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**WATER AND HEALTH: PRODUCTS, MATERIALS, CHEMICALS/MIXTURES AND EQUIPMENT USED IN CONTACT WITH DRINKING WATER AND PROTECTION OF HUMAN HEALTH – IN ACCORDANCE WITH ORDER NO 275/2012**

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**Introduction**

In Romania, the Ministry of Health, as a central authority and in accordance with the requirements of Law no. 458/2002, regarding the quality of drinking water, Art.10, paragraphs (1) and (2), decided – in 2012 – to regulate the procedures for the sanitary approval of products, materials, chemicals/mixtures and equipment used in the production, transport, storage and distribution of drinking water, including for installations within the residential buildings. The aim was to protect human health from any contamination of drinking water. Protecting public health is done primarily by reducing short-term or long-term exposure to risk factors posed by chemicals in materials that come into contact with drinking water, the values of which may exceed the CMA (maximum allowable concentration) set by law. These substances can migrate rapidly in water and thus be absorbed by being ingested, which can cause acute effects in the body, or they can be released from the structure of the product over time, into water, which can cause cumulative toxic effects.

**Material and methods**

The purpose of the study was aimed to describe the evaluation of the products, materials, chemicals/mixtures and equipment from Romania used in contact with drinking water, as well as to analyze the possible risks on the quality of drinking water determined by the products/components of the products, as well as by the substances released during their use.

The evaluation of products, materials, chemicals/mixtures and equipment used in contact with drinking water was performed by the Commissions of materials in contact with drinking water of the Regional Centers of Public Health from Bucharest, Cluj Napoca, Iasi, Targu Mures and Timisoara within the National Institute of Public Health, Romania. Each commission included a doctor, a biologist and a chemist.

The Health Approval Form and the Notification Form are the official documents issued by the Commission at the level of each Regional Centers of Public Health, based on the product file and technical evaluation report carried out by the experts appointed by the director of the National Institute of Public Health, which were ultimately signed by the Coordinator of each commission and by the Medical Chief of the Regional Center of Public Health.

The materials and chemicals used in the production, transport, storage and distribution of drinking water, including that used for residential installations, have been assessed for the nature of the substances from which they are made and for determining the amounts of substances that migrate or dissolve in water. The scope refers to fixed public or private drinking water supply installations.

Products and their components are made of the following types of materials: organic materials (e.g. plastics, polymers, rubbers, resins, etc.), metallic materials (e.g. pure metals or alloys), cements (e.g. concrete, mortar, etc.), glass materials, other materials (e.g. bituminous, lubricants). Products can be made of a single material (e.g. plastic pipes) or they can be made of several components of different materials (e.g. the water meter has organic and metal components).

Although the components of a product can be tested individually, the product is evaluated and certified as a whole, in accordance with the provisions of the harmonized product standard.



According to the Ministry of Health Order no. 275/2012, on the approval of the Sanitary Regulation Procedure for the placing on the market of products, materials, chemicals/mixtures and equipment used in contact with drinking water, for issuing a Health Approval Form or a Notification Form it is necessary, as a first step, to complete an applications which is registered together with the complete file at the National Institute of Public Health. For the evaluation of this file, it is mandatory – in Romania - that the applicant be registered at the Trade Register!

Sanitary approval is the registration process for products, materials, chemicals/ mixtures and equipment used in contact with drinking water, placed for the first time on the Romanian market, produced for the first time in Romania or imported from third countries. Notification is the registration process for products, materials, chemicals/mixtures and equipment used in contact with drinking water, placed for the first time on the Romanian market and approved in Member States of the European Union.

To receive a Health Approval Form or a Notification Form it is mandatory to submit copies of documents in the product file according to the Ministry of Health Order no. 275/2012 (certificates, approvals, toxicological tests, etc.) with the mention "according to the original", signed and stamped, as well as the original analysis bulletins. The product file must be presented in Romanian or, as the case may be, with a certified translation. In order for a product /equipment/material/substance to receive a Health Approval Form or a Notification Form, the file must contain all the documents required in the order. The presence of a document does not exclude the presence of another document, even if certain information is partially or totally found in that document.

A presentation sheet will include: the field of use of drinking water, a brief description of the product(s), including the components that come into contact with drinking water, the working pressure at which it will be used, the nominal diameters, the temperature as is used the product and the product was tested, the substance of the raw material found in the composition of the product that comes into contact with drinking water.

The producer shall declare the quantitative and qualitative chemical composition of the material (s) in which the product comes into contact with drinking water, written on a separate, signed and stamped document. It is not enough if the applicant submits the data sheet/safety data sheet for the material. Test reports/notifications/approvals obtained in the European Union do not replace the document with the quantitative and qualitative chemical composition with the CAS numbers.

Can be requested from the manufacturer: for plastics (e.g. EPDM, polypropylene, polyethylene, etc.) - the quantitative and qualitative chemical composition for the basic chemicals; for metallic materials (e.g. steel, brass, cast iron) - the quantitative and qualitative chemical composition will be found in the material test certificate, which must be issued to the manufacturer of the material declared by the applicant; for cement products - quantitative and qualitative chemical composition for basic chemicals; for fiberglass in the composition of some products - must be checked to see if it is the type used in contact with drinking water; for filter membranes - quantitative and qualitative chemical composition for basic chemicals; for coating (epoxy paint) - quantitative and qualitative chemical composition for basic chemicals.

The analysis forms/tests performed by laboratories accredited in the field, in accordance with the provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 laying down the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93, are presented in the original.

The analysis form on migration tests or approvals obtained in European Union countries for material in contact with drinking water (obtained by the producer), the safety data sheet of the raw material manufacturer (for the material that comes into contact with drinking water) and the declaration of conformity (the producer given this declaration) in according with the terms of health effects and not in terms of technical tests performed shall be submitted to the file.

The defining indicators for different groups of products and materials, which come into contact with drinking water and which need to be investigated, include cast iron (Cr, Ni, Mn, Fe, Pb, As, Cd, pH, color, turbidity); galvanized steel (zinc coated): Pb, Cr, Cd, Ni, Zn, pH, color, odor; galvanized steel (Pb, Cr, Cd, Ni, Mn, pH); copper based materials (Pb, As, Cu, Cr, pH, flavor, TOC for copper pipes); brass (Pb, Zn, Cd, Sb, Cu, Ni, Sn, pH); bronze (Pb, Zn, Cu, Cr, Cd, Ni, Sn, pH, Al for aluminum-based bronze); rubber (OCD, oxidizability, Cd, Pb, Zn, Ba, phenols, pH, aromatic primary amines, PAU, odor, color, turbidity). It is recommended to check the presence of other organic substances by GC/MS qualitative investigation; polyethylene: OCD, oxidizability, pH, Pb, Cd, Ni, V, phenols, odor, color, other indicators in accordance with the additives used (for colored materials, the metals will be investigated according to the pigments used); polyurethane (OCD, primary amines aromatics, oxidability, pH, odor, color, Cr, Pb, Cd, Ni, phenols), other indicators depending on the additives used (for colored materials, metals are determined according to the pigments used); color, styrene, Pb, Cd, pH, other indicators according to the additives used; polypropylene (OCD, oxidizability, pH, Pb, Cd, odor, color, other indicators according to the additives used); polyvinyl chloride (TOC, oxidizability, pH, Pb, Cd, vinyl chloride), phthalates (for PVC plastic), odor, color, other indicators according to the additives used; polyamides (TOC, oxidizability, Pb, Cd, primary aromatic amines, pH, odor, color, other indicators according to the additives used); epoxy resins: OCD, oxidizability, primary aromatic amines, Cd, Pb, Ba, Hg, phenols, pH, epichlorohydrin, color, turbidity, volatile organic substances (especially benzene, toluene, styrene, ethyl benzene, xylene); painted materials: TOC, oxidizability, Cd, Pb, phenols, pH, color, turbidity, odor, volatile organic substances (especially benzene, toluene, styrene, ethyl benzene, xylene); cements (Cr, Pb, pH, Cd, Al, As, TOC, oxidizability, nitrites, ammonium ions, conductivity, turbidity, color, odor); ceramic and silicate materials (pH, color, odor, turbidity, Pb, Cd, As, Ni, Cr, Al, TOC); ion exchangers (pH, conductivity, oxidability, TOC, Pb, Cd, Cr, odor, color, epichlorohydrin, styrene).

These rules do not apply to the substances used in water disinfection processes, which fall under the scope of Government Decision no. 956/2005 on the placing on the market of biocidal products.

## Results

From 2012 to 2021, the Commission on materials in contact with drinking water from the Regional Center of Public Health Bucharest issued the following: 2012 – 26 Health Approval Form, 2013 – 27 Health Approval Forms, 2014 – 32 Health Approval Forms, 2015 – 12 Health Approval Forms, 2016 – 16 Health Approval Forms, 2017 – 23 Health Approval Forms, 2018 – 23 Health Approval Forms, 2019 – 17 Health Approval Forms, 2020 – 2 Health Approval Forms, 2021 – 23 Health Approval Form and 2012 – 34 Notification Forms, 2013 – 63 Notification Forms, 2014 – 63 Notification Forms, 2015 – 29 Notification Forms, 2016 – 29 Notification Forms, 2017 – 11 Notification Forms, 2018 – 26 Notification Forms, 2019 – 21 Notification Forms, 2020 – 8 Notification Forms, 2021 – 27 Notification Forms.

The files were evaluated taking into account that chemicals dissolved in water can be grouped into 3 (three) categories depending on the impact on human health: threshold toxic substances, genotoxic substances, essential elements.

Contaminants that may have originated in construction materials include metals (e.g. copper, lead and cadmium - released from pipes and welds), asbestos fibers (can be released from the inner walls of asbestos-cement pipes); polycyclic aromatic hydrocarbons (HPA) (from pipe and tank coatings); traces of non-reactive vinyl chloride monomer from PVC pipes; radionuclides from sand and activated carbon used as filter media. Contamination of drinking water with these substances must not occur during water treatment or distribution.

The main types of metal products, which interfered in the water supply networks, for which files were submitted within the Regional Center of Public Health Bucharest were grouped into 2 (two) categories: a) pipes and connecting products (e.g. pipes, tubes, fittings, couplings, etc.) b) mechanical devices (e.g. chemical feeders, vacuum pumps, disinfectors, valves, transmission/distribution systems, devices for treatment processes, etc.). When evaluating a metallic material, the relationship

between the chemical characteristics of the water and its corrosion potential on the metallic elements, as well as the area of the water contact surface will be taken into account.

The main categories of devices and equipment used in water treatment processes for drinking water, used for industrial or residential applications, for which files were submitted to the Regional Center of Public Health Bucharest included: (i) filters: automatic filter equipped with various filter cartridges, portable filter for microbiological water purification, filter cup, etc.; (ii) water purifiers: equipped with filtration systems; (iii) reverse osmosis system; (iv) stations for automatic water softening; (v) equipment for ultraviolet water disinfection; (vi) treatment plant - bottled table water.

In Romania, the Health Approval Form or the Notification Form are valid as long as no change is made in the qualitative and quantitative composition or in the field/conditions of use of the respective product. If during the period of validity of a Health Approval/Notification for a product, material, chemical/mixture or equipment that comes into contact with drinking water it is proved, based on the new European regulations, that it has components that are harmful to public health, the commission will withdraw the issued health opinion/notification.

The evaluation of the products was based on a risk analysis of the quality of the drinking water determined by the products/components of the products by the substances released during their use. In our country, in the Commissions of materials in contact with drinking water, it is practiced to verify the conformity of the substances used for drinking water and then tested in accredited laboratories in accordance with the Positive Lists in the European Union countries where they exist.

A "positive list" is a list of raw materials and excipients (including water migration limits) that are toxicologically permitted for manufacturing the products that come into contact with drinking water. There are 3 categories of "positive lists" adapted to the specificity of each family of materials used: positive lists for organic materials (LP); positive lists for metallic materials - approved compositions (LC); positive lists for materials in the cement category - approved constituents (LCA).

The development of positive lists of substances used for the manufacture of materials under a toxicological evaluation must take into account their ability to transform during manufacture, to fix in the finished material or to migrate on contact with water. The basic materials and components used in the manufacture of products that come into contact with drinking water, and which are not found in the Positive Lists, will be evaluated toxicologically. The necessary toxicological information will be provided by the applicant. The toxicology studies that the applicant submits to the dossier will have to be carried out by a qualified laboratory in accordance with the principle of good laboratory practice, in order to authenticate the results by the legal persons (responsible).

The minimum information needed to evaluate a new substance encompasses acute and chronic toxicity studies and mutagenicity tests. Depending on the results of the studies and/or the chemical structure of the substance, the following may be required: long-term toxicity or carcinogenicity studies; sensitivity effects studies; teratogenic studies; studies on the effect on reproduction. In some cases (suspicious structure, large contact area, clear migration of the substance into the water), information on the toxicity of decomposition products may be required. The sanitary approval of the chemicals used for water treatment is determined by the period of exposure (long-term) and the impurities contained in them. Toxicological risk assessment requires a program similar to that used for food additives. Temperatures were assessed for cold water at  $23\pm 2^{\circ}\text{C}$ , and for hot water at  $60\pm 2^{\circ}\text{C}$ ,  $70\pm 2^{\circ}\text{C}$ ,  $80\pm 2^{\circ}\text{C}$ , and  $90\pm 2^{\circ}\text{C}$  (depending on the product class).

Some European Union Member States have both Positive Lists and a National Institute for managing Positive Lists. Registration of new substances requires a request from the manufacturer accompanied by documentation including studies on the substance concerned and testing (e.g. global migration, OCD, impurities, etc.). In our country, as in most European Union Member States, there are no methodologies for testing starting substances and no national body is authorized to manage positive lists or to accept starting substances, compositions or constituents that can be included on a European positive list of starting substances. To date, we do not have a National Positive List, nor can we list initial substances on the existing European List.

## Conclusions

To ensure the safe hygiene of drinking water, four Member States of the European Union (France, Germany, the Netherlands and the United Kingdom) – known as 4MS - made arrangements in 2011 to work together on this important aspect of the regulatory framework.

Currently, about twenty copper alloys are used in the safe transportation of clean drinking water to our homes and businesses. The copper industry has continuously tested different alloys for compatibility with new EU requirements and adapted the chemical composition of existing alloys. New alloys are currently being tested (after years of research) and submitted for approval and submitted by 4MS, they have committed to publish the documents, after their full agreement.

Authorization of substances that are not on the positive list can lead to their rapid migration into the water and thus causing acute effects within the body (these may be irritating to the respiratory system, hence triggering asthma attacks; irritating to the skin, resulting in itchy skin, and rash such as dermatitis and papules) or may be released from the structure of the product over time, causing cumulative toxic effects (being ingested, these may cause gastrointestinal disorders; in kidneys, these may be associated with an increased risk of developing renal carcinomas).

Toxic substances with a threshold effect are substances that become toxic only above a certain concentration (threshold) - cyanides or nitrates or various metals that are toxic above the threshold concentration, which can be reached gradually by the phenomenon of bioaccumulation. Genotoxic substances (arsenic, some synthetic organic substances, many halogenated organic compounds, some pesticides, etc.) are substances that produce harmful effects: carcinogenic (produce cancer), mutagenic (produce genetic mutations), or teratogenic (produce malformations), possibly in any concentration and for which it has not been possible to establish a threshold below which they are not harmful. The higher the risk, the higher the genotoxic substance, the more likely it is to attack more genes. The essential elements (selenium, fluoride, iodine, etc.) are the substances that must be part of the human diet. Some of them reach the body predominantly or exclusively through water and their lack or deficiency affect the health of the living organisms. At high concentrations, these elements can be harmful, such as toxic substances with a threshold effect.

Drinking water quality is a key factor in health, according to the World Health Organization (WHO). High quality, clean and sufficient drinking water is essential for our daily life, drinking and food preparation. European Union policy ensures that water intended for human intake is consumed safely throughout lifetime and this represents a high level of health protection. The protection of human health against any type of contamination of drinking water and the protection of public health is done primarily by reducing short-term or long-term exposure to risk factors posed by chemicals found in materials that come into contact with drinking water, whose values may exceed the CMA (maximum allowable concentration) set by the law. The contribution of the Commissions for materials in contact with drinking water by assessing the files is a very important endeavor. Improving the quality of life of the population and access to the safe drinking water is a priority for us. The new European Drinking Water Directive have set out standards for drinking water quality, including in terms of materials, chemicals/mixtures and equipment used in contact with drinking water. The main objective still refers to the hygienic safety of drinking water.

**Keywords:** *drinking water, materials, chemicals/mixtures and equipment, positive list, health approval forms, notification forms.*