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Оригинальная статья

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Environmental Health Risk Assessment; 16 years of Cooperation between the US EPA, American University and Environmental Institutions of the Russian Federation: Results and Reflections

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Environmental health risk assessment has a long history in both the United States and Russia. Risk assessment methods have arisen and developed to protect against the dangers of the forced use of tens of thousands of chemicals in the modern world. Because chemicals play such an important role, it is impossible to ban their use altogether, and the task of their safe use becomes more and more critical. With the solution of this problem, the creation of modern environmental legislation began, based on an assessment of the hazard or potential hazard associated with the impact of these substances on humans. Risk assessment has become the scientific basis for calculating exposure limits for many chemicals that pollute the environment. Since compliance with environmental legislation is costly to industry, methods have been developed. They are being improved on to quantify the burden of proof and the appropriateness of environmental quality regulation. Environmental Health Risk Assessment was first developed by the United States Environmental Protection Agency (US EPA). Russia has accumulated a great deal of practical experience in assessing environmental risks and developing appropriate methodological recommendations. Thus, the basis was created for long-term cooperation between the two countries. This article summarizes the history of such collaboration, including a joint project to disseminate practical risk assessment in Ukraine.

Keywords: *risk assessment; legislation; unified risk communication system; the maximum allowable level; sanitary protection zone*

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Introduction

Chemicals are everywhere in our world and throughout our economies. The United States' Toxic Substances Control Act (TSCA) requires the US Environmental Protection Agency's (EPA) to "compile, keep current and publish a list of each chemical substance that is manufactured or processed, including imports, in the United States for uses under TSCA" (https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory). According to this inventory there are currently about there are about 85,000 substances. There are exclusions to this inventory, it does not include the hundreds of agricultural chemicals that are generally designed to be toxic; and so, it is not an exact total of chemical substances in the US economy, but it provides background context on the role of chemical compounds in modern life. This is not a "risk-based" list, it is simply a documented list of chemical compounds in industry. But nonetheless, this inventory raises the fundamental question of how to live reasonably safely in a world of chemistry.

One of the most widely used pesticides in the earlier years of industrial agriculture was DDT (dichlorodephenyl-trichlorethane). It was first synthesized in the 1940s and was successfully used to combat malaria and other insect-borne diseases. It was then effectively used for pest control in the US and other countries, but then various insect pests developed resistance. "In 1972, EPA issued a cancellation order for DDT based on its adverse environmental effects, such as those to wildlife, as well as its potential human health risks. Since then, studies have continued, and a relationship between DDT exposure and reproductive effects in humans is suspected, based on studies in animals. In addition, some animals exposed to DDT in studies developed liver tumors. As a result, today, DDT is classified as a probable human carcinogen by U.S. and international authorities." (https://www.epa.gov/ingredients-used-pesticide-products/ddt-brief-history-and-status). This pointed to the need for approaches other than simply banning chemicals. Other compounds, that were not so toxic and/or persistent, could potentially be regulated to manageable levels of use. Risk assessment came into practice to manage potentially harmful compounds, that could potentially be used reasonably safely.

Some Early History of Environmental Risk Assessment in the US

As the practice of risk assessment slowly grew in the US, the National Academy of Sciences (NAS), at the request of the US Congress, reviewed this evolving practice [1]. They reviewed much of the published literature on risk assessment, studied the structures and operations of US federal regulatory and research agencies, and analyzed the history of regulation of selected chemicals. The NAS noted that a number of US Federal agencies that perform risk assessments were challenged to clearly and convincingly present the scientific basis for their regulatory decisions. During that period, decisions on saccharin, nitrites in food, formaldehyde use in home insulations, asbestos, air pollutants and a host of other substances have been called into question. But the NAS recommended that no radical changes in the organizational arrangements for performing risk assessments. Rather, the committee found that the basic problem in risk assessment was the incompleteness of data that were available. Although this is less of a problem now, this is a problem that continues to this day. The roots of the controversies then were due to improvements in scientific and technical capability to detect potentially hazardous chemicals, in changes in public expectations and concerns about health protection, and in the fact that the costs and benefits of regulatory policies fall unequally on different groups within American society. Many of these issues continue today.

As the NAS observed, regulatory actions are based on two distinct elements, risk assessment, the subject of this study, and risk management. Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.

In this landmark report [1], the NAS clarified what has become known as the human health risk assessment paradigm. Risk assessments contain the following four steps: hazard identification; dose-response assessment; exposure assessment; and risk characterization. The NAS went on to say that the greatest improvements in risk assessment would result from the acquisition of more and better data, which decreases the need to rely on inference and informed judgment to bridge gaps in knowledge. And they also recommended that uniform guidelines be developed for the use of federal regulatory agencies in the risk assessment process.

This process of guideline development began at the EPA with the creation of the Integrated Risk Information System (IRIS) by EPA in 1985. The IRIS Program was created to provide an internal database of human health assessments for chemicals found in the environment and to foster consistency in the evaluation of chemical toxicity in the different offices of the EPA (https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#history). In 1986 the EPA published the original cancer risk assessment guidelines [2].

The first author (Brody) came to the practice of risk assessment from the earlier field of environmental impact assessment. His modeling work of hydrologic stress on wetland ecosystems and associated wildlife habitat [3, 4] was analogous to the approach that became ecological risk assessment. And in fact, Brody was one of the co-authors of the EPA's first Agency-level guidance on ecological risk [5]. And this wetlands assessment was written up from the perspective of an ecological risk case study [6]. During the period beginning in 1989, Brody began to apply his modeling skills to exposure analysis for health risk assessment. He did this in the framework of the industrial chemicals program at the EPA, both for new chemicals (https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca) and for the Toxic Release Inventory (https://www.epa.gov/toxics-release-inventory-tri-program).

The second author (Avaliani) first had experience with specialists from the US EPA in 1985 when he attended a World Health Organization (WHO) workshop on air quality guidelines for Europe held in Prague. In 1995 he was a participant in a health risk assessment seminar organized by the Harvard Institute for International Development (HIID) with financial support from the United States Agency for International Development (USAID), and technical and analytical support from the EPA. There were a series of workshops and trainings which led to the

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"Six Cities Project" in Russia, including Volgograd, Perm, Ekaterinburg, Angarsk, St Petersburg and Moscow during the period 1996-1997 (see more in the next section).

Some Early History of Environmental Risk Assessment in the Russian Federation

Risk Assessment began to be used in Russia starting in 1995 through collaboration with the USEPA, the Harvard School of Public Health, and the WHO Regional Office in Europe. Risk assessment training by the USEPA began during the early phases of what became a significant air pollution project in Volgograd [7]. Since those early projects, Russian experts (particularly Avaliani) built programs for continuing professional education in risk assessment for more than 100 experts a year, with currently about 20 regional risk assessment centers across all of Russia. There have been over 100 comprehensive, community-based risk assessments, cost-effectiveness and cost-benefit analyses, and policy recommendations that have been completed in more than 30 regions of Russia. Large industrial companies (Gazprom, oil refineries) have explored the use of risk methods to improve environmental management. Large cities have used risk assessment to mitigate health risk from transport systems and urban development (Moscow City, Voronezh, etc.)

Applications of Risk Assessment / Risk Management Methodology to Environmental Decisions

Risk assessment has been used to ensure safety of populations in the areas of possible impact of industrial facilities, especially to ensure proper design and layout of the sanitary-buffer zones. It has been used for the prioritization of hazardous emissions and sources for regulation. This has better informed federal and local authorities and local populations about environmental conditions; and then to conduct the proactive and preventive measures. This work has led to publications of official guidance documents by governmental authorities [8, 9].

Cooperation in the Field of Environmental Risk Assessment between the US and the Russian Federation, beginning in 2001

Environmental Capacity Building – a USEPA Partnership with the Ministry of Environmental Protection and Natural Resources of Ukraine. In 2001, the first author then with the EPA went to Ukraine to discuss the possibility of a collaborative project in the use of risk assessment for environmental protection, with the Ministry of Environment and Natural Resources (MENR) of Ukraine. Historically, Ukraine had been a major source of industrial production for the former Soviet Union. And eastern Ukraine in particular had many sources of pollution associated with an aging industrial infrastructure. After a second trip that year, the EPA and MENR had a general agreement to pilot the use of risk assessment along with policy-relevant economic analysis to look at priorities for pollution reduction. The regional and municipal governments of Zaporozhe volunteered to participate in this pilot effort. This project was framed as an environmental capacity building project. The main objectives were to provide opportunities for Ukrainian specialists to learn and use risk assessment to see if it might lead to more practical opportunities to help reduce the heavy loads of air pollution [10].

The project began with an international seminar in Kiev, Ukraine in November of 2002; which was where the two authors of this paper first met, along with other key participants in this project. Presentations at the seminar were about project objectives, key aspects of risk assessment as practiced in the US and related experience in Russia and Ukraine.

Ukrainian scientists, local officials, Russian risk experts, and EPA specialists then began a pilot study in the heavily industrialized Zaporozhe Oblast so that the process, analytical tools, and approach for a risk assessment could be developed and specified to the context in Ukraine. The model for this process was based on the development of risk assessment in Russia, particularly under the guidance of Dr. Avaliani. At that time, he was the Director of the Department of communal hygiene of the Russian Academy of Advanced Medical Studies, he also worked at the Research Institute of Human Ecology and Environmental Health named after A.N. Sisin, Moscow. Avaliani had been the lead developer of risk assessment in Russia, and his center was our working model for development of risk assessment capacity in Ukraine.

For the preliminary study [10] the analysis demonstrated that a dominant fraction of health risk came from conventional pollution such as PM_{10} and SO_2. The share of health risk from carcinogens was relatively smaller. The results are similar to those obtained in Russian cities [7]. This initial pilot study demonstrated that this method could be successfully implemented using local primary data and local air dispersion modeling capacity, which is a critical aspect of the risk analysis, as monitoring data can only occasionally be used for risk management.

In the later phases of the study, a much more intensive effort was applied [11]. Much more site-specific information was obtained from multiple sources of air pollution and an emissions inventory of air pollution was developed. Efforts by local scientific experts and environmental officials were critical for constructing the emissions inventory; which was based on the existing Soviet reporting requirements, known as Form 2-TP Air. After refinements were made to the inventory, Ukrainian scientists then performed exposure modeling (with the EPA dispersion model AERMOD) using this information so that ambient concentrations of pollutants could be estimated. 11 out of the 30 industrial enterprises first identified in the preliminary study were identified as major emission sources. The majority of these 11 were metallurgical enterprises.

Results of the modeling effort demonstrated that emissions of particulate matter and a number of carcinogens were consistent with those from other cities with high concentrations of metallurgical industries in other former Soviet Union countries and were above safety standards. Hazard information was gathered from international databases, primarily the Integrated Risk Information System of the USEPA (www.epa.gov/iris).

Particulate concentrations were estimated for 6 receptor points. Since particulate emissions then were still reported as total suspended particulates (TSP), PM_{10} and $PM_{2.5}$ concentrations were extrapolated from modeled TSP concentrations (Table). All receptor point concentrations were significantly higher than the current WHO $PM_{2.5}$ guideline of 10 μg/m^3 (https://www.who.int/news-room/fact-sheets/detail/ambient-(outdoor)-air-quality-and-health) or the EPA standard of 12 μg/m^3 (https://www.epa.gov/criteria-air-pollutants/naaqs-table). Even with the uncertainties related to the quality of the emissions inventories, and the modeling and extrapolations [7, 12] these concentrations are very serious health risks.

Using such data, prioritization and identification of potential health concerns can be made, but most importantly, the expertise and experience gained from the pilot allowed for continued support of risk assessment capacity building in the Ukraine and support by the World Bank. But the most important result of this project was the creation of Center for Environmental Health Risk Assessment, within the O.M. Marzeiev Institute for Hygiene and Medical Ecology,

National Academy of Medical Sciences in Kiev. The Director of Center, Olena Turos, was one of the key experts who participated from the very beginning of the project, including speaking at the opening seminar [13].

Average annual estimated concentrations of the total suspended particles (TSP), PM_{10} and $PM_{2.5}$ (μg/m^3) in Zaporozhye at six receptor points (the values for TSP were obtained from the dispersion model, then the values for PM_{10} and $PM_{2.5}$ were obtained using conversion factors) [11]

Receptor point	TSP	PM_{10}	$PM_{2.5}$	Population size
1	330	180	120	52 958
2	420	230	150	62 146
3	510	280	180	323 963
4	580	320	210	144 292
5	640	350	230	61 695
6	690	380	250	78 978

Project in Russia

The International Science and Technology Center (ISTC) is an international organization that was established in November 1992 as a program to prevent nuclear proliferation and the proliferation of other serious weapons, including chemical and biological weapons by giving scientists and engineers in Russia and other Newly Independent States (NIS) with knowledge and skills of these weapons systems, opportunities to redirect their talents to peaceful activities such as fundamental research, international programs and innovation and commercialization. Projects funded through this program were of all disciplines. And former chemical weapons institutes, with chemists, toxicologists and environmental epidemiologists were well-placed to get involved in projects related to environmental health risk assessment.

The ISTC project #3697, Risk Assessment of human health in the vicinity of plants with a high level of chemical risk by the example of the Maradykovsky chemical weapon destruction facility, was carried out within this framework. It was managed by the USEPA; with a partner institute in the Russian Federation. This was Federal State Unitary Enterprise, “Research Institute of Hygiene, Occupational Pathology and Human Ecology” under the Federal Medical-Biological agency, Russia, Leningradsky Region.

The purpose of this project was to promote a transition among Russian experts to a risk assessment-based analytical approach of potentially harmful emissions - based more consistently on guidance, models and databases of the USEPA. The project scientists were assisted by EPA scientists to become proficient in understanding and carrying out risk assessments that are consistent with general EPA principles and procedures to analyze the potential health risks of the emissions resulting from combustion/destruction of chemical agents/weapons.

The research was focused on the atmospheric pollution directly over the Maradykovsky Chemical Weapons Destruction Facility (CWSDF), at the border of the buffer zone of the CWSDF, as well as in 20 settlements within the Sanitary Protection Zone (SPZ) of the CWSDF, and also on population health parameters in the nearby areas.

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Data from the following sources were used: statistical reporting forms of the facility (form 2TP Air); Maximum Allowable Emissions (MAE) Project of the CWSDF; data of the Environmental Monitoring service at the border of the SPZ of the CWSDF and in the settlements of the SPZ. These settlements included Mirny (2 km from the CWSDF), Bragichi (4.5 km from the CWSDF), and Bystryagi (4.0 km from the CWSDF), where permanent air monitoring was performed at three automated stationary control stations was performed; data from air monitoring at the border of the buffer zone of the CWSDF, obtained by the industrial sanitary laboratory of the Center for Hygiene and Epidemiology.

The Institute's experts calculated the average annual concentrations of the pollutants emitted by the CWSDF, in multipliers of the Maximum Allowable Concentrations (MAC, ПДК). In these calculations the specialists used the appropriate and approved meteorological data for the region, for dispersion modeling. The data were superimposed on the GIS map of the monitored territory for visualizing the results of risk assessment. Here are results of the non-carcinogenic potential risk assessment for nitrogen dioxide, processed with the GIS. Each control point shows the potential risk range from maximum to minimum; it has to be noted that the highest risks (in the industrial zone) are lower than the acceptable risk values or standards. Thus, in this case the analysis did not indicate any serious health risks.

The expertise gained by the Russian scientists in this effort has enabled them to become centers of expertise in risk assessment. This project built upon the ongoing EPA capacity building project in Ukraine. These projects supported the acceptance and continuing use of environmental risk assessment as an extremely practical environmental decision-making tool. So additional Russian scientists have broadened the scope of their activities and have been able help provide risk assessments to other Russian-specific problems.

Final Thoughts and Ongoing Cooperation

Cooperation and communication did not end with the completion of these particular projects. The authors, as well as many of the others cited below in the acknowledgements stay in frequent communication. We share papers, engage in discussions, share questions and answers with each other.

Additionally, Dr. Avaliani created new connections for Dr. Brody in Kazakhstan with another student of Professor Rakhmanin. And risk assessment has been introduced to Kazakhstan under the guidance of Dr. Ussen Kennesariev, formerly of the Kazakh National Medical University [14, 15].

This has been a long-term, very collegial, professional working relationship, but also true friendship between the authors.

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Original article

Afterword

The first Russian-language folder on my computer is called "Avaliani". This is no coincidence. In many areas, Simon, dear to all of us, was the first: no one better than him, except professionals, knew and remembered all football battles, deeply understood and loved jazz, not only the masters of Russian jazz but also many ordinary musicians on the streets of different cities, to which he always approached and began to sing along accurately. When he entered any room, a man of incredible charm - with a smile, tall, handsome, elegantly dressed, as if a tie was chosen to match the suit and shirt - all the women looked prettier. His benevolence towards people was incredible, he never offended anyone, but he was firm in upholding scientific principles and approaches. Even with disagreement with specific passages in the report or publications, he expressed very carefully, without offending the author or listener. This is not an image of an angel, his constant lateness to lectures; meetings took place because everyone needed Simon, could not refuse a person and got stuck on the road due to constant calls. In science, he managed to do a lot. Those provisions of his doctoral dissertation on the time of exposure of toxic substances from the ambient air to the human body for different periods of its activity in urban conditions are incredibly relevant today. Simon Levanovich was the first and one of the founders of a new direction in assessing health risks when exposed to adverse environmental factors

A few additional words to the article by M. Brody and S.L. Avaliani will be presented. For the first time in the world, the methodology for assessing health risks was developed by Academician V. Legasov for radiation and chemical risks back in 1984. In the United States, researchers created a software product for assessing health risks from air pollution and other components of the environment. Thanks to Simon Levanovich and his colleagues, this software product has become an essential tool for improving the quality of the environment and maintaining the population's health. We shall note that the joint Order of the Chief Sanitary Doctor of the Russian Federation G.G. Onishchenko and Chief Inspector of the State Committee for Ecology A.A. Solovyanov 1997 was implemented differently. The Ministry of Natural Resources did not issue any normative documents on environmental risk assessment, and it did not become the direction of work of this environmental department; Federal Service for Supervision in Protection of the Rights of Consumer and Man Wellbeing approved fundamental guidelines for health risk assessment, created a network of professional development courses for health risk assessment specialists in Moscow and St. Petersburg, and published the Health Risk Analysis journal and the journal "Hygiene and Sanitation" constantly publishes articles on this topic; scientific teams in Yekaterinburg, Perm, Angarsk, Irkutsk and other cities are dealing with the problems of public health risks. For the last two years, Simon Levanovich has been actively engaged in assessing health risks in cities included in the Federal Project “Clean Air”.

B. Revich