ESTABLISHING AND PROVING THE FACT OF PUBLIC HEALTH HARM IN THE PRESENCE OF AN UNACCEPTABLE HEALTH HAZARD IN THE ENVIRONMENT[1]

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Abstract: The article demonstrates that the legal framework of the Russian Federation requires the assessment of public health harm to exercise administrative and criminal sanctions in the event of breach of legislation in the sphere of sanitary and epidemiological welfare and consumer rights protection. Modern scientific evidence of causal relationships between the environment and health, as well as the introduction of risk assessment methods into the work of sanitary services make it possible to create a sufficient body of evidence of the adverse effect of certain environmental factors on public health, especially if health hazard rate is determined as unacceptable. We propose an algorithm for creating an evidential basis of public health harm that includes the assessment of health hazard and special medical and biological research. This algorithm may be used for sanitary and epidemiological investigations, inquiries and expert evaluations. We also provide a description of the elements of the evidential basis on group and individual levels.
Key words: health hazard, health harm, negative environmental factors, evidential basis, sanitary and epidemiological investigation.

The right to life and the right to health protection are among the universally acknowledged, basic and inherent human rights and freedoms according to the Constitution of the Russian Federation (Articles 2 and 7.1, 20, 41) and are subject to state protection.

The concept of health harm is used in more than 20 laws of the Russian Federation, which stipulate compulsory compensation of health harm by the party that caused it (Article 1064 “General Attribution of Liability for Damages" of the RF Civil Code (Part 2) No. 13-FZ as of 26.01.1996; Article 14 “Property Liability for Damages Caused by Defective Goods (Works, Services)" of the Federal Law on Consumer Rights Protection”; “On Environmental Protection”, “Framework Legislation on Public Health Protection”, etc.)

Federal Law No. 52-FZ “On the Sanitary and Epidemiological Welfare of the Public” defines sanitary and epidemiological welfare as public health and healthy environmental conditions that present no health hazards. The concept “health harm” is used by a number of sanitary norms and regulations.

RF Government Decree No.522 as of August 17, 2007 “Health Harm Estimation Regulations” defines health harm as breach of the anatomical continuity and physiological functioning of human organs and tissues caused by the impact of physical, chemical, biological and psychogenic factors of the environment.

Articles 11.5 and 12.2 of the RF Administrative Code, Articles 111-113 of the RF Criminal Code and the Decree of the Ministry of Public Health and Social Development No. 194 as of April 24, 2008 determine the medical criteria to estimate severe, medium and mild health harm, classify injuries, cases of poisoning and other health problems, as well as the degree of disability caused by the disease. The list of health disorders is open and can be updated.

Numerous studies have shown that the evidence of health harm described and qualified in this document is also manifested under the impact of a number of environmental factors. Such

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evidence may be: dysfunction of vital functions of human organism [2,5,7,12], acute heart and/or vascular failure, cerebral circulation disorder [8], severe acute respiratory failure, acute poisoning by chemical and biological substances including toxic metals or gases, food poisoning, temporary disorder of functions of organs and/or systems, etc. [1, 5, 10, 12-14].

It is important that the identification and estimation of the severity of health harm should be an integral part of the regulatory and supervision activities of the Federal Service for Consumer Rights Protection and Public Welfare (*Rospotrebnadzor*), as

- in all sanitary and epidemiological expert evaluations, investigations, screening procedures, inquiries and other forms of evaluation (Article 42 of Federal Law No.52-FZ) it is necessary to establish the fact of the harmful effect of environmental factors, and to identify the reasons and conditions for the emergence and spread of infectious diseases and mass non-infectious diseases (poisonings);

- to justify unscheduled inspections according to part 2 of Article 10 of Federal Law No.294-FZ "On the Protection of the Rights of Legal Entities…" and the Decree of the Federal Service for Consumer Rights Protection and Public Welfare No.764[2] as of 16.07.2012, it is necessary to indentify the causes of health harm or the threat to human life and health;

- to apply certain measures of administrative pressure according to Articles 6.17, 14.43, 14.44, 14.46[3] of the Administrative Violations Code, it is necessary to estimate the degree of harm, because in the event of public health harm induced by the inappropriate or unhygienic condition of the object under supervision, the responsibility is much higher than that incurred in the event of simple discrepancy between the actual state of the object and the hygienic requirements and standards[4].

- to substantiate the indicia of crime in order to apply criminal responsibility measures according to the RF Criminal Code (Articles 236 "Breach of Sanitary and Epidemiological Regulations, Resulting by Negligence in Epidemics or Mass Poisoning" and 238 "Production, Storage, Transportation or Sale of Goods and Products, Performance of Works or Services Nonconforming to Safety Standards"[5]. In this case health harm evaluation is the condition for the incurrence of responsibility.

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[2] "The Administrative Procedure for the Federal Service for Consumer Protection and Public Welfare to Ensure the Fulfillment of Health and Consumer Rights Legislation and Sale Regulations by Legal Entities and Individuals"

[3] RF Administrative Offences Code: Article 6.17. "Breach of RF legislation on the protection of children from information that is harmful for their health and/or development"; Article 14.43 "Breach of technical regulations by producer or seller", Article 14.44 "Unreliable Declaration of Product Conformity"; Article 14.46 "Breach of Requirements for Product Labelling".

[4] For instance, the breach of technical regulations by a seller or producer (Article 14.43) leads to an administrative fine of 10,000 to 20,000 rubles for administrative officials and 100,000-300,000 rubles for legal entities. However, if the same violation has caused the infliction of harm to life or health, the fine is increased to 20,000-30,000 rubles for officials and 300,000 to 600,000 for legal entities with a possible attainder of the offending objects.

[5] RF Criminal Code, Article 236 "Breach of sanitary and epidemiological regulations leading to mass infection or poisoning of the public is punishable by a fine up to 80,000 rubles". .. or custodial restrained up to one year. Article 238. "Production, Storage or Transportation… performance of works or services non conforming to safety regulations… if they: Recklessly led to severe health harm... are punishable by a fine of up to 500,000 rubles or imprisonment of up to six years…

Both Article 236 of the Criminal Code on the responsibility for the mass infection and Article 1 of Federal Law No.52-FZ "On Sanitary and Epidemiological Welfare", define "mass non-infectious diseases (poisonings) as "human conditions inflicted by physical and/or chemical and/or social environmental factors". This justifies the need to establish the fact of mass epidemics, i.e. health harm, in order to substantiate the degree of liability.

Article 42 of the Federal law No.122-FZ as of 22.08.2004 "On Sanitary and Epidemiological Welfare" requires that sanitary and epidemiological expert evaluations, investigations, observations, studies, trials, toxicological, hygienic and other kinds of evaluations should be carried out, by right of which Chief State Medical Officers evaluate the situation, confirm the fact of health harm and identify its cause (according to the Decree of the Federal Service for Consumer Rights and Public Welfare No.359 as of 30.04.2009 "On Sanitary-Epidemiological Expert Evaluations, Observations, Studies, Trials and Toxicological, Hygienic and other Evaluations").

The procedure of investigating occupational diseases is prescribed in the Regulations on the Investigation and Record Keeping of Occupational Diseases (approved by the Decree of the RF Government No.967 as of Decemter 15, 2000). Investigations into food poisonings are prescribed by the Instruction on the Procedure of Investigation, Record Keeping and Laboratory Analyses of Cases of Food Poisoning in Institutions of the Sanitary and Epidemiological Service, approved by the Chief State Medical Officer of the USSR on December 20, 1973, No.1135-73.

However, there is no regulation on the procedure and submission of the evidential basis in the event of mass infection or public health harm induced by physical, chemical or other environmental factors.

Many researchers recognize the complexity of establishing and proving the causal link between environmental pollution and health harm [3,11,17,18,23]. Yet there are some in-depth analytical studies of court practice on compensations for environment-induced health harm [18,20,23]. Scholars have proposed and evaluated the types and content of elements required to build an evidential basis of causal links between human health and the impact of environmental factors [1,5,7,13,14]. Methods of biological monitoring to determine impact and response markers are also being developed. Such methods are widely used and appreciated in arbitrage practice worldwide [6,9,15,19,21,22,24,25].

Scholars have also defined the key principles of evidentiary medicine and environmental epidemiology that underline the evidential basis of instances of public health harm induced by a negative impact of environmental factors [18]:

- impact precedes effect;
- several (many) individuals exposed to the impact display an expressed effect of the impact;
- the effect is dependent on the exposure;
- the effect is stable and reproducible;
- a biologically credible link between the exposure and the effect has been established;
- the effect has no other explanations.

A new impulse in the studies of the causal link between public health and the quality of the environment was given by the introduction of the international risk assessment methodology into the practice of the Russian Health Service. An important document adopted in this connection is the “Public Health Hazard Assessment Guide", which should be used in situations when the environment is polluted by chemical substances (Guide 2.1.20.1920 - 04), and a number of other recommended practice guides[6]. The introduction of risk assessment has made the hygienic evaluation of the situation strictly oriented towards danger factors and potential health issues. Although it is not evidence of harm as such, its results considerably narrow the search for evidential basis and substantially improve the results and efficiency of diagnostic tests in relation to both danger factors and human health [4,12,16,22].

In general, the evaluation and proof of health harm is viewed as a feasible task, although it requires a systemic approach and meticulous data processing [11,17,18].

The aim of this research was to develop and test an algorithm for establishing the fact of environment-induced health harm and to substantiate methods of building an evidential basis to prove the causal link between health harm and its sources.

Research methods The general algorithm and methodological approaches were developed on the basis of an analytical generalization of Russian and foreign literature, using the method of logical variables.

To validate the method of health harm assessment and the establishment of the link between health harm and environmental factors, we used official data on the sources and quality of the environment submitted by the Federal Service for Consumer Rights and Public Welfare collected during its sanitary and epidemiological investigations. Spatial exposure evaluation was performed with the help of ArcGIS 9.3 and vector maps of the territories. Health risk assessment was conducted according to "Guidelines for Public Health Risk Assessment” 2.1.10.1920—04 (approved by the Chief State Medical Officer as of 05.03.2004).

The bio-medical tests and examinations were conducted according to the RF National Standard GOST-R 52379-2005 "Good Clinical Practice" (ICH E5 GCP), with strict adherence to the ethical principles stipulated in the Helsinki Declaration of 1975 with the 1983 additions (obtaining the informed agreement of the volunteer).

The collection and storage of biological samples (blood, urine) for the study was conducted according to the requirements in Guide 1.3.2322-08 “Safety of Working with RG3-4 Microorganisms and Parasitical Disease Causative Factors”.

The amount of chemical contaminants in biological media was measured by a certified testing laboratory using standardized testing methods.

The amount of chemical substances in biological media was compared with the indices in samples taken from the population of areas outside the impact area (control group indices) and literature data (reference rate).

[6] Guide 2.1.10.0031-11 “Complex Assessment of Water-Transmitted Bacterial Intestinal Infection Hazard”, Guide 2.1.4.0032-11 “Integral Assessment of Chemical Safety of Drinking Water ”, Guide 2.2.10.0059-12 “Traffic Noise Health Hazard Assessment”, Guide 2.1.10.0061-12 "Alternating Magnetic Field (up to 300 Hz) Health Harm Assessment”, Guide 2.1.10.0062-12 “Evolution Model-based Qantitative Assessment of Non-oncogenous Health Hazard of Chemical Substances Exposure” and a number of others.

While processing the information on the level of chemical substances in biological media (exposure markers) and laboratory response markers, we took into consideration the data distribution pattern, the computation of the statistical performance of data array for different distribution patterns using standardization methods, and the evaluation of variation series and criterial indices. Data evaluation was performed against the following indices: group mean; standard deviation for the data body; data measurement error; the worst indicator value in group (maximum or minimal value depending on the indicator type); the share of samples exceeding the control level (physiological norm for the given age, control group rate); results of confidence estimation of the difference between the group rate and the control rate (by Student's criterion, $t>2$, $p\leq 0.05$).

Medical examinations of patients aimed at detecting clinical evidence of health disorders were accompanied by functional tests validated by literature data of potential negative effects of chemical substance impact. During the examinations, the doctors responded to the presence (absence) of health disorders that were expected at the given level of exposure and had a pathogenic relation to it. They examined functional disorders of critical organs and systems that had been exposed to unacceptable health hazard factors. Each patient was given the main and secondary diagnoses factoring in a complex of laboratory indicators and functional tests results.

The results of medical examinations and functional and laboratory tests were processed with due consideration for data distribution patterns and the computation of the statistical performance of the data array for different distribution patterns, using standardization methods. We also factored in the evaluation of variation series and criteria indices. Data evaluation was performed against the following indices: frequency of each diagnosis in the group (the proportion of diagnosed patients in the total number of patients); frequency of detection of objective health disorder symptoms; mean physiological function parameter (if attributable); standard deviation of the parameter for the data body under study; parameter measurement error for the data body; frequency of abnormalities (the share of abnormal samples in the total number of samples); the maximum value of the index in the group; results of confidence estimation of the group rate divergence from the control rate (by Student's criterion, $t>2$, $p\leq 0.05$).

Key findings

We used a case study where health harm inflicted by exposure to chemical substances was estimated to propose and validate the algorithm for building the evidential basis. The algorithm includes seven consecutive stages.

1. Proper establishment of the circumstances that require health harm estimation validates the whole chain of evidence and helps plan a system of analytical, sanitary, epidemiological, medical and other inquiries.

2. The accumulation and analysis of information on the sources of impact and the quality of the environment is needed to identify and properly document the presence of a source of adverse impact. If at this stage (investigations, expert evaluations) the source can not be identified, the investigation is stopped, as the further chain of evidence makes no legal sense.

3. The assessment of the health hazard rate allowed addressing a number of tasks: detect danger factors (danger identification stage), obtain data on the level of human contact with the danger factor (exposure evaluation), determine the kinds of potential negative effects (evaluation

of the 'exposure-response' link and its expression), obtain quantitative values of the severity of the health hazard in relation to critical human organs and systems. The indicator of health harm infliction included in the evidential basis consisted in a) the fact of public exposure to chemical substance(s) substantiated by computation and instrumental methods, and 2) an unacceptable level of health hazard revealed by standardized methods.

4. Medical and biological tests were the key stage for the establishment and estimation of the type and degree of health harm. The tests were performed in several significant directions.

4.1. Tests of the qualitative and quantitative content of chemical substances (exposure markers) in biological media (tissues, excretes, biological liquids, exhaled air, etc.) were regarded as evidence for the individual's contact with a certain environmental factor. To be included into the evidential basis, data was compared against the following criteria: scientific data (data bases of WHO, EPA, Russian regulatory and methodological documents, etc.) confirm the possibility of the presence of substance(s) in the environment or persistent metabolite in the biological media under known exposure; the mean content of chemical substances in the biological media (M±m) (exposure marker) increases to a credibly higher level in comparison with that of the control group ($M_k \pm m_k$[7]) ($p \leq 0.05$); it is possible to establish a credible link between the amount of the substance in the biological media and the exposure level ($p \leq 0.05$).

4.2. Laboratory, functional and instrumental tests were performed using programs appropriate for the character and level of exposure and obligatorily involved the detection of effect markers. The effect markers were selected on the basis of scientific analysis of the available data. The criteria for the inclusion in the evidential basis were as follows: several patients in the group had similar abnormalities of laboratory indices reflecting the impact of a chemical substance ($nP > P_k \pm p_k$; $n > 5\%$); it was possible to detect a credible link between the index and the level of exposure or an exposure marker ($p \leq 0.05$); several patients in the group displayed homogenous (similar) complexes of laboratory abnormalities revealing functional disorders ($n > 5\%$), there was scientific data on the biological credibility of the index or complex of indices with the given level of exposure (exposure marker).

4.3. Medical examinations involving the description and analysis of individual and group rates of the clinical evidence of health disorders adequate to the impact of the harmful environmental factor were aimed to confirm the presence of health harm as such. The facts to be included into the evidential basis were identical diagnoses revealed in the group of exposed individuals substantiated by clinical symptoms and a system of laboratory indices and functional tests having credible biologically justifiable connections with the exposure (exposure markers) ($n > 5\%$). Only those diagnoses (disorders) were examined whose frequency was credibly higher than that in the control group ($p \leq 0.05$) if they affected critical organs and systems subjected to an unacceptable level of health hazard. All scientific data on similar diseases emerging in similar exposure cases was taken into account.

5. Information on individual and group average lifestyle features, occupational, genetic and other factors was collected and analyzed with the aim to rule out all other factors that could have caused similar health disorders. This aspect of health harm estimation and its connection with environmental factors is of key importance and it was carefully documented.

[7] Here and elsewhere 'k' subindex stands for 'control' or 'comparison level'

6. The aim of systemic processing of the whole body of information on the types of effects, impact criteria, the available models of the "exposure – effect" link was to build an integrated evidential basis of presence or absence of health harm inflicted by the impact of environmental factors.

7. The final stage consisted in data documentation and the preparation of the supporting materials and expert reports on health harm inflicted by the negative impact of the environment.

During the final stages, all elements of the evidential basis were built into a system to analyze credible connections between individual elements with the help of mathematical operations with logical variables that could assume two values: TRUE (logical 1) or FALSE (logical 0). Each connection was evaluated separately as "proven" or "not proven" (see Fig. below).

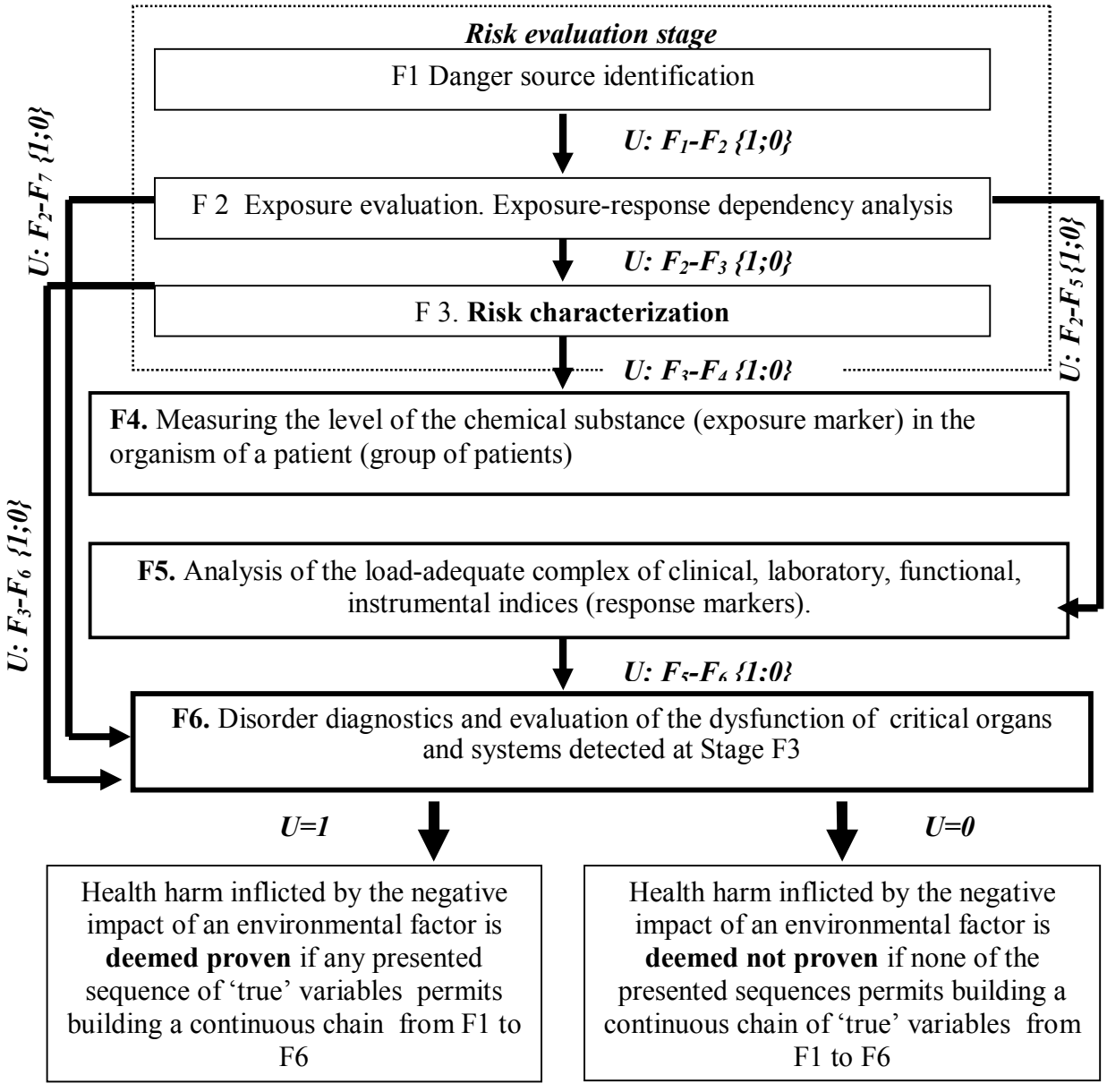

Fig. General procedure of proving environment-infilicted health harm

The formalized scheme for proving health harm based on establishing connections between individual elements expressed by logical variables is represented in the following equation:

$$U = \sum_{i=1}^{N_ó} U_i^{1-2} \cdot \left(\sum_{j=1}^{N_{çàá}} U_{ij}^{2-6} + U_i^{2-3} \sum_{j=1}^{N_{çàá}} U_{ij}^{3-6} + \left(\sum_{k=1}^{N_{êë}} U_{ik}^{2-5} + U_i^{2-4} \sum_{k=1}^{N_{êë}} U_{ik}^{4-5} \right) \sum_{j=1}^{N_{çàá}} U_{kj}^{5-6} \right)$$

Where U is the harm inflicted by a certain factor that is deemed proven if any presented sequence of "True" logical variables permits building a continuous chain from the first factor (F1: presence of a source of harmful impact) until the last one (revealed fact of health violation expressed by a functional disorder of critical organs and systems determined at the stage of risk assessment).

This algorithm was used to assess the health harm inflicted on people living within the impact area of a large cable-producting factory. The results of the investigation have shown that:

- Only this factory had discharged into the atmosphere emissions containing phenol and o-, m and p-cresols that were able to form a significant concentration of these contaminants in the ground-level air;

- The ground-level concentration of phenol around preschool institutions in the area was up to 3.6 MPC one-time concentration and up to 2.7 MPC daily average, and the concentration of cresols was up to 1.7 MPC one-time concentration and 2.0 daily average;

- Chronic exposure to tricresol and phenol leads to the increase of the risk of developing nervous system pathology to 10.02 (with the contribution of tricresol of approximately 99.77%), CNS pathology to 9.23 (with the contribution of phenol up to 65.34%), blood system disorder to 12.08 (with the contribution of phenol up to 82.78%), liver disorder to 2.3 (with the contribution of phenol up to 94.08%, renal disorder to 2.7 (with the contribution of phenol up to 86%). The health hazard was assessed as unacceptable.

- Children living in the exposed area were found to have the amount of contaminants in their blood that credibly exceded the comparison levels: the amount of phenol exceded the comparison level by a factor of 1.7, while the amount of o-cresol and p,m-cresol was 11.8 and 5.8. times higher respectively ($p<0.05$);

- A comparative analysis (against the age-related physiological norm and the control group indices) of the in-depth laboratory tests of the children has revealed a series of deviating laboratory and cytogenetic indices associated with the development of negative effects: activated lipid peroxidation (increased level of lipid hydroperoxide, malondialdehyde) dependent on the increased level of phenol ($R2 = 0.13 \div 0.45$; $7.2 \leq F \leq 33.8$; $p=0.000$); strained activity of the antioxidant system (increased level of general antioxidant activity) dependent on the increased level of phenol and m-cresol ($R2 = 0.18 \div 0.36$. $29.26 \leq F \leq 30.97$; $p=0.000$); activation of a cytolitic process (increased ASAT level) dependent on the high level of phenol ($R2=0.11$; $F= 6.73$; $p = 0.012$); disruption of the synthesis of blood-coagulation factors in the liver (reduced bleeding

time) dependent on high phenol level (R2=0.46; F=154.25; p=0.000); inflammatory reaction (high content of leucocytes and segmented neutrophyls) dependent on the high level of phenol in blood ((R2=0.59; F=79.29; p = 0.011); cytogenetic changes (qualitative polymorphism-type changes of chromosomes, genetic instability in expholiative cells of buccal epithelium expressed in a high frequency of nuclear apparatus disorders) dependent on high levels of phenol and o,m-cresol (R2=0.10-0.20; 6.13≤F≤11.85; p=0.000-0.028) with the contribution of these contaminants to the development of polymorphic changes of 10-20% (p=0.000-0.028); activation of oxidation process on the DNA level of cells (elevation of 8-hydroxide-2-deoxiguanosine) dependent on the high level of phenol and o-,m-cresol in blood (R2=0.15-0.25; 7.22≤ F≤10.25; p=0.000-0.021), with the contribution of these contaminants to the development of oxidative damage on the DNA level amounting to 15-25% (p=0.000-0.028).

- A series of immunological deviations has been revealed signaling of the development of negative effects with an elevated level of m-cresol, o-cresol and/or phenol in blood: a) disorder of the cellular component of immunity: reduced activity of phagocytosis, inhibited expression of T-helpers and T-activation cells (R2=0.24-0.78; p=0.000-0.008); b) disorder of humoral immunity: suppressed IgM (R2=0.76, p<0. 05); c) specific response to factor loading components (elevated phenol antibody level); d) disorder of neurohumoral regulation on cortisol and serotonin levels against control group, etc.

- Medical examinations accompanied by laboratory tests have revealed that children from the test group developed nervous system pathology (75.7% against 49.1%, p≤0.001) 1.5 times more often than children from the control group. The predominant type of NS disorders revealed was vegetative-vascular dystonia (40.1% against 35.2%; p=0.49). Over a third of the children (35.6%) were diagnosed with a neurosis-like syndrome (25.0%), compared to a much lower rate in the control group (10.7%, ρ<0.01). The study has established the causal link between the incidence of health disorders of children from the exposed area with an elevated phenol level in blood: disorders of nervous system (R2=0.03; F=6.19; p=0.01), blood circulation organs dysfunction (R2=0.99; F=2479.17; p<0.001), digestive system dysfunction (R2=0.22; F=68.10; p<0.001) and urinary system dysfunction (R2=0.43; F = 169.52; p<0.001).

The results of indepth testing and special questionnairing data have shown that 7% of children met the whole set of conditions that permit the conclusion that their disease had been inflicted by environmental factors (i.e. met all the criteria for proving the link between the health harm with the environmental factors):

- Each patient lived in the high exposure area and attended a pre-schol institution in the same area;

- Each child had phenol and one of the cresol isomers in their blood at a rate credibly exceeding the top permissible level for the control group (Mi>M±m). A series of biochemical and immunological indices credibly linked with the levels of chemical contaminants in blood exceeded the top (bottom) limit of the physiological norm (i.e. the effects were expressed and displayed by several individuals, were persistent and biologically credible);

- The diagnosis “Secondary immunodeficient condition (D83.9)" factored in the system of clinical and laboratory indices and functional tests having credible biologically justified

connections with exposure (exposure markers), i.e. the health harm was proven by a complex of indices.

- Neither the medical history nor parent questionnairing revealed any other reasons that could have triggered the health disorders.

So, the health harm on the population and, in a number of cases, individual level, was deemed proven, which was acknowledged by representatives of the factory. The results of the sanitary-epidemiological investigation and expert evaluation made the factory consider using phenol- and cresol-free technologies.

Children who had developed health disorders inflicted by environmental factors received specialized medical treatment.

Using the proposed approach, the health harm and the mass character of incidence of digestion and immune system disorders were proven relating to the population (children) of Krasnokamsk, where drinking water was contaminated with chlor-organic compounds, products of water hyperchlorination. The evidential basis was used in the lawsuit of Perm Krai Office of the Federal Service for Consumer Rights and Public Welfare against the water supplying company "Navogor-Prikamie". As a result, the company was ordered to take mitigation measures, and the local administration was advised to use an alternative water supplier.

Health harm and mass incidence of respiratory disorders among children was proven by a prosecutor's investigation and sanitary-epidemiological expert evaluation following the complaints of residents of the Russkoye Pole industrial area (Kungur, Perm Krai). After the harmful impact was proven, the company took emergency measures to reduce its harmful emissions into the atmosphere before the start of the lawsuit.

A joint pilot project of the Federal Budget Institution of Science and the Saint-Petersburg Office of the Federal Service for Consumer Rights and Public Welfare proved health harm (respiratory, nervous system and sense organs disorders) inflicted on both children and adults living in the proximity of Pulkovo Airport (Saint-Petersburg). The investigation revealed such harmful factors as a high level of equivalent noise and chemical pollution of the air.

Practice has shown that up to 12% of all patients subject to the harmful impact had the full range of indices allowing to attribute their conditions to the environmental impact.

The results obtained lead to the following conclusions:

- The legal framework of the Russian Federation requires the estimation of health harm for a range of causes including the management of sanitary and epidemiological welfare by legal methods;

- A sanitary and epidemiological investigation (study, expert evaluation) including a preliminary examination of the circumstances, health hazard assessment, controlled medical and biological trials, complex statistical data processing, elements of mathematical modeling and logical links analysis permits establishing the fact of health harm and proving the causal link between this harm and the negative impact of environmental factors and sources of such impacts.

- Normative consolidation of the procedure of collecting and presenting the evidential basis of health harm inflicted by negative environmental factors has yet to be completed;

- It is necessary to develop domestic criteria and methodological basis of health harm estimation on individual, group and population levels, including the determination of exposure

and response markers, and to obtain mathematical models of the connection between individual factors and groups of factors with public health indices appropriate for Russian conditions;

- Another important task is to improve the system of chemico-analytical and laboratory methods of building the health harm evidential basis with regard for best laboratory practices, and modern methods of pre-clinical and clinical tests from the perspective of evidential medicine.

- It is also necessary to further develop the practice of health harm estimation to justify a system of preventive and medical measures, plans of actions, unscheduled check-ups, etc., and to expand the practice of lawsuits for compensations for harm inflicted by the impact of environmental factors.

References

1. Ananyev V.Yu. Faktory riska sredy obitaniya, vliyayushchiye na zdorovye naseleniya Primorskogo kraya [Environmental risk factors that affect the health of the population of Primorye Territory]. *Zdravookhraneniye Rossyskoy Federatsii*, 2011, no. 4, pp. 13a.

2. Vlasov V.N. Reaktsiya serdechno-sosudistoy sistemy na sochetannoye vozdeystviye khimicheskikh i fizicheskikh faktorov maloy intensivnosti [Reaction of the cardiovascular system to the combined effect of chemical and physical factors, the low intensity]. *Byulleten Nauchnogo soveta "Mediko-ekologicheskiye problemy rabotayushchikh"*, 2006, no. 1, pp. 47–52.

3. Vorobyov V.A. K voprosu o ponyatii i soderzhanii prava cheloveka na kompensatsiyu vreda, prichinennogo zhizni i zdorovyu [On the concept and content of the human right to compensation for damage caused to life and health]. *Pravo i gosudarstvo: teoriya i praktika*, 2008, no. 1, pp. 37–39.

4. Gildenskiold R.S., Vinokur I.L., Bobyleva O.V., Gorelenkova N.A Risk narusheniya zdorovya v usloviyakh tekhnogennogo zagryazneniya sredy obitaniya [The risk of health problems in man-caused environmental pollution]. *Zdravookhraneniye Rossyskoy Federatsii*, 2003, no. 3, pp. 23–24.

5. Zaytseva N.V., Alekseyev V.B., Kiryanov D.A. Vozdeystviye faktorov okruzhayushchey sredy na reproduktivnoye zdorovye rabotayushchikh zhenshchin fertilnogo vozrasta [The impact of environmental factors on the reproductive health of working women of child-bearing age]. *Ekologiya cheloveka*, 2005, no. 6, pp. 56–59.

6. Zaytseva N.V., Dolgikh O.V., Dianova D.G. Kharakteristika limfotsitarnogo zvena u detey, prozhivayushchikh na tekhnogenno izmenennykh territoriyakh [Characterization of lymphocyte level in children living in areas of technologically modified]. *Laboratoriya*, 2011, no. 1, pp. 10.

7. Zaytseva N.V., May I.V., Balashov S.Yu. Mediko-biologicheskiye pokazateli sostoyaniya zdorovya naseleniya v usloviyakh kompleksnogo prirodno-tekhnogennogo zagryazneniya sredy obitaniya [Medical and biological indicators of the health of the population in conditions of complex natural and man-caused environmental pollution]. *Izvestiya Samarskogo nauchnogo tsentra Rossyskoy akademii nauk*, 2009, vol. 11, no. 1–6, pp. 1144–1148.

8. Kadyrmayeva D.R. Klinicheskoye znacheniye kompleksa faktorov sredy obitaniya v rasprostranennosti ostrykh narusheny mozgovogo krovoobrashcheniya Avtoreferat dissertatsii na soiskaniye uchenoy stepeni kandidata meditsinskikh nauk [The clinical significance of complex environmental factors in the prevalence of stroke dissertation for the degree of Candidate of Medical Sciences]. *Orenburgskaya gosudarstvennaya meditsinskaya akademiya. Orenburg*, 2004.

9. Koldibekova Yu.V. Obosnovaniye biokhimicheskikh markerov tsitotoksicheskikh effektov u detey pri khronicheskoy vneshnesredovoy ekspozitsii aromaticheskikh uglevodorodov [Justification of biochemical markers of cytotoxic effects in children with chronic exogenous exposure of aromatic hydrocarbons]. *Uralsky meditsinsky zhurnal,* 2011, no. 7, pp. 43–46.

10. Kuzmin S.V., Gurvich V.B., Plotko E.G., Selyankina K.P., Makarenko N.P Faktory riska sredy obitaniya i zdorovye novorozhdennykh detey v rayonakh razmeshcheniya predpriyaty alyuminiyevoy promyshlennosti [Risk factors for the environment and health of newborn children in the areas where the aluminum industry]. *Sistemnaya integratsiya v zdravookhranenii*, 2009, no. 1, pp. 40–44.

11. May I.V., Khoroshavin V.A., Yevdoshenko V.S. Algoritm i metody sanitarno-epidemiologicheskogo rassledovaniya narusheny prav grazhdan na blagopriyatnuyu sredu obitaniya s etapom otsenki riska dlya zdorovya [Algorithm and methods of sanitary-epidemiological investigation of violations of the rights of citizens to a healthy environment to the stage of health risk assessment]. *Zdorovye naseleniya i sreda obitaniya*, 2010, no. 11, pp. 28–30.

12. Onishchenko G.G. Vliyaniye faktorov vneshney sredy na zdorovye cheloveka [The influence of environmental factors on human health]. *Immunologiya*, 2006, vol. 27, no 6, pp. 352–356.

13. Protasova V.V., Korenevsky N.A., Artemenko M.V., Smirnov V.S. Issledovaniye vliyaniya ekologicheskikh faktorov na dinamiku urovney serdechno-sosudistoy zabolevayemosti v gorode [Investigation of the influence of environmental factors on the dynamics of the levels of cardiovascular disease in]. *Vestnik Voronezhskogo gosudarstvennogo tekhnicheskogo universiteta*, 2010, vol. 6, no. 1, pp. 123–127.

14. Sadovnikova Yu.M., Zolotnikova G.P. Pokazateli fizicheskogo razvitiya i neyropsikhologichesky status doshkolnikov iz detskikh sadov tekhnogenno-zagryaznennykh urbanizirovannykh territory [Indicators of physical development and neuropsychological status of preschool children kindergarten technologically-contaminated urban areas]. *Ekologiya urbanizirovannykh territory,* 2011, no. 2, pp. 34–37.

15. Simonova N.I., Fasikov P.M., Larionova T.K., Garifullina G.F. Ispolzovaniye biologicheskikh markerov pri otsenke zagryazneniya sredy obitaniya metallami [The use of biological markers in the evaluation of environmental pollution metals]. *Meditsina truda i promyshlennaya ekologiya*, 2008, no. 5, pp. 37–41.

16. Brunekreef B. Environmental Epidemiology and Risk Assessment. *Toxicology Letters*, 2008, vol. 180, no. 2, pp. 118–122.

17. Identifying the environmental cause of disease: how should we decide what to believe and when to take action? UK, London, Academy of Medical Sciences, available at: http://www.acmedsci.ac.uk/index.php.

18. Human Right & Environmental Protection: Linkages in Law & Practice. *Health and Human Rights Working Series*, 2002, no. 1. 174 p.

19. Garte S., Taioli E., Popov T., Kalina I., Sram R., Farmer P. Role of GSTT1 Deletion IN DNA Oxidative Damage by exposure to Polycyclic Aromatic Hydrocarbons in Humans. *International Journal of Cancer*, 2007, vol. 120, no. 11, pp. 2499–2503.

20. Lin A.C. Beyond tort: compensating victims of environmental toxic injury. *Southern California Law Review*, 2005, pp. 1439–1511.

21. Ong C.N., Shen H.M., Chia S.E .Biomarkers for male reproductive health Hazards: are they Available. *Toxicology Letters*, 2002, vol. 134, no. 1–3, pp. 17–30.

22. Phillips D.H. DNA Adduts as Markers of Exposure and Risk. *Mutation Research / Fundamental and Molecular Mechanisms of Mutagenesis*, 2005, vol. 577, no. 1–2 Spec. iss. pp. 284–292.

23. Rosenberg D. The Causal Connection in Mass Exposure Cases: «A public Law» Vision of the Tort System. *Harvard Law Review*, 1984, vol. 97, pp. 849–919.

24. Schulte P.A., Talaska G. Validity Criteria fro the Use of Biological Markers of Exposure to Chemical agents in environmental Epidemiology. *Toxicology,* 1995, vol. 101, no. 1–2, pp. 73–88.

25. Zeka A., Sullivan Ja.R., Vokonas P.S., Sparrow D., Schwartz J. Inflammatory Markers and Particulate air Pollution: Characterizing the pathway to Disease. *International Journal of Epidemiology*, 2006, vol. 35, no. 5, p. 1347.

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