## SCIENTIFIC AND METHODOLOGICAL APPROACHES TO RISK ANALYSIS IN HYGIENE AND EPIDEMIOLOGY

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## METHODOLOGICAL APPROACHES AND PRACTICES FOR ASSESSING CONSUMERS' HEALTH RISKS CAUSED BY DURABLE GOODS (ON THE EXAMPLE OF CONSTRUCTION AND FINISHING MATERIALS)

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The article deals with an issue related to risk assessment as a criterion of durable consumer goods safety for population health; construction materials and finishing materials are a very relevant example of such goods. We showed that legislative and methodological grounds for assessing such risks were not sufficient. So we developed approaches to risk assessment on the basis of evolution models which allowed to examine risks growth under chronic exposure. We revealed that even if certain goods conformed to sanitary standards set forth by technical regulations they could still cause unacceptable health risks for consumers. And the risks tended to grow dramatically when several goods with similar or identical hazardous effects were consumed together.

We performed epidemiologic and profound medical-biological examinations and obtained authentic mathematical dependencies of correlation between exposure and consumer health disorders; these models are adequate to the data taken from relevant scientific literature. We tested methodological approaches to application of the detected "dose - effect" dependencies for evolution modeling. These approaches were tried out in real-life situations when certain construction and finishing materials were used in precast frame low-rise housing construction. We proved that long living in houses which were built with the use of 7-8 and more polymer-containing materials formed unacceptable risks for citizens' health after 10-12 years. The results we obtained helped to justify a decision that people should moved houses as it was unacceptable to live in them any longer; it was also considered inadvisable to use newly-built and still uninhabited houses of the studied lines for constant living.

Basically, these methodical approaches can be applied in assessing risks caused by a wide range of durable consumer goods.

Key words: durable consumer goods, health risks, risks evolution, technical regulation, chronic exposure, polymer-containing materials.

Durable consumer products are the prod- rable product requires long-term constant or ucts with a long service life to failure, which systematic contact of a person with the goods, takes three years or longer<sup>1</sup>. Purchase of a du- and consequently – with dangers and threats

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<sup>&</sup>lt;sup>1</sup> On approval of the list of durable consumer goods, including components (parts, assemblies, units), which after a certain time-period may pose danger to life and health of a consumer, cause damage to his property or environment, and manufacturer is obliged to establish service-life period in relation thereto, and the list of goods, which, upon expiration, are considered nonsuitable for intended use (with amendments and additions): Resolution of RF Government No. 720 of June, 16, 1997. [esource]. - URL: http://pravo.gov.ru/proxy/ips/?docbody=&nd=102047733 (12.03.2017).

that are the inherent properties of the product (if any). The specified resolution of the government legislatively set forth the list of durable goods, which are potential sources of danger. This is the document of a definite focus – to oblige manufacturers to set a time-period upon the expiry thereof the product loses its consumer properties, and can pose threat to life, health of a consumer, cause damage to his property or environment. It is assumed that the product is safe before the specified time limit. Construction and finishing materials are not subject to this regulation, as they do not have a limited period of safety. However, undoubtedly, by definition, materials used in construction and interior decoration of premises, including residential ones, belong to durable goods.

The system of technical regulation in Russia (as well as in the Eurasian Economic Union, as a whole) defines "safety as the absence of unacceptable risk associated with the possibility of causing harm and (or) causing damage"<sup>2</sup>. During the entire useful life, products should not form an unacceptable risk to health of a consumer. At the same time, "risk" is considered as the "combination of the probability to cause harm and the consequences of this harm to human life or health, property, environment, life or health of animals and plants".

However, the methodology for assessing risk of non-food consumer products, especially

of a long-term use, is being developed only recently [12], and has an extremely poor application practice. In Russian Federation, this situation is conditioned by several reasons.

First, in a number of technical regulations, the definition of safety does not fully comply with the above definition, which eliminates the need for a full-fledged risk assessment procedure. Thus, for example, TR TS "On the safety of furniture"3 defines "...chemical safety as a state of a piece of furniture, in which there is no unacceptable risk associated with causing harm to life and health of a consumer due to exceeded concentration level 4 of harmful chemicals in the premises air" (Article 3). As it follows from the definition, an unacceptable risk to health is absent provided the observance of the standards established by the regulations. The same or similar definitions are contained in the technical regulations "On the safety of products intended for children and adolescents"5, TR TS "On the safety of light industry products"6 and some others. For instance: "Biological safety is the absence of unacceptable health risk due to compliance of biological, toxicological, physical and physicochemical properties with the established requirements". Thus, the conclusions on products safety can be made based on comparative assessment of the products parameters with the established standards. It is specified that, if the excreted impurities that

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<sup>&</sup>lt;sup>2</sup> Agreement on implementation of a coordinated policy in the field of technical regulation, sanitary and phytosanitary measures: Agreement of the Governments of the Eurasian Economic Community member states of January 25, 2008 (as amended on 19.05.2011, with amendments ddt. 10.10.2014) [e-source]. – URL: <a href="http://www.consultant.ru/document/cons\_doc\_LAW\_135270/">http://www.consultant.ru/document/cons\_doc\_LAW\_135270/</a> (10.03.2017).

<sup>&</sup>lt;sup>3</sup> On the safety of furniture products: Technical Regulations of the Customs Union [e-source]/approved by the resolution of the Eurasian Economic Committee Council No. 32 ddt. 15.07.2012 – URL: <a href="http://www.tsouz.ru/KTS/KTS31/Pages/R\_32.aspx">http://www.tsouz.ru/KTS/KTS31/Pages/R\_32.aspx</a> (01.04.2017).

<sup>&</sup>lt;sup>4</sup> This refers to the "maximum permissible concentration".

<sup>&</sup>lt;sup>5</sup> On the safety of products intended for children and adolescents: Technical Regulations of the Customs Union 007/2011 2012 [e-source] /approved by the resolution of the Customs Union Commission No. 797 ddt. September, 23, 2011 – URL: <a href="http://www.tsouz.ru/KTS/KTS31/Pages/R">http://www.tsouz.ru/KTS/KTS31/Pages/R</a> 797.aspx (01.04.2017).

<sup>&</sup>lt;sup>6</sup> On the safety of light industry products: Technical Regulations of the Customs Union [e-source]/ approved by the resolution of the Eurasian Economic Committee Council No. 876 ddt. 09.12.2011 – URL: <a href="http://www.tsouz.ru/KTS/KTS31/Pages/R\_876.aspx">http://www.tsouz.ru/KTS/KTS31/Pages/R\_876.aspx</a> (01.04.2017).

<sup>&</sup>lt;sup>7</sup> GN 2.1.6.1338-03. Maximum permissible concentration of pollutants in the atmospheric air of populated areas: Hygienic Standards (with amendments and additions) [e-source]. – URL: http://www.gosthelp.ru/text/GN216133803Predelnodopust.html (12.03.2017).

have a summation effect are present, this summation must be taken into account. However, the current normative document Hygienic Standards 2.1.6.1338-037 gives a closed list of summation groups. The application of this document, for example, in assessing furniture safety (Annex 2 to the TR TS, the list of excreted standardized chemical impurities is given) makes it possible to take into account only the summation of ammonia and formaldehyde action (group 6005). When assessing the risk of the same materials for the health of a consumer, simultaneous effects on critical organs and systems could be taken into account for a much wider range of impurities [15].

Secondly, the legislation in the sphere of technical regulation is extremely weak in regulating the aspects of assessing goods safety at a long-term, or systematic products using. It is assumed that applying MPC<sub>daily average</sub> as a safety criterion guarantees safety, i.e. absence of risks in case of chronic exposure. At the same time, the established safety standards specified in the regulations of the Customs Union mainly exclude the procedures for assessing health risks. Justification of the risk-based safety standards is the most promising direction for improving technical regulation system [2, 3, 13, 14, 16].

In addition, Federal Law No. 184-FZ<sup>8</sup> contains a provision (clause 7, Article 7), which states that "...technical regulations cannot contain requirements for products that cause harm to life or health of citizens, accumulated with the long-term use of this products ... and depending on other factors that do not allow to determine the acceptable risk level. In these cases, the technical regulations may contain a requirement to inform the acquirer of the possible harm, and the factors it depends thereon".

Thus, a manufacturer shall not be held liable for any negative health consequences that can arise either as a result of long-term continuous use of the same products of short-term, one-time use (food, cosmetic, household chemicals), or as a result of using durable products (furniture, construction and finishing materials, etc.).

It should be noted that this provision does not coincide with a number of principal provisions adopted in global legislation. Thus, the European Union General Product Safety Directive 2001/95/EC <sup>9</sup> admits that products conformity to the criteria, intended to guarantee general safety, does not prevent the possibility for taking the appropriate measures in limiting product release, withdraw or recall from the market, if, despite the specified conformity, this product turns to be dangerous (see Article 3, paragraph 5). Consequently, a situation is admitted where, in observance of all requirements and standards, under real-life conditions, the products can turn to be dangerous for life and health of a consumer.

Third, the risk assessment for non-food products is poorly demanded by the consumers themselves, primarily because of low awareness of the risks. So, for example, according to a number of researchers [9], buyers of construction materials pay attention to the goods production technology in 13% of cases only, but focus more on the price and appearance of a product (more than 70% of respondents). At the same time, informing about the main risk factors and the related health consequences is necessary to develop adequate management decisions to ensure sanitary and epidemiological well-being of the population [4, 6, 8].

In addition to toys, perfumes and cosmetics, goods for children and adolescents, researchers most often pay attention to the need to assess and minimize risks to human health when using polymer-containing construction materials and furniture [1, 5, 17, 18, 20-24]. With respect to the latter, the time factor is quite critical, since these are durable goods.

<sup>&</sup>lt;sup>8</sup> On technical regulation: Federal Law No. 184-FZ of December 27, 2002 [e-source]. – URL: <a href="http://www.consultant.ru/document/consdocLAW">http://www.consultant.ru/document/consdocLAW</a> 40241/Access date: 01.03.2017/ (12.03.2017).

<sup>&</sup>lt;sup>9</sup> Directive 2001/95/EC of the European Parliament and Council of 3 December, 2001 on the general safety of products [e-source] – URL: <u>www.icqc.eu/userfiles/File/directiva%202001%2095%20ec%20gpsd%20ru.pdf</u> (01.03.2017).

The foregoing determined **the purpose of the study** – the rationale for methodological approaches to assessing the risk of exposure to a number of durable goods to human health and testing these approaches in practice to make management decisions on minimizing risks.

As the objects of research, we selected polymer-containing construction materials, used in real-life conditions of precast frame low-rise housing construction, the health of the population living in precast frame houses and brick houses, the air quality in the premises of precast frame houses.

Materials and methods. The health risk assessment was carried out in accordance with the generally accepted stage-by-stage procedure [4, 12], supplementing each stage with indepth studies.

The construction materials hazard was identified according to the technical documentation data for the products, and the results of chamber tests in samples of 18 types of construction materials. The materials chamber research was conducted in accordance with the approved methodology MU 2.1.2.1829-04 "Sanitary and hygienic assessment for polymeric and polymer-containing construction materials and structures intended for use in residential and public housing construction". The chamber impregnation with a construction material corresponded to the real-life average impregnation of the living accommodation with this material. A total of 71 samples of goods were examined for the migration of formaldehyde, ammonia, dioctyl phthalate, diphosphopentoxide, acrylonitrile, dibutyl phthalate, sulfur dioxide and styrene. Chemical impurities quantitative and qualitative analysis was carried out using the generally recognized methods: RD 52.04.186-89, MUK 4.1.598-96, MP 01.022-07, MUK 4.1.1478-03, MUK 4.1.1045-01. Residents exposure to the impurities excreted from the construction materials was estimated by calculations (based on the results of chamber tests, and technical documentation for construction), and by the results of the direct instrumental measurements of indoor air quality. In total, 852 air samples of 152 rooms were selected and analyzed. Based on the questionnaire survey findings, the average duration of stay of different age people was taken into account in the conditions of exposure to the indoor air.

The construction and parameterization of the dose-effect models were performed according to the epidemiological and in-depth medical and biological research, taking into account the relevant literature data on the proven effects of excreted impurities on human health. The resulting paired dependencies were adapted to the evolutionary model of the accumulation of risk to the health of products (goods) consumers. As a computational form of the evolutionary model, a system of recurrence relations recorded for each type of response (health disorder) was adopted in a general form [7, 10, 11]:

$$R_{t+1}^{i} = R_{t}^{i} + (a_{i}R_{t}^{i} + \mathring{a}_{j}^{i}DR_{t}^{ij})C$$
,

where  $R_{i+1}^i$  is health disorders risk from *i*-th response, at a time t+1;  $R_i^i$  is health disorders risk from *i*-th response, at a time t;  $a_i$  is the coefficient that takes into account the evolution of risk due to natural causes.

The study design for the formulation of dependencies included the exposure assessment for the group of observations (the population living in precast frame houses) and the personalized health status assessment based on the findings of the directed biomedical research performed by the experts of the FBSI "Federal Scientific Center for Medical and Preventive Health Risk Management Technologies" (license for medical activities No. FS-59-01-001197). At the final stage of the study, we established and parameterized dependences between the concentrations (as indicators of the population exposure), and the responses in the form of health disorders in the population living in the precast frame houses. To confirm the dependencies obtained, the data of the in-depth health survey of the population living in the precast frame

houses were compared with the survey data of the reference group.

The observation group consisted of 93 people who were permanently living under conditions of a known exposure to chemical impurities excreted from the construction materials of the precast frame buildings (69 adults aged 18 to 83, and 26 children aged 1 to 17). The structure of the observation group was completely determined by the actual living of people in the houses under study. The reference group (79 people), adequate in age and sex composition, was selected from the residents of other territories and houses, at the condition of the absent higher levels of chemical impurities in the air of their houses, excreted from the construction materials.

Examination of the somatic status in the population of the observation and reference groups was identical, and included an in-depth clinical examination by pediatrician, therapist, neurologist, gastroenterologist, allergistimmunologist, and oculist.

Clinical and functional studies were conducted according to traditional methods in compliance with the ethical principles set forth by the Helsinki Declaration (1975, with amendments of 1983) and the Russian Federation National Standard GOST-R 52379-2005 "Good Clinical Practice" (ICH E6 GCP).

Data processing was carried out with statistical methods (Statistica 6.0). To compare the groups and assess reliability, Student's and Fisher's criteria were used. Differences in the results were statistically significant at p < 0.05. The dependencies between the signs were evaluated by single-factor variance and correlation-regression analysis.

Results and discussion. Based on the review of documentation submitted by the developers of the precast frame houses, it was established that up to 9 types of polymer-containing materials were used in the construction of each precast frame house. The materials were directly in contact with the air of the residential housing (covering the walls, ceiling, floor, etc.) or with the air of the rooms

through technical openings (for example, insulation materials).

The results of chamber studies showed that the materials excreted such chemical impurities as formaldehyde (in 29.6% cases, or 21 samples out of 71), xylene (77.8% cases, or 7 samples out of 9), methanol (in 1.4% cases, or 1 sample out of 71) into the air.

Samples of mineral wool  $(0.0071 \pm 0.0014 \text{ mg/m}^3)$ , noise insulation  $(0.005 \pm 0.0014 \text{ mg/m}^3)$ , expanded polystyrene  $(0.003 \pm 0.0014 \text{ mg/m}^3)$ , plywood  $(0.0028 \pm 0.0006 \text{ mg/m}^3)$ , gypsum-fiber sheet  $(0.0027 \pm 0.0005 \text{ mg/m}^3)$  formed the highest concentrations of formaldehyde in the climate chambers air. The excretion of other chemical impurities into the air inside the chambers from the materials samples was at the levels below the determination thresholds of chemical analytical methods.

The chamber studies results for the construction and finishing materials, and the degree of their impregnation in residential premises showed that for almost all of the precast frame houses built within different projects, violations of hygienic standards, in terms of formaldehyde content, were likely expectable. The latter is determined by the migration of impurities to the environment at the combined use of materials, even taking into account the unprotected surfaces shielding. The average calculated concentrations inside the premises, owing to construction and finishing materials, made  $0.018 \pm 0.008$  mg/m³; with the values ranged from 0.011 to 0.025 mg/m³.

The calculated data were satisfactorily correlated with the results of instrumental measurements for the air quality inside the living spaces. The average measured concentration of formaldehyde in the residential space air was  $0.0154 \pm 0.008$  mg/m³. Moreover, during the cold period, the average daily concentrations for formaldehyde reached 0.083 mg/m³ (8.3 MPC<sub>daily average</sub>); in summer days, when the air temperature was 30°C and more, the concentrations were recorded at 0.143 mg/m³ (14.3 MPC<sub>daily average</sub>). The concentrations of other chemical impurities measured (benzene, toluene, ethylbenzene, xylene) did not exceed a tenth of the hygienic standards.

The evidence that contamination is formed by the sources inside the room is enhanced by the measurements of chemical impurities in the air in the immediate vicinity of the residential buildings. The average daily level for formal-dehyde in the atmospheric air did not exceed 0.001 mg/m<sup>3</sup>. As a consequence, further risk assessment of the products was carried out considering formaldehyde as the main hazard factor.

Reviewing the results of the health status' in-depth assessment for the population living in precast frame houses showed that the adult population had higher incidence rates relative to the reference group for respiratory diseases (1.7 times), skin and subcutaneous tissue (1.5 times).

Five logistic dependencies were obtained  $(R^2 = 0.023 - 0.87, p < 0.05)$ , which describe an increase in the population morbidity level, as formaldehyde concentration in the air increases. These dependences were established for the classes of respiratory, skin and subcutaneous tissue diseases (Figure 1), and individual nosological forms of these classes: other allergic rhinitis (J30.3), other atopic dermatitis (L20.8), acute upper respiratory tract infection, unspecified (J06.9).

The results analysis of a comprehensive health status survey of the population in the observation group (as compared to the reference) showed that they have deviations in clinicallaboratory indicators, which may subsequently lead to the formation of morbidity corresponding to the models obtained.

Thus, it was established that formaldehyde content level in the blood of children' population living in precast frame houses was authentically higher than the reference level. Formaldehyde level in the blood of children was  $0.0127 \pm 0.0014$  mg/dm<sup>3</sup> at a reference level of  $0.0041 \pm 0.00041$  mg/dm<sup>3</sup> (p < 0.05).

Nonspecific sensitization of human organism was established in the population of the observation group, as evidenced by the increased value of eosinophilic lymphocyte index by a factor of 1.3 in children in the observation group  $(0.09 \pm 0.02$  conventional units), compared with the children in the reference group  $(0.074 \pm 0.0081$  conventional units) (p = 0.00). In adults of the observation group, this index made  $0.1 \pm 0.013$  conv. units, and exceeded the index of the reference group by 1.4 times  $(0.071 \pm 0.015$  conv. units) (p = 0.003).

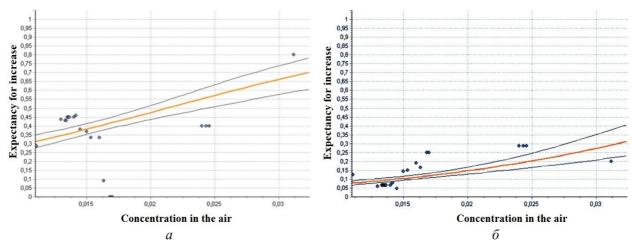


Fig. 1. Expectancy for an increasing morbidity: a – respiratory diseases in the population living in precast frame houses at changes in formaldehyde concentration in the air,  $y = \frac{1}{1 + e^{-(-1,622 + 77,135' X)}}$ , (p < 0,05); b – for skin and subcutaneous tissue diseases class in the population of precast frame houses at changes in formaldehyde concentration in the air,  $y = \frac{1}{1 + e^{-(-3,334 + 81,152' X)}}$ , (p < 0,05)

The higher level in relative number of eosinophils (3.75  $\pm$  0.37%) was recorded in the adult observation group comparing to the reference (2.16  $\pm$  0.38%) (p = 0.0).

In general, 15-17% of the residents had early activation changes in the immune response to formaldehyde, consisting in the increased activation of interleukin-10 in functional samples. The children of the observation group had authentically higher IgE index specific to formaldehyde (1.14  $\pm$  0.36 IU/cm<sup>3</sup> vs 0.746  $\pm$  0.28 IU/cm<sup>3</sup>, p = 0.036).

The paired dependencies obtained and confirmed by the in-depth studies made it possible to construct a model for the evolution of an extra risk for respiratory functions impairment in the residents under the influence of formaldehyde. The general form of the dependence looked like this:

where

 $R_{(t+1)}$  is the risk of respiratory system disorders at time t+1;

g – severity of health disorders in respiratory system diseases:

 $R_t$  – risk of respiratory system disorders at time t;

X – average annual formaldehyde concentration in the indoor air, mg/m<sup>3</sup>;

K – is the inactive concentration of formaldehyde, mg/m $^3$ .

The value recommended by the World Health Organization for upper respiratory tract diseases (g = 0.07) [19] was taken as the severity of a disorder, which allowed to further apply standard risk profile criteria [15].

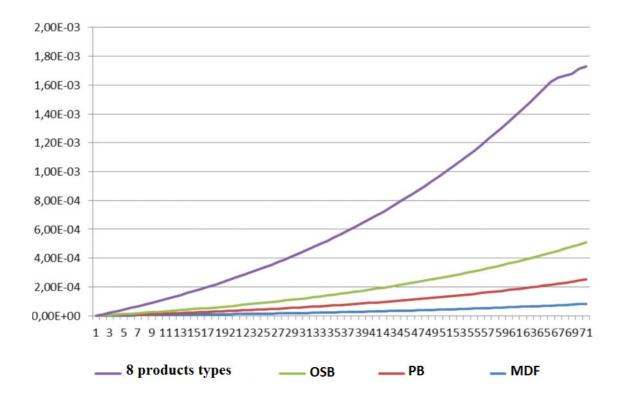


Fig. 2. Model for increasing risks of respiratory diseases in people living under conditions of exposure to formaldehyde excreted in the air of residential buildings from a number of construction and finishing materials.

Health risk parameters to the consumers of construction and finishing materials that excrete harmful impurities into internal environment of premises, when living under specified conditions of exposure to formaldehyde, starting from 0 years

Period of exposure	Linoleum	MDF	PB	OSB	8 types of products
0	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00
1	4,55E-07	9,28E-07	9,28E-07	1,42E-06	7,60E-06
2	9,21E-07	1,88E-06	1,88E-06	2,88E-06	1,54E-05
3	1,40E-06	2,85E-06	2,85E-06	4,37E-06	2,34E-05
4	1,89E-06	3,85E-06	3,85E-06	5,89E-06	3,15E-05
5	2,39E-06	4,88E-06	4,88E-06	7,46E-06	3,99E-05
12	6,26E-06	1,28E-05	1,28E-05	1,95E-05	1,05E-04
25	1,54E-05	3,15E-05	3,15E-05	4,82E-05	2,58E-04
30	1,98E-05	4,05E-05	4,05E-05	6,19E-05	3,31E-04
35	2,48E-05	5,05E-05	5,05E-05	7,73E-05	4,14E-04
40	3,03E-05	6,19E-05	6,19E-05	9,48E-05	5,07E-04
42	3,28E-05	6,69E-05	6,69E-05	1,02E-04	5,47E-04
45	3,66E-05	7,48E-05	7,48E-05	1,14E-04	6,12E-04
50	4,38E-05	8,93E-05	8,93E-05	1,37E-04	7,31E-04
55	5,18E-05	1,06E-04	1,06E-04	1,62E-04	8,65E-04
60	6,08E-05	1,24E-04	1,24E-04	1,90E-04	1,02E-03
65	7,11E-05	1,45E-04	1,45E-04	2,22E-04	1,19E-03
70	8,26E-05	1,69E-04	1,69E-04	2,58E-04	1,22E-03

The resulting mathematical model made it possible to assess the additional risks that being formed for the residents health both with a separate type of product, for instance, wood-fiber-boards (MDF), particle board (PB), oriented strand board (OSB), as well as their combination. A graphical representation example of the risk evolution is shown in Fig. 2.

As the criteria for a risk profile, we used the recommended scale, the risk of serious illness or death, according thereto, was considered acceptable, if it made not more than 1°10<sup>-4</sup> [17]. Exceeding this level was considered as the situation of unacceptable risk.

It's established that a number of materials (linoleum, fiber-board, insulation, etc.), if used separately, do not form unacceptable health risk during the maximum possible exposure period, which was assumed to be 70 years, when living under the specified conditions of exposure to formaldehyde from 0 years.

For a number of products types (particle boards, mineral wool, OSB plates), the critical time point for the transition to the "unacceptable" category is the periods of 15-20 years or longer. However, the most significant finding obtained was the conclusion that cumulative use of a number of durable goods forms unacceptable risks to the health of consumers already after 10-12 years of exposure (please, see the table above).

The results allowed for predicting the unacceptable risk formation scenario for the people living in precast frame houses. The obtained data, among others, provided basis for a conclusion of unacceptability for the people to keep living in the already populated houses, and the inexpediency of using the still uninhabited houses of the studied series for permanent residence.

**Conclusions.** The assessment of the health risk for consumers of durable products is an extremely urgent and compulsory procedure that requires methodological approaches allow-

ing considerations of the risks increasing in a long term.

The obtained results show that products compliance with the established standards is not always a guarantee for the absence of unacceptable health risks, which should be taken into account, in particular, when making decisions on the combined application of certain goods, or when informing users about the risks.

The developed approaches that take into account evolution (growth) of negative health effects in the long-term impact of consumer products are adequate to the tasks for assessing risks of durable consumer goods, and can be used to substantiate a wide range of management decisions aimed at ensuring sanitary and epidemiological well-being of the population

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