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RULES AND RECENT TRENDS FOR SETTING HEALTH-BASED OCCUPATIONAL EXPOSURE LIMITS FOR CHEMICALS

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Abstract
The working environment is the special case of the non-natural environment created by man in which the increased production activity brings about the concentration of stimulators particularly aggressive to the human organism, such as chemical hazards, noise, vibration, extreme temperatures, and finally, intensified psychological and emotional stress. Depending on the nature and intensity, working environment factors have been classified into dangerous, harmful and annoying. The workers are more and more frequently exposed to dangerous chemicals in the working environment. The chemicals cause many diseases including, in the 1st place, respiratory insufficiency, inflammatory skin conditions, psychoneurological disorders and neoplastic diseases. Occupational exposure limit values (OELs), the main criteria for occupational exposure assessment, constitute an important factor for the safe use of chemicals in the working environment. In Poland, to date there are 524 chemical substances and 19 dusts for which maximum admissible concentrations (MAC) have been established.

Key words:
Occupational exposure limit, Chemicals, Legislation, MAC, OEL

THE HISTORY

The history of establishing occupational exposure levels for agents harmful to health in the working environment in Poland begins around 1956. There were 14 substances for which maximum admissible concentration (MAC) values were established without documentation [1]. The values did not differ from those which were at that time valid in the Soviet Union.

Maximum admissible concentrations for chemical agents were published in the regulation of Ministry of Labour, Earnings and Social Policy in 1982 [2]. Since 1983, occupational exposure limits for chemical and physical agents are established by the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment [3].

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On 15th December, 2008, the Prime Minister appointed new members of the Commission [4]. The Interdepartmental Commission includes representatives of the health and labor administration, various sectors of industry, representatives of trade unions, employers and of course representatives of research institutes in the fields of occupational medicine and occupational safety. The main responsibility of the Commission is to consider, evaluate and adopt exposure limits for chemical and physical agents in the working environment and submit them to the Minister of Labor and Social Policy, who is responsible for implementing those values into Polish legislation.

The Commission has appointed a Group of Experts for Chemical and Dust Agents, a Group of Experts for Biological Agents and a Group for Physical Agents. Those groups consist of independent experts in the fields of toxicology, occupational medicine and occupational hygiene. The secretariat of the Commission is based at the Central Institute for Labor Protection – National Research Institute (Figure 1).

The MAC values for chemicals are published in the Journal of Law. These are hygienic standards valid for all branches of the national economy [5].

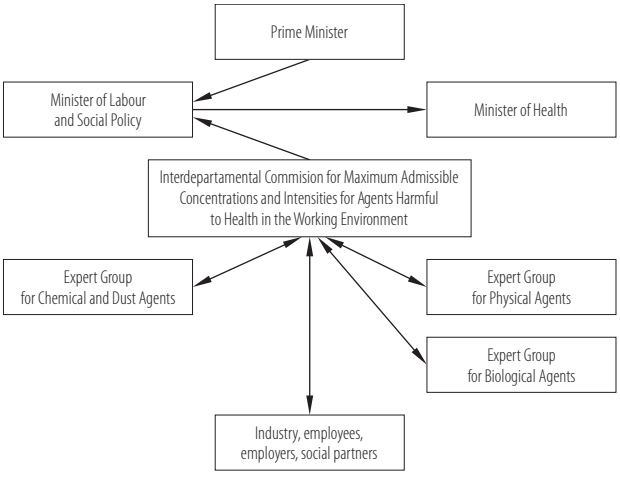


Fig. 1. Polish system for setting occupational limit values of agents harmful to health in the working environment

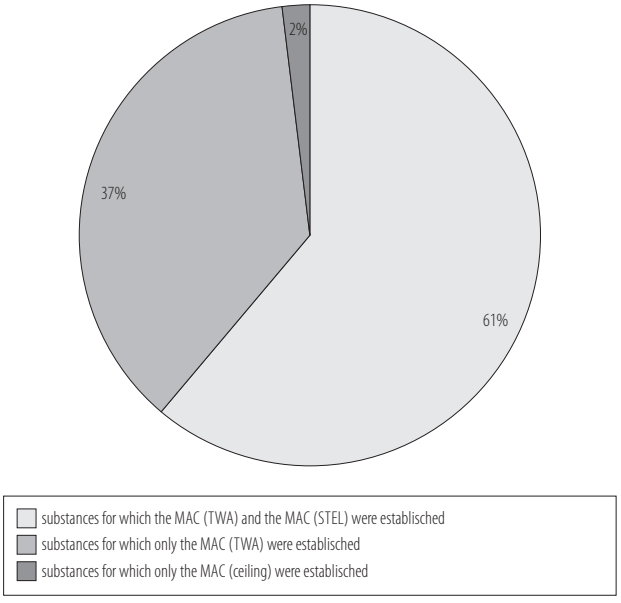
One of the first-in-the-World systems of establishing and revising occupational exposure limits was launched by the non-governmental corporation of industrial hygienists and safety specialists – American Conference of Governmental Industrial Hygienists® (ACGIH) [6]. The ACGIH was formed in 1938 and released its 1st list of OELs in 1941 [7]. In the European Union (UE), since 1995 [8], the Scientific Committee for Occupational Exposure Limits (SCOEL) has been developing indicative occupational exposure limit values (IOELVs) for chemical agents in the working environment. Directives 98/24/EC [9], 91/322/EWG [10], 2000/39/EC [11], 2006/15/EC [12], 2009/161/EC [13] contain current lists of indicative values for 122 chemical substances and binding occupational exposure limit values (BOELVs) for 10 substances (98/24/EC [9], 2004/37/EC [14], 2009/148/EC [15]). In Europe – France, Germany, Sweden, and Finland have developed their national systems of establishing occupational exposure levels for chemicals in the workplace air.

INTRODUCTION

The Maximum Admissible Concentrations of chemicals (MAC (TWA), OELs) are defined as values the effect of which on workers during their whole productive lives should not cause adverse changes in the state of their health and the health of their next generations. The respective values were based on health criteria and assessment of health risk performed using the latest scientific data. The MACs are based on information available from epidemiological and experimental human and animal studies [5].

According to the type of toxic effects and time of exposure, the following categories of MAC values are used:

– MAC (TWA) – maximum admissible concentration (time-weighted average) – the time-weighted average concentration for a conventional 8-hour workday and a workweek defined in the Labor Code, to which workers may be exposed during their whole working lives, without any adverse effects on their health (also when retired) or on the health of the next generations.



MAC (TWA) – maximum admissible concentration – the time-weighted average concentration; MAC (STEL) – maximum admissible short-term concentration; MAC (ceiling) – maximum admissible ceiling concentration.

Fig. 2. The chemicals for which MAC (TWA / STEL) or MAC (ceiling) values were established (524 chemicals in the list in 2014)

– MAC (STEL) – maximum admissible short-term concentration – the short-term exposure limit is an average concentration to which workers may be exposed without any adverse health effects if it does not last longer than 15 min and does not occur more than twice during a workday at interval not shorter than 1 h.
– MAC (Ceiling) – maximum admissible ceiling concentration – ceiling concentration which, because of the threat to workers' health or life, should not be exceeded even instantaneously [5] (Figure 2).

The experts of the Group for Chemicals prepare health-base documentation for recommended occupational exposure limits along with recommendations on pre-employment and periodical medical examinations and contraindications to exposure and, if possible, on biological tolerance limits.

The documentation prepared by experts is thoroughly reviewed at the meetings of the Group, where the recommended values undergo careful scientific evaluation.

Uniform documentation for each compound includes: (1) Contents, (2) Summary, (3) Substance characterization, uses and occupational exposure, (4) Toxic effects in humans, (5) Toxic effects in laboratory animals, (6) Carcinogenicity, mutagenicity, teratogenicity, embriotoxicity, and effects on reproduction, (7) Toxicokinetics, (8) Mechanism of toxicity, (9) Combined effects, (10) Dose-effect and dose-response relationships, (11) Bases for existing MAC or MAI values and biological tolerance limits, (12) Bases for proposed MAC or MAI values and biological tolerance limits, (13) Methods of determining the agents harmful to health in the air and in biological material, (14) Pre-employment and periodical medical examinations and (15) References [1].

There are 3 major independent steps in the Polish procedure, leading to the establishment of MACs:

– an independent scientific expertise phase (only health criteria and assessment of health risk),
– evaluating and adopting exposure limits for chemicals in the working environment by the Commission and submitting them to the Minister of Labor and Social Policy, who is responsible for implementing those values into legislation,
– a social and interdepartmental dialogue phase through consultation on the labor ministry legislative proposal for MACs.

After the Minister's approval, the MAC lists are published in Journal of Law. They are hygienic standards valid for all branches of the national economy.

In the Polish system, the documentation of MAC values is published quarterly in the publication of the Interdepartmental Commission: Principles and Methods of Assessing the Working Environment, which makes it possible for occupational physicians and sanitary inspectors to become acquainted with the problem.

The specified MAC values constitute guidelines for the designers of new and updated technologies and products, criteria for the evaluation of working conditions, and a basis for planned preventive activities in industrial plants. Industrial plants are obliged to estimate concentrations of chemicals to facilitate steps intended to keep them below the values specified in the MAC list, and keep records of those estimates. An improvement of working conditions is the aim of those activities [16].

Setting occupational exposure limits for substances with threshold effects

For many substances, it is possible to establish a level at which toxicological reactions no longer appear if the exposure level is sufficiently low, i.e., such substances show no-observed-adverse-effect level (NOAEL). The adverse effects of chemicals on the organism may be classified either as local (corrosive, irritant) or systemic and remote (genotoxic, carcinogenic, embryotoxic, fetotoxic, teratogenic). The evaluation of adverse effects of occupational exposures is carried out in a case-by-case manner [17].

The NOAEL for critical effects is the common point of establishing the occupational exposure limits, preferably from human data, or from chronic toxicity inhalation studies on experimental animals. The MAC values are set lower than the experimentally determined NOAEL due to the uncertainty factors (UF) reflecting interspecies and intraspecies differences, differences in duration of exposure, issues related to dose-response relationship and quality of data [1].

Uncertainty factor (UF) is calculated using the formula:

$$UF = A \times B \times C \times D \times E \quad (1)$$

where:

A – max 2 – average human to sensitive human,

B – max 10 – for tests using exposures other than inhalation; max 3 – for tests using inhalation exposure,

C – max 3 – short term to long-term exposure,

D – max 3 – extrapolation from the lowest-observed-adverse-effect level (LOAEL) to NOAEL,

E – max 5 – modifying factor (related to expert's opinion on the comprehensiveness and possible long-term effects).

Calculating of MAC values for substances with systemic activity [1]:

1. The dose of the substance absorbed by the animal (D_W), is given in mg/kg/day, and calculated from the formula:

$$D_W = NOAEL \times V \times T/W \quad (2)$$

where:

V – volume of air inhaled by the animal (m^3/day),

T – time of exposure (days),

W – mean weight of the animal (kg).

2. The extrapolation of the dose of substance absorbed by the animal to humans D_C (g/m^3):

$$D_C = D_W \times W_H/V_H \quad (3)$$

where:

W_H – mean weight of the human,

V_H – volume of air inhaled by the human during 8 h.

3. Calculation of MAC value from the formula:

$$MAC = D_C/UF \quad (4)$$

where:

D_C – dose of the substance absorbed by the animal (mg/m^3),

UF – uncertainty factor.

4. Calculation of MAC for irritant substances:

$$MAC = NOAEL/UF \quad (5)$$

Uncertainty factor (UF) to 5 resulting from interspecies differences and human sensitivity.

5. Calculation of MAC values from RD_{50} data (exposure concentration producing a 50% respiratory rate decrease in mice exposed to a geometric series of concentrations of airborne irritants) [1,18].

The above data serve to calculate the values of the MAC for the substances which irritate the airways. A MAC value determined as RD_{50} is selected from the range between 1/10 and 1/100 concentration values causing an irritation in the animals (Table 1).

Table 1. Calculation of maximum admissible concentrations (MACs) from exposure concentration producing a 50% respiratory rate decrease in mouse exposed to a geometric series of concentrations of airborne irritants (RD_{50})

Concentration of substance causing an irritation in the animals	Expected effects of the irritating activity of the substances in humans
RD_{50}	concentration tolerated by humans
1/10 RD_{50}	concentration resulting in slight irritation of eyes, nose and throat
1/100 RD_{50}	none or very slight irritating activity

6. If an experiment is lacking a clear NOAEL/LOAEL, benchmark dose (BMD) is applied in health risk assessment and for setting limit values. BMD is the lower limit of the confidence interval, e.g., 95% for the level of exposure (or dose taken), which may cause a small increase, e.g., 5 or 10% of the incidence of health effects [1].

The MACs refer exclusively to concentrations of chemicals in the air, i.e., the values only prevent adverse effects if no skin absorption occurs. Where contact chemicals with skin can add significantly to the body burden in addition to that caused by inhalation, a skin notation should be used [19]. In Poland, the skin notation (Sk) was set mainly based on a dermal LD_{50} being below 1000 mg/kg and it occurs only in the Commission booklet "Harmful agents in the working environment – limit values" [20].

Setting occupational exposure limits for carcinogenic compounds

For carcinogenic agents, the Polish MAC Commission has adopted socially accepted risk at the level of 10^{-4} to 10^{-3}. That means that Polish society has accepted the possibility of the extra risk of one cancer per 10 000 or 1000 people exposed to a carcinogenic substance. At the same time when MACs are established for compounds that have been proven to be carcinogens or mutagenic, their admissible concentrations are lowered. Enterprises in which carcinogenic or mutagenic substances are found, should strive to eliminate them from technological processes or maintain their concentrations below maximum admissible values, at a possibly low level. Moreover, endeavors should be made to minimize exposure to non-threshold carcinogenic substances [21].

When preparing draft MAC values for carcinogenic substances, health risk assessment resulting from human exposure to the carcinogens can be also used. The following considerations have been valid when performing the assessment based on the results of animal studies [21]:

- The relationship between the dose (expressed in suitable units) and tumor frequency in animals is determined from the results of biological research on animals.
- The dose-response relationship is the same in humans and in the animals.
- Both mg/kg body weight and mg/m^2 body surface area *per diem* may be used as the suitable units of the equivalent dose.
- The carcinogenic activity after received small doses is linear.

The experts who prepare the documentation and propose the MAC for carcinogen or mutagen should use the following terms: risk, accepted risk, unit risk, slope factor [21].

To-date, the MAC values have been set for 49 carcinogenic chemicals and 3 dusts [20,22].

Work involving exposure to carcinogenic agents is prohibited for pregnant and breast-feeding women, and for juvenile workers. This results from the regulation of the Council of Ministers on the list of the types of work that are particularly strenuous or harmful to women's health [23] and the regulation of the Council of Ministers on the list of jobs prohibited for juvenile people [24].

Biological monitoring

Biological monitoring entails the measurement of substances and/or metabolites in biological media, and the measurement of biological effects induced by the substances.

The Interdepartmental Commission also propose BEI values, but they are regarded only as recommended values. They are published in a Commission booklet "Harmful agents in the working environment – limit values." The last issue of the booklet was published in 2012. The Commission has established BEIs for 33 chemical substances [20]. In Poland, only workers exposed to lead in the working environment must be tested for their blood lead content – this test has been made obligatory by the regulation of the Minister of Health of December 30, 2004 on safety and health related to the prevalence of chemicals in the workplace [25].

DISCUSSION AND CONCLUSIONS

The process of harmonizing exposure limits in EU countries began with the establishment of indicative occupational exposure limit values (IOELVs) by the Scientific Committee on Occupational Exposure Limits (SCOEL) [8].

Indicative occupational exposure limit values are health-based, non-binding values established on the basis of newest data and with the use of available measuring techniques. They determine threshold exposure levels below which exposure is not expected to result in adverse health effects [10–13]. IOELVs are necessary for determination and assessment of risk by the employer in accordance with Art. 4 of Directive 98/24/EC [9].

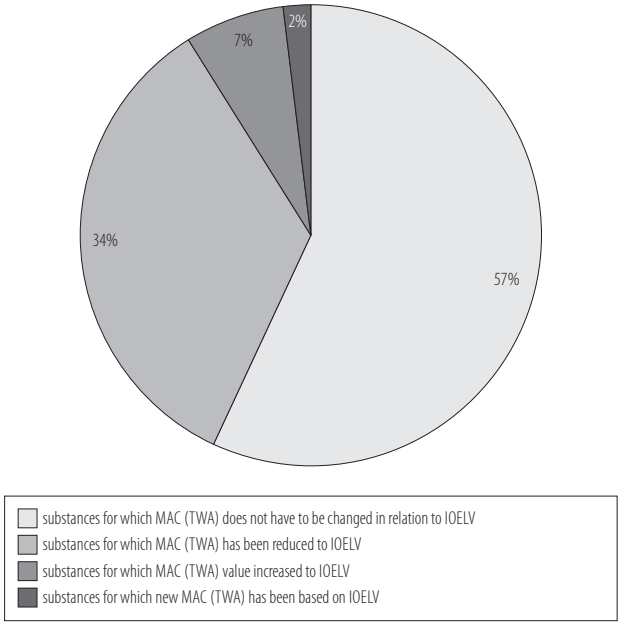
For every chemical agent for which indicative occupational exposure limit values have been established at the Community level, the Member States have been obliged to determine the national occupational exposure value, taking into account the Community admissible value.

For some non-threshold carcinogenic substances for which IOELVs cannot be set, BOELVs (binding occupational exposure limit values) have been adopted. They are established on the basis of currently available scientific data, socio-economic conditions and technical feasibility of achieving these values in industry. Contrary to IOELVs, which are implemented into EU law by the Council Directive, BOELVs are introduced by the decision of the European Commission and European Parliament. For substances for which BOELVs have been set, Member States establish appropriate national values which may be at the same or lower levels than the values established by the EU. The binding values have been set for the following substances: asbestos (actinolite, anthophyllite, chrysotile, gruenerite, crocidolite, tremolite), benzene, hardwood dusts, lead and its inorganic compounds, vinyl chloride monomer [9,14,15].

Transposition of directives containing indicative values for 122 chemicals required inclusion since 2002 to the Polish list of MAC (TWA) 3 new chemicals (2–(2-butoxyethoxyethanol, neopentane, bisphenol A), and reducing the occupational exposure limits for 41 chemicals.

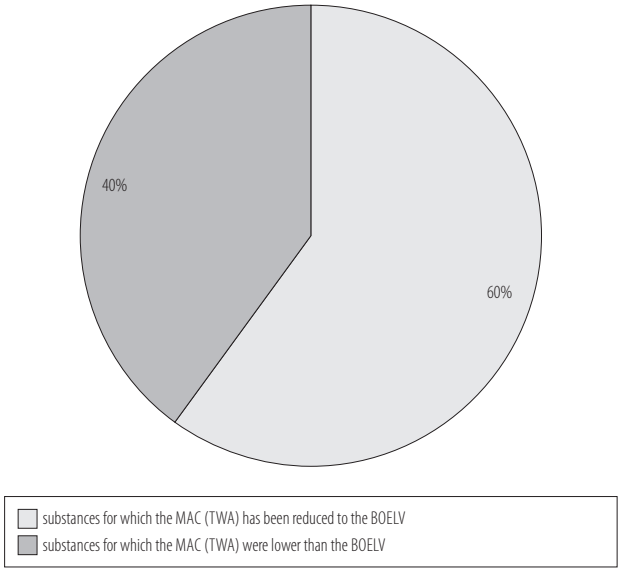
However, for 8 substances (ethylamine, butan-2-one, ethyl benzene, pentane, cresol – a mixture of isomers, N,N-dimethylformamide, methyl methacrylate, 1,4-dioxane) in the light of current data MAC (TWA) value was increased. For 70 chemicals, earlier Polish MAC (TWA) and/or MAC (STEL) values have remained unchanged (Figure 3).

Implementation in the Polish law of the directives specifying the binding limit values resulted in reduction of the MAC (TWA) for dust containing asbestos (6 types). For other 4 compounds (benzene, hardwood dust, lead and its



MAC (TWA) – as in Figure 2.

Fig. 3. Transposition of the directives on indicative occupational exposure limit values (IOELV) for 122 chemicals to Polish regulations



MAC (TWA) – as in Figure 2.

Fig. 4. Transposition of the directives on binding occupational exposure limit values (BOELV) for 10 chemicals to Polish regulations

inorganic compounds, vinyl chloride) MAC (TWA) values are compatible with the EC BOELV values [5] (Figure 4).

The scientific basis for MACs in Poland are in line with EU principles. For some adverse effects (in particular carcinogenicity and genotoxicity), it is – according to current knowledge – impossible to identify such limits. In these cases, the Polish MAC Commission recommends values of the socially accepted risk. The system for establishing MACs has to produce a certain number of new and revised values each year to keep up with the growing number of substances used in the industry.

In a book "Global Occupational Exposure Limits for over 6000 Specific Chemicals" the authors have analyzed over 6000 chemical exposure limits from 50 countries and 15 organizations [26]. They have revealed some interesting variations and trends:

- For a global economy to work satisfactorily, all participants in the working environment should be using the same high standards. They all should be sharing their cumulative knowledge and experience in the area of worker safety and health to the benefit of all.
- The most countries have OELs that date back to 2003 or more recent.
- Most countries have 3 sets of OELs. One for dusts, one for carcinogens and one for volatile or gaseous chemicals. Many countries also have separate standards for lead and asbestos.
- The OEL definition in a number of countries clearly state that OELs do not protect sensitive workers.
- The EU has established minimum uniform OEL standards for all EU countries. These include standards for carcinogens. EU members must adopt these as minimum standards.
- A number of countries adjust their OELs for altitude.
- A number of countries adjust their OELs for standard temperature and pressure.
- Of the 6000+ OELs worldwide, over 4200 are regulated in more than 1 country [25].

The overview on Occupational Exposure Limits (OELs) at the European and Member States level (25 countries in 2007) showed that the levels of OEL values were equal or very similar in most of the Member States. The lowest deviation in some Member States was 50% of the limit value chosen by the majority, in other cases, the highest OEL value was set at 200% of the average Member States value.

The largest difference was identified for acrylamide; OEL values differed by a factor of 10 between 2 Member States at the upper end and 2 Member States at the lowest end.

The same deviations were recorded for the short term and peak levels (10 lists contain such levels), which were also found to be very similar between the Member States.

The sources of scientific background knowledge for OELs are mixed in the majority of Member States. Some Member States have their own scientific committee for the development and discussion of OELs. Many different descriptions and definitions are in use, such as: OELV (IR), WEL (UK) (formerly OES and MEL), OEL (E), LV (DK), LLV (S), MAC (NL, DE, PL) and BOELV/IOELV (EU) [27].

Within the frame of the Community regulation on chemicals and their safe use (REACH), the DNELs (Derived No Effect Levels) have been introduced in Europe [28]. These represent levels of exposure above which humans (including consumers, workers, etc.) should not be exposed. Manufacturers and importers are required to calculate DNELs as part of their chemical safety assessment (CSA) for any chemical used in quantities of 10 t or more per year. DNELs reflect the likely routes and duration and frequency of exposure. If more than 1 route of exposure is likely to occur (oral, dermal or inhalation), then a DNEL must be established for acute and repeated exposure, for each route of exposure and for the exposure from all routes combined. It may also be necessary to identify different DNELs for each relevant human population (e.g., workers, consumers or humans subject to exposure indirectly via the ambient environment) and possibly for certain vulnerable sub-populations (e.g., children, pregnant women) [28].

The starting point in establishing DNELs is a NOAEL or a LOAEL from human data or animal studies. The next step in the calculation of a DNEL is to address assessment factors by extrapolation from experimental data to a real human exposure situation [29]. Thus, up to 15 DNELs may be defined for each substance. DNELs calculated by individual manufacturers and importers are not subject to any requirement for consultation or to any opportunity to be modified by other interested parties [28,29].

The IOELVs or BOELVs are set via a well-established process involving Scientific Committee on Occupational Exposure Limits (SCOEL), governmental, employers' and workers' representatives [30,31].

Which level should be used to assess workers' inhalation exposure in the workplace: an EU IOELV or manufacturer's DNEL?

In the opinion of some scientist, it is unacceptable for limit values that are relevant to occupational exposure, to be set in the context of other EU legislation. But the DNEL for 2-butyne-1,4-diol according to REACH was lower than any corresponding health-based OEL for that chemical. According to the authors, this indicates that the OEL does not provide the appropriate level of protection required by REACH [31].

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