published international evidence concerning the averaging periods applied to carcinogen concentrations for the prevention of both acute and chronic health effects. To address these issues, the databases of the US EPA Integrated Risk Information System (IRIS) [12], the World Health Organization (WHO) [13-14], and the classification database of the International Agency for Research on Cancer (IARC) [15] were analysed with respect to exposure levels and their associated health hazards. The analysis included chemical substances classified by IARC as carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2A), and possibly carcinogenic to humans (Group 2B).

Carcinogenic substances included in the analysis were selected on the basis of the Ukrainian hygienic regulations [6]. From the complete list, 45 substances with established carcinogenic properties were identified for evaluation. The specific carcinogenic hazard associated with these substances in the ambient air of populated areas was assessed using the methodological recommendations "Assessment of Carcinogenic and Non-Carcinogenic Health Risks from Chemical Air Pollution", approved by Order of the Ministry of Health of Ukraine No. 1811 [5]. Risk estimates were calculated across the range from 1×10^{-2} to 1×10^{-2}. The exposure dose was determined using the following equation:

$$LADD_{a.a.} = C \times CR \times EF \times ED / BW \times AT \times 365, \quad (1)$$

where $LADD_{a.a}$ – intake (or lifetime average daily dose), mg/(kg × day); C – concentration of the compound in polluted ambient air, mg/m^3; CR– inhalation rate, m^3/d (20 m^3/d); EF – exposure frequency, days per year; ED – exposure duration, years (70 years for carcinogens); BW – body weight, kg (70 kg); AT – averaging time, years (70 years for carcinogens); 365 – number of days per year.

After applying the relevant abbreviations, the formula takes the form:

$$LADD_{a.a.} = 0.286 \times C. \quad (2)$$

The individual carcinogenic risk from exposure to a compound in ambient air in populated areas ($ICR_{a.a.}$) was calculated on the basis of the lifetime average daily dose of the carcinogen $LADD_{a.a.}$ and the carcinogenic potential factor SF_i [10]:

$$ICR_{a.a} = LADD_{a.a.} \times SF_i, = 0.286 \times C_. \times SF_i. \quad (3)$$

The data obtained on the maximum permissible concentrations of carcinogenic substances for risk conditions ranging from 1×10^{-2} to 1×10^{-6} were compared with similar figures for EU countries and the USA, on the basis of which an acceptable risk for Ukrainian conditions for the study period (early 2026) was determined at a level of 1×10^{-4}, and the maximum permissible concentrations calculated at this level were proposed for approval and subsequent use in Ukraine [12].

RESULTS AND DISCUSSION

The integration of Ukrainian approaches to the regulation of carcinogenic substances in the ambient air of populated areas with international experience in establishing environmental quality standards made it possible to identify the key components of a hygienic standard-setting system consistent with the fundamental principles of Law of Ukraine No. 2573-IX [4]. The main provisions of the Law are aimed at regulating public health and ensuring the sanitary and epidemiological well-being of the population. A cornerstone of this framework is the establishment of state medical and sanitary standards, compliance with which should ensure the protection of public health through appropriate scientific research and risk assessment in accordance with requirements for the protection of human life and health. To implement this approach in practice, the principal elements of the hygienic standard-setting system were examined, including the acceptable level of risk, the maximum permissible concentrations corresponding to that risk level, and the appropriate averaging periods for pollutant concentrations.

Acceptable risk is defined as the level of risk considered tolerable in view of the medical, environmental, social, and economic consequences that society is prepared to accept in exchange for the benefits derived from a particular activity. In preventive medicine, the US Environmental Protection Agency (US EPA) has, until recently, recommended an acceptable lifetime excess cancer risk in the range of 1×10^{-4} to 1×10^{-6} for the regulation of carcinogenic substances [12-13]. Depending on their economic, technological, and social circumstances, individual countries establish by legislation the level of acceptable risk deemed appropriate for their populations. In Ukraine, however, no official acceptable risk level has yet been established within the field of preventive medicine. Consequently, the authors relied on international practice and adopted the upper limit of the internationally accepted risk range, namely 1×10^{-4}, as the benchmark for the present study. A comparative assessment was therefore undertaken to evaluate the compliance of the current Ukrainian medical and sanitary (hygienic) standards for carcinogenic substances with international standards, based on the acceptable carcinogenic risk level of 1×10^{-4} and the reference concentrations (RfCs) applied in the European Union and the United States. Medical and sanitary standards, including MPCs and RfCs, were determined for 45 carcinogenic substances for which carcinogenic potency data are available (Table 1).

Table 1. Hazard assessment of carcinogenic substance concentrations in ambient air in populated areas at the maximum permissible concentration (MPC) level based on risk criteria and reference concentrations

Substance	MPC		RfC	
	mg/m^3	Risk	mg/m^3	Risk
1	2	3	4	5
Benzo/a/pyrene	0.000001	1.1×10^{-6}	0.000001	1.1×10^{-6}
Benzene	0.1	7.7×10^{-4}	0.03	2.3×10^{-4}
Beryllium	–		0.00002	4.8×10^{-5}
1,3-Butadiene	1.0	3.0×10^{-2}	0.002	6.0×10^{-5}
1,2-Dichloropropane	0.18	1.9×10^{-3}	0.004	4.1×10^{-5}
Ethylene oxide	0.03	3.0×10^{-3}	0.005	5.0×10^{-4}
Cadmium	0.0003	5.4×10^{-4}	0.00002	3.6×10^{-5}
Arsenic	0.003	1.3×10^{-2}	0.00003	1.3×10^{-4}
Nickel	0.001	2.4×10^{-4}	0.00005	1.2×10^{-5}
Carbon black	0.05	2.2×10^{-4}	0.05	2.2×10^{-4}
Trichloroethylene	1.0	1.8×10^{-3}	0.04	7.2×10^{-5}
Formaldehyde	0.003	3.9×10^{-5}	0.003	3.9×10^{-5}
Hexavalent chromium (Chromium VI)	0.0015	1.8×10^{-2}	0.0001	1.2×10^{-3}
Aniline	0.03	4.9×10^{-5}	0.001	1.6×10^{-6}
Dibenz/a,h/anthracene	5.0×10^{-6}	4.4×10^{-6}		
Dichloromethane	8.8	4.0×10^{-3}	0.4	1.8×10^{-4}
Epichlorohydrin	0.2	2.4×10^{-4}	0.001	1.2×10^{-6}
2-Mercaptobenzothiazole	0.12	9.9×10^{-4}	0.35	2.9×10^{-3}
N-Nitrosodiethylamine	15×10^{-6}	6.4×10^{-4}		
N-Nitrosodimethylamine	50×10^{-6}	7.0×10^{-4}		
Styrene	0.002	1.1×10^{-6}	1.0	5.7×10^{-4}
Tetrachloroethylene	0.06	3.4×10^{-5}	0.035	2.0×10^{-5}
1,2,3-Trichloropropane	0.05	1.1×10^{-1}	0.021	4.2×10^{-2}
Aziridine (Ethyleneimine)	0.001	1.9×10^{-2}	0.006	1.1×10^{-1}
Acrylonitrile	0.03	2.1×10^{-3}	0.002	1.4×10^{-4}
Acetaldehyde	0.01	2.2×10^{-5}	0.009	2.0×10^{-5}
Petrol (gasoline)	1.5	1.5×10^{-2}	0.071	7.1×10^{-4}
Hexachloroethane	0.05	2.0×10^{-4}	0.08	3.2×10^{-4}
1,2-Dichloroethane	1.0	2.6×10^{-2}	0.4	1.0×10^{-2}
1,3-Dichloropropene	0.01	1.1×10^{-5}	0.02	2.2×10^{-5}
Ethylbenzene	0.02	2.2×10^{-5}	1.0	1.1×10^{-3}
Cobalt and its compounds	0.001	2.8×10^{-3}	0.00002	5.6×10^{-5}
Naphthalene	0.003	1.0×10^{-4}	0.003	1.0×10^{-4}
Nitrobenzene	0.008	3.2×10^{-4}	0.03	3.6×10^{-4}
2-Chloronitrobenzene (ortho-chloronitrobenzene)	0.004	2.9×10^{-5}	0.001	7.2×10^{-6}
3-Chloronitrobenzene (meta-chloronitrobenzene)	0.004	2.1×10^{-5}	0.001	5.1×10^{-6}
4-Chloronitrobenzene (para-chloronitrobenzene)	0.004	2.1×10^{-5}	0.001	5.1×10^{-6}
Propylene oxide	0.08	3.0×10^{-4}	0.03	1.1×10^{-4}
Lead	0.0003	3.6×10^{-6}	0.0005	6.0×10^{-6}
Antimony trioxide	0.02	2.3×10^{-6}	0.0002	2.3×10^{-8}
Tetrahydrofuran	0.2	3.9×10^{-4}	0.3	5.8×10^{-4}
1,1,2,2-Tetrachloroethane	0.06	3.4×10^{-3}	0.2	1.1×10^{-2}
Carbon tetrachloride	0.7	1.1×10^{-2}	0.04	6.1×10^{-4}
p-Chloroaniline	0.01	1.8×10^{-4}	0.014	2.6×10^{-4}
Chloroprene	0.002	6.3×10^{-4}	0.02	6.3×10^{-3}

Source: compiled by the authors based on [5-6]

The data presented in Table 1 clearly demonstrate that the current hygienic standards for 45 carcinogenic substances in the ambient air of populated areas, in the overwhelming majority of cases, do not provide an adequate level of public health protection. They are associated with estimated lifetime cancer risks ranging from approximately 8 cases per 10,000 people (7.7×10^{-4}) to 2 cases per 100 people (1.8×10^{-2}), and even as high as 1 case per 10 people (1.1×10^{-1}), as calculated for the MPCs of benzene, hexavalent chromium (chromium VI), and 1,2,3-trichloropropane, respectively. These findings raise the question of establishing permissible concentrations for chemical carcinogens corresponding to a level of risk consistent with international requirements, namely 1×10^{-4}. To address this issue, the authors developed dose-response risk scales covering the range from 1×10^{-3} to 1×10^{-6}. For the derivation of the proposed medical and sanitary standards, concentrations corresponding to an excess lifetime cancer risk of 1×10^{-4} were selected (Table 2). This risk level has been adopted and validated in EU countries, although there is currently ongoing discussion within the EU regarding the possible adoption of a more stringent acceptable risk level of 1×10^{-5}, reflecting the increased effectiveness of environmental protection measures in recent years and the resulting reduction in chemical pollution of ambient air.

Table 2. Recommended annual average MPCs of carcinogenic substances in ambient air in populated areas

Concentrations	Substance		Criteria
	Current (daily average), mg/m^3	Recommended (annual average), mg/m^3	
1	2	3	4
Benzo/a/pyrene	0.000001	0.000001	Carcinogenic risk
Benzene	0.1	0.01	Carcinogenic risk
Beryllium	–	0.00002	Reference concentration / Resorptive effects
1,3-Butadiene	1.0	0.002	Reference concentration / Resorptive effects
1,2-Dichloropropane	0.18	0.004	Reference concentration / Resorptive effects
Ethylene oxide	0.03	0.001	Carcinogenic risk
Cadmium	0.0003	0.00002	Reference concentration / Resorptive effects
Arsenic	0.003	0.00002	Carcinogenic risk
Nickel	0.001	0.00005	Reference concentration / Resorptive effects
Carbon black	0.05	0.023	Carcinogenic risk
Trichloroethylene	1.0	0.04	Reference concentration / Resorptive effects
Formaldehyde	0.003	0.003	Reference concentration / Resorptive effects
Hexavalent chromium (Chromium VI)	0.0015	0.00001	Carcinogenic risk
Aniline	0.03	0.001	Reference concentration / Resorptive effects
Dibenz/a,h/anthracene	5.0×10^{-6}	0.000005	Carcinogenic risk
Dichloromethane	8.8	0.22	Carcinogenic risk
Epichlorohydrin	0.2	0.001	Reference concentration / Resorptive effects
2-Mercaptobenzothiazole	0.12	0.012	Carcinogenic risk
N-Nitrosodiethylamine	15×10^{-6}	0.000015	Carcinogenic risk
N-Nitrosodimethylamine	50×10^{-6}	0.00005	Carcinogenic risk
Styrene	0.002	0.002	Reference concentration / Resorptive effects
Tetrachloroethylene	0.06	0.035	Reference concentration / Resorptive effects
1,2,3-Trichloropropane	0.05	0.00005	Carcinogenic risk
Aziridine (Ethyleneimine)	0.001	0.000005	Carcinogenic risk
Acrylonitrile	0.03	0.0015	Carcinogenic risk
Acetaldehyde	0.01	0.01	Reference concentration / Resorptive effects
Petrol (gasoline)	1.5	0.01	Carcinogenic risk
Hexachloroethane	0.05	0.025	Carcinogenic risk
1,2-Dichloroethane	1.0	0.004	Carcinogenic risk
1,3-Dichloropropene	0.01	0.01	Reference concentration / Resorptive effects
Ethylbenzene	0.02	0.02	Reference concentration / Resorptive effects
Cobalt and its compounds	0.001	0.00002	Reference concentration / Resorptive effects
Naphthalene	0.003	0.003	Reference concentration / Resorptive effects
Nitrobenzene	0.008	0.002	Carcinogenic risk
2-Chloronitrobenzene	0.004	0.001	Reference concentration / Resorptive effects
3-Chloronitrobenzene	0.004	0.001	Reference concentration / Resorptive effects
4-Chloronitrobenzene	0.004	0.001	Reference concentration / Resorptive effects
Propylene oxide	0.08	0.03	Reference concentration / Resorptive effects
Lead	0.0003	0.0003	Reference concentration / Resorptive effects
Antimony trioxide	0.02	0.0002	Reference concentration / Resorptive effects
Tetrahydrofuran	0.2	0.05	Carcinogenic risk
1,1,2,2-Tetrachloroethane	0.06	0.002	Carcinogenic risk
Carbon tetrachloride	0.7	0.007	Carcinogenic risk

***Table 2.** Continued*

Concentrations	Substance		Criteria
	Current (daily average), mg/m^3	Recommended (annual average), mg/m^3	
p-Chloroaniline	0.01	0.005	Carcinogenic risk
Chloroprene	0.002	0.0003	Carcinogenic risk

Source: compiled by the authors based on [5]

The data presented in Table 2 indicate that the EU and the US assume that the effectiveness of environmental protection measures has recently increased in many countries, leading to a reduction in the level of chemical pollution in the atmosphere. To summarise this point, it can be noted that of the 45 chemical carcinogens included in the Ukrainian database of medical and sanitary standards for permissible concentrations in ambient air in populated areas, the MPCs for 11 compounds do not require revision and are at levels of acceptable risk and reference concentrations. At the same time, for 34 compounds, there is a question as to whether permissible concentration limits need to be reduced, as their current standards do not comply with international standards.

To address the issue of setting hygiene standards for carcinogenic substances in line with EU requirements, as provided for by Regulation (EC) No. 1272/2008 [9], another question arises concerning the averaging of MPCs. As of early 2026, Ukraine applies average daily MPCs, which are used to assess both short-term and long-term (chronic) periods of exposure to chemical carcinogens, although MPCs are calculated based on the lifetime exposure dose. Furthermore, international practice already employs annual average concentrations to prevent chronic exposure to carcinogens, whilst daily average levels are recommended to prevent acute exposure. This circumstance necessitates the establishment of two maximum permissible concentrations for each carcinogenic substance – an annual average and a daily average. It is precisely on the basis of these principles that the authors have proposed an improved, modern system of standards for carcinogenic substances in the ambient air of populated areas, taking into account annual average concentrations for the assessment of chronic exposure and daily average concentrations for acute exposure, as set out in Table 2. Thus, the proposed approaches to hygienic standard-setting require amendments to Ukrainian legislation governing medical and sanitary regulation.

To summarise the results obtained, it should be emphasised that they concerned two aspects of the system of hygienic standardisation: the determination of safe concentrations of chemical carcinogens in ambient air and general characteristic indicators of their application in practical activities. This includes, for Ukraine in 2026, the selection of an acceptable level of societal risk associated with environmental factors, taking into account the country's social, economic, technological, and environmental characteristics, as well as the determination of appropriate concentration averaging periods and sampling durations for environmental monitoring. All of these issues were fundamentally new for Ukrainian specialists in preventive medicine at the beginning of 2026, and the proposed hygienic standards are specifically intended for the assessment of the health hazards posed by chemical environmental factors. In the practice of hygiene science, the methodology for setting hygiene standards for harmful environmental factors, which was established in the 1960s, has remained virtually unchanged. Concentrations set at the level of hygiene standards are ideologically regarded as non-toxic, that is, safe for people living under the influence of harmful chemicals at the levels specified by the approved standards. At the same time, similar approaches proposed by experts from EU countries and the USA hold that there are no "non-effect" concentrations of harmful substances; depending on their level, there is a risk of contributing to the development of disease, which, for carcinogenic substances, corresponds to a specific incidence of cancer relative to the size of the population. In global practice, as of early 2026, according to the definition by IARC experts [15] and WHO specialists [13-14], an acceptable risk for ambient air in populated areas is considered to be a risk level of 1×10^{-4}, i.e. where exposure to a specific chemical compound may result in one case of cancer per 10,000 people over a lifetime. Thus, whilst the air pollution levels are assessed and their safety for the population is indirectly assumed on the basis of the chemical substance standards established by Ukrainian experts as of early 2026, under the risk-based approach, hygiene standards directly assess the risk to human health.

Thus, the results obtained in this study are consistent with the findings of international organisations and are in line with current scientific research, which points to the need to adopt a risk-based approach when regulating carcinogenic air pollutants. For instance, the WHO guidelines on air quality state that, for carcinogens, a safe threshold level of exposure cannot be scientifically justified and standards must be determined on the basis of an acceptable level of risk [13-14, 16]. A similar concept underpins the regulatory policy of the US Environmental Protection Agency, which recommends using individual carcinogenic risk indicators as the primary criterion for regulatory decision-making [17]. Based on this, for example, the MPC of benzene in Ukrainian regulations is 7.7×10^{-4}, which is almost eight times higher than the risk level of 1×10^{-4}. Furthermore, WHO experts [14] emphasise that any level of benzene exposure is associated with a certain probability of developing leukaemia; therefore, regulatory decisions should be based on risk assessment rather than on the concept of a safe threshold concentration. Similar conclusions are presented in the work by A. Sekar *et al*. [18], who, after analysing air quality standards in various countries, concluded that a significant proportion of existing standards do not provide adequate protection for public health and need to be revised on the basis of current assessments of carcinogenic risk. The authors of this study reached a similar conclusion.

A significant exceedance of the acceptable risk was also identified in this study for chromium (VI), arsenic, cadmium, cobalt, ethylene oxide and a number of other substances. Particular attention is drawn to the calculated risk values for chromium (VI) and 1,2,3-trichloropropane, which exceeded the level of 10^{-4} by several orders of magnitude. Similar results were obtained by D.M. Proctor *et al*. [19], who demonstrated that even at low concentrations of Cr(VI), risk levels may exceed those recommended by regulatory authorities. The authors emphasise the need for periodic review of regulatory standards, taking into account new data and approaches to carcinogenic risk assessment. It is also important to note that the list of substances for which the authors of this article propose a review of regulatory limits largely coincides with the list of priority atmospheric carcinogens identified by the International Agency for Research on Cancer [15], including benzene, benzo(a)pyrene, cadmium, arsenic, nickel, formaldehyde, and hexavalent chromium compounds, all of which are classified as carcinogenic to humans (IARC Group 1).

The second aspect of the study concerns the advisability of revising approaches to the averaging of concentrations of carcinogenic substances. The results obtained confirm the need to review approaches to averaging the concentrations of carcinogenic substances. Unlike the current Ukrainian system, where the daily average concentration is predominantly used to assess both acute and chronic effects, international practice involves the use of annual average concentrations to assess long-term carcinogenic effects, whilst daily average concentrations are used to prevent acute toxic reactions [13, 20]. This approach is considered to be more scientifically sound, as the development of malignant tumours is primarily associated with prolonged exposure to low concentrations of carcinogenic agents. The lifetime exposure dose used in risk assessments is also relevant. Furthermore, the List of Air Quality Standards for the Protection of Public Health, as recommended in the EU Directives, clearly stipulates the need to average concentrations over the course of a year (annual concentrations) for substances such as benzo(a)pyrene, benzene, lead, arsenic, cadmium, nickel, chromium other priority pollutants [21].

Finally, in summarising their work, the authors emphasise the need to establish, for the social, economic and technological conditions prevailing in Ukraine in 2026, a level of acceptable risk of 1×10^{-4}, which has been tested in EU countries and the USA and is recommended by the International Agency for Research on Cancer [15]. Not only will this serve as a national indicator of the danger posed by existing actual pollution, but it will also be the single benchmark against which all chemical compounds will be assessed. It is important to note that the results of this study are consistent with the European Union's current environmental policy, according to which the priority approach to preventing carcinogenic effects is not only the establishment of standards but also the maximum reduction or elimination of sources of carcinogens entering the environment [9, 22]. It is precisely this approach that is gradually replacing the traditional concept of hygiene standardisation in Ukraine. Thus, the results of this study confirm the need to harmonise the Ukrainian system of medical and sanitary standardisation of carcinogenic substances with international standards. The implementation of a risk-based approach is scientifically sound and, in the long term, should be developed through legislative measures and the refinement of Ukrainian principles for establishing permissible medical and sanitary standards; the application of these standards will enhance the effectiveness of preventing the adverse effects of environmental factors on the health the population and the formulation of practical steps for management decisions aimed at improving the environment and preventing environmentally-induced morbidity among the population.

CONCLUSIONS

1. The studies conducted show that the standards currently in force in Ukraine for carcinogenic substances in the ambient air of populated areas, in the vast majority of cases, exceed the level of permissible or acceptable risk of probable cancer development in the population.

2. When comparing these standards with the requirements of the EU and the USA, the question arises as to the need to revise Ukraine's regulatory framework for carcinogenic substances in line with international legislation, which provides for the determination at national level of an acceptable risk of exposure to harmful factors affecting the human body and the development of medical and sanitary standards for different levels of concentration: annual averages to prevent chronic exposure and daily averages to prevent acute exposure. This approach to justifying medical and sanitary standards focuses them on preventing the harmful effects of environmental factors on the human body and ensuring an acceptable state of the environment.

3. In view of Ukraine's current economic conditions, the existing technological capabilities of industrial pollution sources, and the social pressures associated with ongoing military conflict, an acceptable lifetime excess cancer risk of 1×10^{-4} is recommended as the basis for establishing medical and sanitary standards. This benchmark has already been formally recognised in countries with higher levels of human development, including the EU and the USA.

4. Continuing scientific research on this topic will enable Ukrainian health legislation to be brought into line with EU legislation, thereby ensuring that medical and health standards for the permissible concentration of carcinogenic substances in the ambient air of populated areas in Ukraine comply with European standards.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

REFERENCES

[1] Decree of the President of Ukraine No. 5/2015. On the Sustainable Development Strategy Ukraine – 2020 [Internet]. 2015 January 12 [cited 2026 January 2]. Available from: https://zakon.rada.gov.ua/laws/show/5/2015#Text

[2] Shapovalov YeB, Salavor OM, Yakymenko IL. Comparative analysis of EU and Ukrainian legislation in the field of air protection. Ecol Sci. 2018;2(21):192–7

[3] Yakymenko IL, Nychyk OV, Madzhd SM. Harmonization of Ukrainian environmental legislation with EU requirements. Ecol Sci. 2024;6(57):250–4. DOI: 10.32846/2306-9716/2024.eco.6-57.37

[4] Law of Ukraine No. 2573-IX. On the Public Health System [Internet]. 2022 September 6 [cited 2026 January 2]. Available from: https://zakon.rada.gov.ua/laws/show/2573-IX

[5] Order of the Ministry of Health of Ukraine No. 1811. Methodological Recommendations Assessment of Carcinogenic and Non-Carcinogenic Risks to Public Health from Chemical Air Pollution [Internet]. 2023 October 18 [cited 2026 January 2]. Available from: https://surli.cc/foqnpx

[6] Order of the Ministry of Health of Ukraine No. 52. On Approval of Hygienic Standards for Chemical and Biological Substances in Ambient Air [Internet]. 2020 January 14 [cited 2026 January 2]. Available from: https://zakon.rada.gov.ua/laws/show/z0157-20#Text

[7] Chernychenko IO, Lytvychenko OM, Babii VF, Kondratenko OYe, Hlavachek DO. Determining the compliance of the domestic database of hygienic standards for carcinogenic substances with EU requirements. Environ Health. 2023;4(109):23–8. DOI: 10.32402/dovkil2023.04.023

[8] Chernychenko IO, Balenko NV, Lytvychenko OM, Babii VF, Kondratenko OYe, Hlavachek DO. Analysis of regulatory and methodological frameworks in the EU and USA for determining occupational exposure limits for carcinogenic substances. Environ Health. 2024;1(110):66–74. DOI: 10.32402/dovkil2024.01.066

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council. On Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No 1907/2006 [Internet]. 2008 December 12 [cited 2026 January 2]. Available from: https://eur-lex.europa.eu/eli/reg/2008/1272/oj/eng

[10] Council Directive 67/548/EEC. On the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances [Internet]. 1967 June 27 [cited 2026 January 2]. Available from: https://eur-lex.europa.eu/eli/dir/1967/548/oj/eng

[11] Directive (EU) 2019/983 of the European Parliament and of the Council. Amending Directive 2004/37/EC on the Protection of Workers from the Risks Related to Exposure to Carcinogens or Mutagens at Work [Internet]. 2019 June 5 [cited 2026 January 2]. Available from: https://surl.li/mhhmxy

[12] List of Substances on IRIS [Internet]. [cited 2026 January 2]. Available from: https://iris.epa.gov/AtoZ/

[13] World Health Organization. Air quality guidelines for Europe. 2nd ed. Copenhagen: WHO Regional Office for Europe; 2000. 273 P.

[14] World Health Organization. WHO guidelines for indoor air quality: Selected pollutants. Copenhagen: WHO Regional Office for Europe; 2010. 454 P.

[15] International Agency for Research on Cancer (IARC). Arsenic, metals, fibres, and dusts. Lyon: IARC; 2012. 501 P.

[16] Mudu P, Pérez Velasco R, Zastenskaya I, Jarosinska D. The importance and challenge of carcinogenic air pollutants for health risk and impact assessment. Eur J Public Health. 2020;30(5):ckaa165.841. DOI: 10.1093/eurpub/ckaa165.841

[17] United States Environmental Protection Agency. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (HHEM), Part A: Interim Final. Washington (DC): U.S. Environmental Protection Agency, Office of Emergency and Remedial Response; 1989. 291 P.

[18] Sekar A, Varghese GK, Ravi Varma MK. Analysis of benzene air quality standards, monitoring methods and concentrations in indoor and outdoor environment. Heliyon. 2019;5(11):e02918. DOI: 10.1016/j.heliyon.2019.e02918

[19] Proctor DM, Bhat V, Suh M, Reichert H, Jiang X, Thompson CM. Inhalation cancer risk assessment for environmental exposure to hexavalent chromium: Comparison of margin-of-exposure and linear extrapolation approaches. Regul Toxicol Pharmacol. 2021;124:104969. DOI: 10.1016/j.yrtph.2021.104969

[20] World Health Organization Regional Office for Europe. AirQ+: Software tool for health risk assessment of air pollution [Internet]. [cited 2026 January 2]. Available from: https://surl.li/zaoguq

[21] European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Clean Air Programme for Europe [Internet]. 2013 December 18 [cited 2026 January 2]. Available from: https://surl.li/bgwqvb

[22] Directive 2004/37/EC of the European Parliament and of the Council. On the Protection of Workers from the Risks Related to Exposure to Carcinogens or Mutagens at Work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) [Internet]. 2004 April 29 [cited 2026 January 2]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0037

Ігор Черниченко

Доктор медичних наук, професор
ДУ «Інститут громадського здоров’я ім. О. М. Марзєєва НАМН України»
02094, вул. Гетьмана Павла Полуботка, 50, м. Київ, Україна
https://orcid.org/0000-0002-4784-4628

Ольга Литвиченко

Доктор біологічних наук
ДУ «Інститут громадського здоров’я ім. О. М. Марзєєва НАМН України»
02094, вул. Гетьмана Павла Полуботка, 50, м. Київ, Україна
https://orcid.org/0000-0003-2039-3318

Діана Главачек

Магістр, науковий співробітник
ДУ «Інститут громадського здоров’я ім. О. М. Марзєєва НАМН України»
02094, вул. Гетьмана Павла Полуботка, 50, м. Київ, Україна
https://orcid.org/0000-0002-0512-6927

Сергій Гаркавий

Доктор медичних наук, професор
Національний медичний університет ім. О. О. Богомольця
01601, бульвар Тараса Шевченка, 13, м. Київ, Україна
https://orcid.org/0000-0001-7344-1980

Віталій Бабій

Доктор медичних наук, професор
ДУ «Інститут громадського здоров’я ім. О. М. Марзєєва НАМН України»
02094, вул. Гетьмана Павла Полуботка, 50, м. Київ, Україна
https://orcid.org/0000-0003-2519-1440

Олена Кондратенко

Кандидат біологічних наук
ДУ «Інститут громадського здоров’я ім. О. М. Марзєєва НАМН України»
02094, вул. Гетьмана Павла Полуботка, 50, м. Київ, Україна
https://orcid.org/0000-0002-9504-7228

Обґрунтування медико-санітарних нормативів допустимого вмісту канцерогенних речовин в атмосферному повітрі населених місць з урахуванням досвіду країн ЄС

Анотація

Актуальність. Інтеграція України до Європейського Союзу вимагає гармонізації національного законодавства з європейськими стандартами. Одним із пріоритетних напрямів є вдосконалення системи медико-санітарних нормативів шкідливих речовин в атмосферному повітрі. На відміну від країн ЄС та США, де нормування

канцерогенів базується на ризик-орієнтованому підході з допущенням прийнятного рівня ризику та можливістю регулярного перегляду лімітів, в Україні гранично допустимі концентрації (ГДК) канцерогенів традиційно встановлюються на основі токсикологічних експериментів без обов'язкового подальшого перегляду величин.
Мета. Провести аналіз відповідності чинних медико-санітарних (гігієнічних) нормативів канцерогенних речовин в атмосферному повітрі населених місць України міжнародним стандартам.
Матеріали та методи. Було досліджено українську нормативну базу канцерогенних речовин в атмосферному повітрі, законодавство і директиви ЄС, стандарти США та рекомендації Міжнародної агенції з вивчення раку.
Результати. Проведено порівняльну оцінку чинних українських нормативів канцерогенних речовин щодо їх відповідності міжнародним рівням прийнятного канцерогенного рику (1×10^{-4}) та референтних концентрацій. Проаналізовано показники гігієнічних нормативів для 45 канцерогенних речовин із визначеним канцерогенним потенціалом. Установлено, що діючі нормативи для 34 речовин не відповідають міжнародним стандартам. Запропоновано удосконалену систему нормативів із впровадженням середньорічних концентрацій для оцінки хронічного впливу та середньодобових – для гострого.
Висновки. Доведена необхідність гармонізації української системи медико-санітарного нормування канцерогенів із міжнародними стандартами. Науково обґрунтовано впровадження ризик-орієнтованого підходу на основі прийнятного рівня ризику (1 × 10-4), диференціації нормативів за періодами осереднення (середньорічні та середньодобові) та регулярного перегляду нормативної бази відповідно до сучасних токсикологічних й епідеміологічних даних.
Ключові слова: прийнятний ризик; система показників допустимого рівня; середньодобові та середньорічні концентрації; попередження шкідливого впливу на здоров'я людини та стан довкілля.