

REACH Restrictions on the Presence of Some Chemical Substances Toxic to Humans, Animals and the Environment in Articles on the Market in Europe

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ABSTRACT

The aim of this article is to update the restrictions on the presence in Europe of substances toxic to humans, animals and the environment according to regulations by the European Chemicals Agency, the European Parliament and the Montreal Protocol. The following compounds are considered and analysed: one- and two-carbon chlorinated compounds, mercury, cadmium and lead compounds, phthalates, formaldehyde, polymer micro-particles and additives of PVC. The increasing and continuous dissemination of these restrictions exalts the positive side of Chemistry and depresses its negative side.

Keywords: European Chemicals Agency, Polymer, Groundwater, Veterinary and Cosmetic Products, Dental Amalgam, Mercury.

ABBREVIATIONS

ECHA: European Chemical Agency; REACH: Registration Evaluation, Authorization of Chemicals; PVC: Polyvinyl Chloride; RL: Restriction List; WHO: World Health Organization.

INTRODUCTION

The purpose of this article is to report the restrictions on the presence in articles in Europe of substances toxic to humans, animals and the environment by ECHA (European Chemical Agency), by the European Parliament and Commission and only for some substances by the Montreal Protocol, which is a global restriction. The task of ECHA (an institution of the European Community) is to make the REACH Regulation (Registration Evaluation, Authorization of Chemicals) [1] effective, the aim of which is to have safer chemical products on the European market. Two great ambitions drive the leaders of the European Community and ECHA: to make REACH a global legislation, a driver for innovation and to make the European chemical industry more competitive. The main aspects of REACH that will favour innovation are three. The first is the great push for information exchanges that ECHA is encouraging along the entire

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production chain, which for industrial researchers means knowing in advance the needs of the manufacturing industry, of which it is necessary to know promptly the availability of new raw materials and for academics to know in depth the use of chemical products and the related exposure scenarios.

The second aspect is that old and new products have been put on the same level and for both, in order to keep them on the market it will be necessary to demonstrate their safety with regard to humankind and the environment. The third aspect is that there are no constraints for productions lower than 1 t/a, a fact that will allow the development of new products without problems up to the pilot, demonstration scale and in the early stages of marketing. The European restrictions, due to the presence on this market of extremely problematic chemical substances, are introduced by ECHA in the Restriction List for which it is necessary to improve production processes, eliminate or strongly reduce the concentrations in products that contain these substances subject to restrictions and to find alternatives. It is necessary to intervene with green and sustainable chemistry, where, already in the first research phase, the dangerousness along the entire production chain of the substances that are used or synthesized must be assessed. This article reports the restrictions by ECHA [2] on the presence of highly toxic substances in the products on the market in Europe to achieve sustainable development of the following compounds: one- and two-carbon chlorinated compounds, mercury compounds, cadmium compounds, phthalates, lead compounds, formaldehyde, polymer micro-particles and restrictions on PVC additives. In addition, articles are reported on the restrictions, on the presence on the market in Europe, of chemical substances that consist in their elimination from products or a reduction of the concentration limit in products [3].

Restrictions of chlorinated compounds of C1 and C2 hydrocarbons

This paragraph reports the chlorinated compounds of methane, ethane and ethylene, generally used only as intermediates, which are subject to restrictions for their toxicity by ECHA [2] and some by the Montreal Protocol [3] for their negative effects on the environment and generally used only as intermediates. The presence of these substances in various products on the market in Europe is prohibited or permitted only at very low concentrations and many of these chlorinated compounds are accused of being the major

pollutants of groundwater.

The use of some compounds of this family are forbidden by ECHA by the Reach Regulation and some by the Montreal Protocol that is fit the elimination, for this reason it has been not necessary to eliminate them from the market by ECHA, as it is eliminated in all the world, and for this reason is not necessary that it is present in the Restriction List. The phase-out plan of the compounds introduced in the Montreal Protocol includes both the production and consumption of ozone-depleting substances. The Montreal protocol was signed in 1987 and entered into force in 1989 [4]. These chlorinated compounds are stable, they are not miscible with water and are denser and the accusation is that they accumulate in the deepest areas of aquifer systems and in the soil, moreover many of these chlorinated compounds are very toxic for the human race and for the aquatic system [4]. In this family there are three historical pollutants: vinyl chloride which was one of the first molecules considered carcinogenic; chloroform used in the past as an anaesthetic in hospitals; and trichloroethylene which was widely used as a stain remover and degreaser for clothing. Furthermore, chlorinated compounds are under accusation by society not only for their toxicity, but also for the dangerousness of their production. Chlorination reactions are among the most dangerous reactions due to their exothermic nature, the risk of "run-away" (explosion), because they are synthesized largely with chlorine, a very toxic reagent, and for the presence of toxic by-products that can be dispersed into the environment during production. The substances described in this note are used largely as solvents, propellants and refrigerants due to their low flammability and as intermediates due to their reactivity due to the presence of chlorine and/or the presence of the double bond.

Restrictions of chlorinated compounds of C1.

CH_2Cl_2 is present in the Restriction List (RL) [2] in position 59 and it is reported that when it is used for the production of paint strippers must be in a concentration equal or lesser 0,1 % for the following applications: a) when it is placed on the market for the first time for supply to the general public or to professionals after 6 December 2010; b) for supply to the general public or to professionals after 6 December 2011; (c) or it is used by professionals after 6 June 2012. The CHCl_3 (Chloroform), it is present in Restriction List in position 32 [2], and it must not be placed on the market, or used, as

substances and as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1% by weight. This restriction cannot be applied when it is used in industrial installations and present in the following products: medicals, veterinary and cosmetics. Restriction of CCl₄ (Cat.1 stratospheric ozone depleter) is restricted for use worldwide by.

Restrictions on chlorinated compounds of ethane

1,1,1-trichloroethane (methyl chloroform) is category one as a stratospheric ozone (ozonosphere) depleter and is therefore subject to restrictions in products on the market by the Montreal Protocol [3] and is used essentially as a monomer in particular to produce vinylidene chloride (1,1-82 di-chloroethylene), while in the past it was used as a solvent [3]. The following four chlorinated ethane compounds used in the past essentially as solvents are reported the Restriction List [2] in different positions: 1,1,2-trichloroethane, (position 34), 1,1,1,2- tetrachloroethane (position 35), 1,1,1,2 tetrachloroethane (position 36) and pentachloroethane (position 37). These compounds shall not be placed on the market, or used as substances, as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1% by weight, where the substance or mixture is intended for supply to the general public and/or is intended for diffusive applications such as in surface cleaning and cleaning of fabrics. This restriction is not valid for medicinal, veterinary and cosmetic products. Esachloroethane (position 41) [2] shall not be placed on the market, or used, as substance or in mixtures, where the substance or mixture is intended for the manufacturing or processing of non-ferrous metals.

Information on Ethylene chlorinated

Chloroethene (vinyl chloride) has been introduced in "Restriction List" in position 2 [2] and it shall not be used as propellant in aerosols for any use. There is no restriction in the production of PVC as practically it is not present. 1,1-dichloroethene is present in Restriction List in position 38 [2] with the following restrictions: shall not be placed on the market or used as substances, as constituents of other substances, or in mixtures in concentrations equal to or greater than 0.1% by weight, but can be used in industrial environments, with the exclusion of the cosmetic, pharmaceutical and veterinary industries. This chlorinate

compound is now used essentially as a monomer to produce polymers and copolymers with other monomers.

Restrictions on mercury and its compounds

This paragraph refers to the presence in the restrictions in the Restriction List of ECHA [2,8] on the use of mercury in instruments, industrial applications and on the use of products containing metal organic and inorganic chemical compounds of mercury; several compounds of mercury and in particular compounds based on phenyl-mercury [8]. Furthermore, are reported the recent proposals of the European Parliament and Commission to eliminate dental amalgam and some lamps containing mercury are reported, with the aim of significantly reducing the presence of mercury on the European market.

Mercury and its compounds are extremely toxic to humans, ecosystems and wildlife [10,11], high doses of mercury can be fatal for humans, but even relatively small quantities can have serious negative effects on neurological development. A possible link with negative effects on the cardiovascular system, the immune system and the reproductive system has been identified [10]. Mercury is considered a persistent pollutant on a global scale that circulates, in various forms, in air, water, sediments, soil and biota and that, dispersed in the environment, can transform into methyl mercury, its most toxic form. Mercury compounds cause severe skin burns, serious eye lesions and organ damage in case of prolonged or repeated exposure. Furthermore, they are suspected of damaging fertility or the fetus and are very toxic to aquatic organisms. Mercury is considered by the World Health Organization (WHO) to be one of the 10 chemical substances (or groups of substances) that cause the greatest concern for the effects it can produce in the exposed population [12].

Restrictions of mercury compounds

In position 18 of the Restriction List are reported the following restrictions of mercury compounds (metal-organics and inorganic) that are used as substances or in mixtures to prevent the fouling by micro-organisms, plants or animals for the following uses: for the hulls of boats, cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, and or partly submerged appliances or equipment; for the preservation of wood; in of heavy-duty industrial textiles and yarn intended for their manufacture; in the treatment of industrial waters, irrespective of their use.

Restrictions of mercury

In the Restriction List [3] in position 18a are reported the restrictions of the use of mercury that will start from 10 April 2024 in the following apparatus: in fever thermometers; in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers; mercury pycnometers; mercury metering devices for determination of the softening point (devices intended for professional and industrial uses).

These last restrictions shall not apply: in sphygmomanometers to be used in epidemiological studies which are ongoing on 10 October 2012 and as reference standards in clinical validation studies of mercury-free sphygmomanometers; in thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; in mercury triple point cells which are used for the calibration of platinum resistance thermometers. The previous restrictions shall not apply also to the following applications: to measuring devices that were in use in the Community before 3 April 2009; to measuring devices more than 50 years old on 3 October 2007; to measuring devices which are to be displayed in public exhibitions for cultural and historical purposes to barometers until 3 October 2009.

Restrictions for phenyl mercury compounds

In the Restriction List in position 62 [2] are reported that Phenyl mercury acetate, Phenyl mercury propionate, Phenyl mercury 2-ethyl hexanoate, Phenyl mercury octanoate and Phenyl mercury neo-decanoate are subjected to the following conditions of restrictions: shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01% by weight. These products are primarily used as catalysts in polyurethane systems for coatings, adhesives, sealants and elastomer applications. These compounds remain in the final article, from which mercury can be released into the environment producing methyl mercury, which is highly hazardous.

Proposals of restrictions from European Parliament

The June 2024 [13,14], the European Parliament and Council reported the need for the Union to regulate emissions of mercury and mercury compounds from crematoria, the feasibility of phasing out the use of dental amalgam and phasing out mercury in electronic lamps.

From 1 January 2025, dental amalgam shall not be used for dental treatment in the Union, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient and shall be banned also the export. By 31 December 2029, the Commission shall report to the European Parliament and to the Council on:

(a) The implementation and impact of the guidance, developed by the Commission by 31 December 2025,

(b) Abatement technologies for emissions of mercury and mercury compounds from crematoria applied in Member States;

The export, import and manufacturing of mercury the following lamps containing mercury will be eliminating with following data: tri-band phosphor lamps for general lighting purposes the 31.12.2027; halophosphato phosphor lamps for general lighting purposes the 31.12.2025 4c: non-linear triband phosphor lamps; the 31.12.2027 non-linear halophosphate phosphor lamps; the 31.12.2025 high pressure sodium (vapour) lamps (HPS) for general lighting purposes the 31.12.2025.

The restrictions of the phthalates

This paragraph reports the restrictions on the use of phthalates (phthalic acid alkyl esters), which are produced by the reaction of phthalic anhydride with linear and branched C4 to C10 atoms of alkyl alcohols [2]. Phthalates are a family of organic chemicals used largely as plasticizers to give flexibility, deformability and resilience to polymers, but they are also used as solvents and optimizers of the consistency and yield of various products [15,16]. Phthalates are the most widespread plasticizers in the world and have been used for decades essentially in the processing of polyvinyl chloride (PVC), helping to make it more flexible and soft. There are also other products on the market that use phthalates: cosmetic creams, shampoos, adhesives, paints, pesticides, containers of various kinds (including food and fast food), bags, cables and packaging materials. Many phthalates are toxic for reproduction of cat. 1B and also endocrine disruptors. An important accusation against their use is that foods can contain phthalates, both emitted by the containers that contain them, and as contaminants of the soil and, consequently, of agricultural products and animal feed [17-19]. Furthermore, the other accusation is that all products containing phthalates used in products aimed at children (currently only those of

extra-European origin) are high risk, because they can be sucked and/or chewed, and so the phthalates can be ingested and easily migrate outside the products.

Phthalates with higher number of carbon atoms are called 1,2-benzenedicarboxylic acid, di-x-y branched alkyl esters.

Phthalates in position 51 of Restriction List

In the Restriction List [2] in position 51 are 188 reported the following phthalates: di-butyl phthalates (DBP), di-isobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl) phthalate (DEHP). The restriction for these phthalates are the followings: shall not be used, as substances or in mixtures, in a concentration equal to or greater than 0,1 % by weight of the plasticized material, in toys and childcare articles ('childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children); and starting from 2016 shall not be placed on the market. From July 2020 in all articles, individually or in any combination of the previous phthalates in a concentration equal to or greater than 0,1 % by weight of the elasticized material.

These restrictions are not applied for the following articles (a) those used exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticized material comes into contact with human mucous membranes or into prolonged contact with human skin; (b) those ones for aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; (c) those ones used in motor vehicles placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; (d) in articles placed on the market before 7 July 2020; (e) in measuring devices for laboratory use, or parts thereof; (f) in materials and articles intended to come into contact with food; (g) medical devices; (h) electrical and electronic equipment (i) the immediate packaging of medicinal products.

Phthalates in position 52 of the Restrictions List

In the Restriction List [2] are reported in position 52 the following phthalates: di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP),

1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich. These phthalates are subjected to the following restrictions: from 12 March 2015: shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the elasticised material, in toys and childcare articles (articles which can be placed in the mouth by children).

Restrictions on Cadmium Compounds

In this paragraph are reported the restrictions of cadmium and cadmium compounds in several articles [2,18,19], we shall start with the information on the use of cadmium in the world reported on the website of the "International Cadmium Association" [20-22], the world association of producers of cadmium compounds. Cadmium is an element discovered in Germany in 1817, as a by-product of zinc refining. Its name derives from the city of Cadmia in Thebes, where the mineral containing zinc was extracted. The first products that used cadmium were dyes based on cadmium sulfide, which had been used at the end of the nineteenth century by van Gogh for its bright colors, in particular red, orange and yellow. Later, Thomas A. Edison in the United States and Waldemar Junger in Sweden developed the first nickel-cadmium batteries at the beginning of the 20th century. In 2019, 25,000 t of cadmium were used worldwide, with the largest use being in rechargeable Ni-Cd batteries (73%), followed by the production of metal alloys with other metals for welding, electrical conductors and other uses (16%), coatings and plating (4%), dyes (3%), stabilizers for plastics (2%) and others (1%). Cd-Te alloys are used in photovoltaics to absorb light and transform it into electricity, and the following other alloys are available on the market for various applications: Cd-Cu, CdZn, Cd-Pb, Cd-Ag, Cd-Sn, Cd-Se and Cd with many precious metals. For example, cadmium-zinc sulfide and cadmium-selenium sulfide are used in dyes for glass, ceramics, metals and plastics, with the property of being resistant to light and heat. Cadmium-based stabilizers for plastics and in particular for PVC, for example cadmium stearate, have the property of increasing the resistance to heat, sunlight and corrosion of plastic articles; these stabilizers, in the past, were the most used in Europe, but currently their use has been prohibited, even before it was born. The toxicity of cadmium [22] and of cadmium compounds [23] is well known and it is evidenced from the fact that are inserted in Restriction List just after the compounds of arsenic and lead.

The restrictions of cadmium and its compounds

In position 23 of the Restriction List of ECHA [2] are reported the restriction of metallic cadmium, inorganic and organic cadmium compounds for several applications. In the restriction lists there are 9 compounds (also metallic cadmium) used in Europe in amount >1 t/a and other 287 compounds those used in Europe in amount >1 t/a and, many other compounds not used in Europa, practically all known cadmium compounds. As an example of some cadmium compounds that are on the market in Europe and are in the "Restriction List" and also well-known on the market are the following: cadmium telluride, cadmium selenide, cadmium selenium sulphide and finally cadmium zinc sulphide yellow. These 296 cadmium compounds when they are used in mixtures and in articles for the production of plastic materials they shall not be placed on the market if the concentration of cadmium (expressed of metal cadmium) equal or higher 0,01 % by weight of the plastic material. This restriction cannot be applied to articles placed on the market before December 2011.

The cadmium compounds used on the market in paints with codes the concentration of Cd must be lesser than 0,01 % by weight. For paints with codes with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium metal must be lesser 0,1 % by weight of the paint. Beside painted articles shall be placed on the market only if the concentration of cadmium metal is lesser than 0,1 % by weight of the paint on the painted article. By way of derogation, these restrictions shall not apply to articles coloured with mixtures containing cadmium for safety reasons. In mixtures produced from PVC wastes, the concentration of cadmium metal must not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications: profiles and rigid sheets for building applications; doors, windows, shutters, walls, blinds, fences and roof gutters; decks and terraces; cable ducts; pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC. The use of cadmium plating, that means any deposit or coating of metallic cadmium on a metallic surface, is not allowed in the following equipments and machinery: for food production in agriculture; for cooling and freezing; for printing and book-binding; for the production of household goods, furniture, in sanitary ware, in central heating and air conditioning plan. Further restrictions

are in equipment 266 and machinery for the production of the following materials: paper and board; textiles and clothing; equipment and machinery for the production of industrial handling equipment and machinery; road and agricultural vehicles; rolling stock and vessels.

However, these restrictions shall not apply to articles and components of the articles for the following uses: in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed.

Other restrictions are in brazing fillers (brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C) these articles shall not be placed on the market if the concentration of cadmium metal is equal to or greater than 0,01 % by weight. This restriction shall not apply to brazing fillers for the followings uses: in defence and aerospace applications and in applications used for safety reasons. The last restrictions are on cadmium used in metal beads and other metal components for jewellery making and metal parts of jewellery and imitation jewellery articles and hair accessories. In these applications cadmium shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of cadmium metal. These jewellery includes bracelets, necklaces and rings, piercing jewellery, wrist-watches and wrist-wear, brooches and cufflinks. By way of derogation, all these last restrictions shall not apply to articles placed on the market before, 10 December 2011 and for jewellery more than 50 years old on 10 December 2011.

Requests for further restrictions

It is important to remember that in 2015, by an ECHA commission [23] it has been published the Annex XV Report Assessment, whether the use of cadmium must subject to more restriction and it was proposed to extend the restrictions on the presence of cadmium in a greater number of polymers than those reported in the "Restriction List" and only some of those requested to be included in the new restrictions will be reported: polytetrafluoroethylene, polyethylene tetrafluoroethylene polyamide, silicone, poly-acrylonitrile-butadiene-styrene, fluorinated ethylene and propylene and others. However, no extension of the restrictions to other

polymers has been achieved so far and for the Association of Cadmium Industries these further restrictions should not have been achieved, because according to them, the contamination of the human race by cadmium came essentially from emissions from incinerators from the use of fertilizers, from the production of metals and from cigarette smoke, not from plastics, but there is some doubt about these interpretations. However, the danger of the presence of cadmium in Europe, even today, and the need for future restrictions, is highlighted by the recent directive of the European Community. In it, restrictions on the concentration of cadmium in many food products, present on the market in Europe, have been increased, for example the limit concentration of cadmium in meat must be <0.05 mg/kg [24]. The toxicity of plant and animal substances is not a problem within the competence of ECHA, because they are not chemical substances, but the presence of cadmium in these food products is indirectly linked to the use of chemical products that contained cadmium used in the past and that have contaminated the soil, and also those that contain cadmium still present on the market in Europe, which continue to contaminate the environment. Therefore, further restrictions on the use of cadmium in many articles present in Europe are expected within the scope of the Reach Regulation in the coming years.

Restrictions of lead and lead compounds

In this paragraph we will report the ECHA restrictions on the presence of organometallic, inorganic and even metallic lead compounds in products on the market in Europe [2,25]. The 70% largest use of lead in the world today is in batteries for electric and hybrid cars and in energy accumulators, and to a lesser extent in bullets for weapons, in fishing tools, in metal alloys, in PVC stabilizers, in safety systems for aircraft and in radiotherapy equipment in hospitals. It is interesting to remember that there is a consortium called precisely "Lead (Pb) Reach Consortium" [28] which is an initiative created by the "International Lead Association" (the association of industries that produce or use lead), which has the objective of highlighting the vital, safe and sustainable use of lead in their industries at ECHA and countering its proposals for restrictions on the use of lead within the Reach Regulation, before they are officially approved.

Lead compounds in position 16 and 17 of the Restriction List

The first lead compounds included in the "Restriction List"

were: PbCO_3 , and $2\text{PbCO}_3 + \text{Pb}(\text{OH})_2$ in position 16[2]; PbSO_4 and the mixture $\text{PbSO}_4 + \text{H}_2\text{SO}_4$ in position 17 [2]. These compounds shall not be placed on the market, or used, as substances or in mixtures, when they are used in paints, but their use is permitted for the restoration and maintenance of works of art and historic buildings and their interiors. It is interesting to underline (to highlight their dangerousness) that these lead compounds were included in the "Restriction List" immediately before those of mercury and arsenic whose toxicity is well known.

Lead compounds in position 62 of the Restriction List

In the Restriction List in position 62 [2] are present the following compounds: phenyl mercury acetate, phenyl mercury propionate, phenyl mercury 2-ethylhexanoate, phenyl mercury octanoate and phenyl mercury neodecanoate. The restrictions for these compounds are the followings: shall not be manufactured, placed on the market or used as substances or in mixtures articles or any part after 10 October 2017 if the concentration of mercury in the mixtures equal to or greater than 0,01 % by weight. These five phenyl mercury compounds are known to be used especially as catalysts in polyurethane systems used for coatings, adhesives, sealants and elastomer applications. The mercury catalysts are incorporated into the polymer structure and remain in the final article from which mercury or phenyl mercury compounds are not released intentionally.

Lead compounds in position 63 of the Restriction List

In the Restriction List in position 63 [2] under the heading "lead and its compounds" 648 inorganic and organometallic lead compounds have been inserted in addition to metallic lead, in this group there are those compounds which are used in Europe in quantities > 1 t/a, those used in quantities < 1 t/a and therefore not subject to control for their use and those not used in Europe, practically all known lead compounds. All the previous substances containing lead, not yet present on the market in Europe or present in low quantities have been inserted in the "Restriction List" to prevent them from being used, when those already present on the market would have been subject to restrictions due to their toxicity and dangerousness in their use. In the Restriction List there are restrictions for the use of all compounds in many articles and all the 648 compounds shall not be placed on the market or used in any individual part for several articles reported separately in the restriction List.

Lead and its compounds must be present in jewellery articles in concentration of lead (expressed as metal) lesser 0,05 % by weight. The 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, and are the followings: bracelets, necklaces and rings; piercing jewellery; wrist watches and wrist-wear; brooches and cufflinks. These restrictions shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961.

These previous restrictions are not applied to the following articles: crystal glass; internal components of watch timepieces inaccessible to consumers; non-synthetic or reconstructed precious and semiprecious stones unless they have been treated with lead or its compounds or mixtures containing these substances; enamels, defined as verifiable mixtures resulting from the fusion, verification or sintering of minerals melted at a temperature of at least 500 °C. Leads and compounds that during normal or reasonably foreseeable conditions of use, can be placed in the mouth by children shall be placed on the market or supplied to the general public, with a concentration of lead (expressed as metal) lesser 0,05 % by weight. All the 648 compounds of lead cadmium present in articles produced from polymers or copolymers of vinyl chloride ('PVC') [26] that shall be placed on the market or used with a concentration of lead lesser 0,1 % by weight of the PVC material. This restriction was start from 29 November 2024, but they it is not applied to PVC articles containing recovered flexible PVC until 28 May 2025 and articles containing recovered rigid PVC until 28 May 2033, if the concentration of lead is lower than 1,5 % by weight of the recovered rigid PVC.

These restrictions on PVC compounds are not applied to the following articles:

- (a) profiles and sheets for exterior applications in buildings and civil engineering works, excluding decks and terraces;
- (b) profiles and sheets for decks and terraces, provided that the recovered PVC is used in a middle layer and is entirely covered with a layer of PVC or other material for which the concentration of lead is lower than 0,1 % by weight; profiles and sheets for use in concealed spaces or voids in buildings and civil engineering works (where they are inaccessible during normal use, excluding maintenance, for example, cable ducts); profiles and sheets for interior building applications, provided that the entire surface of the profile or sheet facing

the occupied areas of a building after installation is produced using PVC or other material for which the concentration of lead is lower than 0,1 % by weight; multi-layer pipes (excluding pipes for drinking water), provided that the recovered PVC is used in a middle layer and is entirely covered with a layer of PVC or other material for which the concentration of lead is lower than 0,1 % by weight; (f) fittings, excluding fittings for pipes for drinking water. From 28 May 2026, rigid PVC 380 recovered from the first four categories of previous articles shall only be used for the production of new articles of any of those categories. The following further restrictions of lead compounds have been proposed, by the European Commission on 10 February 2022 [27] to be included in the REACH Regulation: restrictions on the use of bullets and shot containing lead for hunting and sporting activities for all outdoor activities, not only in wetlands, as previously legislated; furthermore, it has been proposed that restrictions should be applied to the use of lead in fishing gear (sinks and bait, nets, ropes and lines).

Lead compounds in position 62 of the Restriction List

In the Restriction List in position 62 [2] are present the following compounds: phenyl mercury acetate, phenyl mercury propionate, phenyl mercury 2-ethylhexanoate, phenyl mercury octanoate and phenyl mercury neodecanoate. The restrictions for these compounds are the followings: shall not be manufactured, placed on the market or used as substances or in mixtures articles or any part after 10 October 2017 if the concentration of mercury in the mixtures equal to or greater than 0,01 % by weight. These five phenyl mercury compounds are known to be used especially as catalysts in polyurethane systems used for coatings, adhesives, sealants and elastomer applications. The mercury catalysts are incorporated into the polymer structure and remain in the final article from which mercury or phenyl mercury compounds are not released intentionally.

Lead compounds in position 63 of the Restriction List

In the Restriction List in position 63 [2] under the heading "lead and its compounds" 648 inorganic and organometallic lead compounds have been inserted in addition to metallic lead, in this group there are those compounds which are used in Europe in quantities > 1 t/a, those used in quantities < 1 t/a and therefore not subject to control for their use and those not used in Europe, practically all known lead compounds.

All the previous substances containing lead, not yet present on the market in Europe or present in low quantities have been inserted in the "Restriction List" to prevent them from being used, when those already present on the market would have been subject to restrictions due to their toxicity and dangerousness in their use. In the Restriction List there are restrictions for the use of all compounds in many articles and all the 648 compounds shall not be placed on the market or used in any individual part for several articles reported separately in the restriction List.

Lead and its compounds must be present in jewellery articles in concentration of lead (expressed as metal) lesser 0,05 % by weight. The 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, and are the followings: bracelets, necklaces and rings; piercing jewellery; wrist watches and wrist-wear; brooches and cufflinks. These restrictions shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961.

Restrictions of formaldehyde in articles used indoors

Starting from 27 July 2023 in the ECHA Restriction List in position 77 [28] formaldehyde has been included as "formaldehyde and formaldehyde releasers" and as "formaldehyde" with the following restrictions: shall not be placed on the market in articles, after 6 August 2026, if, the concentration of formaldehyde released from for furniture and wood-based articles exceeds 0.062 mg/m³ articles and 0.080 mg/m³ for other articles. The low molecular weight, electronegativity and high solubility of formaldehyde are considered negative values [29, 30].

These restrictions cannot be applied to the following articles; in which formaldehyde or formaldehyde releasing substances are exclusively naturally present in the materials from which the articles are produced; in articles that are exclusively for outdoor use under foreseeable conditions; in articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air; in articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use; second-hand articles.

There are also the following other restrictions for formaldehyde: shall not be placed on the market in road vehicles after 6 August 2027 if the concentration of

formaldehyde in the interior of those vehicles exceeds 0,062 mg/m³. This restriction cannot be applied to the following applications: road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use; second hand vehicles.

Restrictions of formaldehyde in cosmetic preservatives

On 30 July 2022, the European Community [31] established that certain cosmetic preservatives that are used to preserve the finished cosmetic product shall be labelled with the warning "releases formaldehyde" where the total concentration of formaldehyde released in the finished product exceeds 0.001%. It is useful to remember that the European Community had published in a previous Regulation of 2009 [32], that if the formaldehyde emissions of cosmetic preservatives were >0.05%, the wording "releases formaldehyde" had to be reported on the label of the article. In the same regulation of 2009, it was established that formaldehyde could only be present in cosmetic preservatives with the previous limitations.

The restrictions of formaldehyde in toys

The 19 November 2019 the European Parliament and the Council had declared the following limit values for formaldehyde used in certain toys [33]:

- 1,5 mg/l (migration limit) in polymeric toy material;
- 0.1 ml/m³ (emission limit) in resin-bonded wood toy material;
- 30 mg/kg (content limit) in textile toy material;
- 30 mg/kg (content limit) in leather toy material;
- 30 mg/kg (content limit) in paper toy material;
- 10 mg/kg (content limit) in water-based toy material;

Restrictions of formaldehydes in textiles

Starting from 13th December 2018, in position 72 in the ECHA Restriction List [34], restrictions have been reported for all substances that have the following toxicities: they are carcinogenic, mutagenic or toxic for reproduction of category 1A and 1B and among these substances there is also formaldehyde.

For this restriction, after 1st November 2020, leather and hide textile products could not be placed on the market that contained formaldehyde in concentrations 455 > 75 mg/Kg

and that were used in the following sectors: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear.

Restrictions of formaldehyde in medical devices

On 5 April 2017, the European Community established that formaldehyde had to be absent from medical devices and medical diagnostic with the aim of increasing the protection of the health of patients and users [35].

Restrictions of formaldehyde in personal protective equipment

On 9 March 2016, the European Community had established a directive [36] that came into force on 21 April 2018 on the elimination of formaldehyde from personal protective equipment (PPE) intended to be used by workers or by persons who were exposed to risks to their health and safety.

Restrictions of formaldehyde in biocidal products

On 22 May 2012, the European Community had established [37] the restriction of the presence of formaldehyde in biocides on the European market. Biocides that are necessary to combat organisms harmful to human or animal health and organisms that damage natural or manufactured materials, but can create risks for humans, animals and the environment and for this reason could no longer contain toxic substances such as formaldehyde.

Restrictions of formaldehyde in materials and products in contact with food

On 27 October 2004, the European Community had established [38] that materials and objects intended to come into contact with food products, directly or indirectly, should no longer contain toxic substances such as formaldehyde. Formaldehyde present in food products not only created a danger to human health, but also produced a change in their composition or a deterioration in their organoleptic characteristics.

Restrictions on the use of synthetic polymer micro-particles

This paragraph reports the restrictions imposed by ECHA under the Reach Regulation on the presence of synthetic polymer micro-particles in products in Europe present in the Restriction List of ECHA [2] and also in a Regulation of European Parliament dedicated to these compounds with

further information [39].

In these documents are reported information on the nature of these micro-particles, on the products in which they are present, on polymeric products not yet subject to restrictions and on the postponements of the restriction dates. It is significant to start this paragraph with the first words of the document on the Regulation of European Parliament on the restrictions [2,39].

The ubiquitous presence of tiny fragments of synthetic or chemically-modified natural polymers, which are insoluble in water, degrade very slowly and can easily be ingested by living organisms, raises concern about their general impact on the environment and, potentially, on human health. Those polymers are widespread in the environment and have also been found in drinking water and food. They accumulate in the environment and contribute to micro-plastic pollution.

A big part of micro-plastic pollution forms unintentionally, for example as a result of the breakdown of larger pieces of plastic waste, or the wear and tear of tires and road paint, or the washing of synthetic clothes. However, tiny fragments of synthetic or chemically-modified natural polymers are also manufactured to be used as such or added to products.

In the ECHA "Restriction List" are reported the following properties that characterize of synthetic polymer micro-particles [2,39] they are contained in particles and constitute at least 1 % by weight of those particles or build a continuous surface coating on particles, At least 1 % by weight of the particles referred previously fulfil the following properties: (i) all dimensions of the particles are equal to or less than 5 mm; (ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3 However the following polymers are excluded from the restriction i: polymers that are the result of a polymerization process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances; polymers that are degradable; polymers that have a solubility greater than 2 g/L polymers that do not contain carbon atoms in their chemical structure.

These micro-particles of synthetic polymers can be present alone as products, or used as additives in many products, or obtained from the degradation by wear, abrasion and washing of many polymeric products used in everyday life

and from the emissions of their waste abandoned in the environment. However, it is worth remembering that, in many published articles and documents, these micro particles are called micro-plastics, but they are also produced by rubbers, fibers and other polymeric products. Furthermore, there are polymeric products that do not produce micro-particles and therefore are not subject to restrictions by ECHA [2,39] and these are the following: a) natural polymers that have not been subjected to chemical modifications; b) polymers that are degradable; c) polymers with a solubility greater than 2 g/l; d) polymers that do not contain carbon atoms in their chemical structure.

Therefore, the ECHA restrictions are for polymeric micro-particles that are organic, insoluble and resistant to degradation, as well as for their size as specified above.

The danger of synthetic polymer micro-particles

The polymer micro-particles mentioned above, if not disposed of or recycled correctly, can end up in the environment, where they remain for centuries and degrade into increasingly smaller pieces. These micro-particles are not only dangerous for themselves, but also for the additives and residual impurities that were present in the products that contained them [40-43]. These micro-particles can also accidentally form from larger pieces of plastic, car tires and road paints, agricultural products, construction products and from plastic films due to their wear or from synthetic fabrics during their washing. The danger of these polymer micro-particles is that they spread into the environment, disperse in marine and terrestrial ecosystems and remain stable forever. In addition, these polymeric micro-particles, when they reach the water, dissolve into small fragments due to various chemical or physical processes and those present in the sea are swallowed by marine animals and end up directly in our food, becoming a danger for humans. In addition, polymeric micro-particles are also present in the air, drinking water, fruit, vegetables and other foods. Recently they have also been found in human vital organs, as well as in feces, food and drinks, including beer, honey and tap water. The health effects of these micro-particles are still under analysis, but just recently Italian researchers discovered, after removing atherosclerotic plaques from the arteries and examining them with an electronic microscope, that micro- and nano-plastics were present in the fat of the plaques of many patients and linked this presence to a higher risk of heart attack, stroke and premature death. In another

more recent article the various effects of micro-plastics on human health are reported. Furthermore, there are no restrictions on polymeric micro-particles that are present unintentionally, for example in sludge and compost (also called compost, the result of bio-oxidation and humidification of a mixture of organic waste). Finally, there are currently no restrictions on emissions of micro-particles from polymeric products due to their wear, degradation and washing.

Synthetic polymer micro-particles are present in the following products: glitter, facial scrubs and other types of cosmetics; detergent, waxes, polishes and air freshener, certain fertiliser, plant protection products and seeds treated with them, biocides other agricultural and horticultural products other than those listed above; certain medical device granular infill for use in synthetic sports surfaces (such as rubber substrate for artificial turf sports surfaces).

Polymer micro-particles in the Restriction List

In the Restriction List pos. 78 [2,39] is reported that polymer micro-particles shall not be placed on the market as substance and as on their own or, in mixtures in a concentration equal to or greater than 0,01 % by weight. The previous restrictions for the several uses of polymer micro-particles shall start at the following years: from 17 October 2027 for "rinse-off products" unless they are used as abrasives; from 17 October 2028 for detergents, waxes, polishes and air care products, for fertilizing products for agricultural and horticultural uses, for detergents, for products for agricultural and horticultural for waxes, polishes and air care products; from 17 October 2029, for use in the encapsulation of fragrances, for leave-on products (intended to stay in prolonged contact with the skin, the hair or the mucous membranes) for medical devices not containing microsphere, for synthetic polymer micro-particles for use in the encapsulation of fragrances from 17 October 2031 for plant protection products and seeds treated with those products, and biocidal products, or granular infill for use on synthetic sports surfaces, for plant protection products and seeds treated with those products, and biocidal products, for granular infill for use on synthetic sports surfaces, and for lip products from 17 October 2035 for lip products, nail products and make-up products.

This reported restriction shall not apply to the placing on the market of synthetic polymer micro particles, for the following uses: at industrial sites, in medicinal and veterinary products, in fertilizing products, in food additives, in vitro

diagnostic devices, in food and feed. This restriction cannot be applied also to the placing on the market of the following synthetic polymer micro-particles, as substances on their own or in mixtures: synthetic polymer micro-particles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use; synthetic polymer micro-particles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry; synthetic polymer micro-particles which are permanently incorporated into a solid matrix during intended end use.

The above restrictions do not apply to the emission of polymeric micro-particles in all products that were placed on the market alone or in mixtures with other products before 17 October 2023. Furthermore, polymeric micro-particles that are present unintentionally, for example in sludge and compost (also called compost, resulting from the bio-oxidation and humidification of a mixture of organic waste), are not subject to restrictions. Finally, there are currently no restrictions on the emission of micro-particles from polymeric products due to their wear, degradation and washing.

Changes in PVC on the market in Europe

This paragraph reports the latest news provided by ECHA on its restrictions on PVC additives, that is, on a product not on chemical substances as is its main activity. In fact, in the Reach Regulation, applied by ECHA [44], the restrictions of highly toxic chemical substances (inorganic, organic and organometallic) are reported, which are or could be present in products on the market in Europe present in the Restriction List [2]. This paragraph reports the various changes that have been made to PVC, following the restrictions by ECHA of its additives and strangely not of its highly toxic raw materials and in the future perhaps of a product of its decomposition (micro-plastics) [1]. In 2022, the European Commission, within its directive "Chemicals strategy for sustainability", issued a document called "Roadmap Restriction", to define the priority substances to be subjected to an evaluation for a possible restriction according to the parameters defined by the Reach Regulation. Within this program, the European Commission had also asked ECHA to carry out a study on PVC additives and the report and related annexes [45,46] were published in November 2023. Finally, ECHA also published at the end of November 2023 [47] the first verification data on

the effects of its directives on the elimination of toxic chemical substances in products in Europe, finding that there is an excess of Pb, phthalates and to a lesser extent also Cd in many products and also present in PVC, compared to the limits set by its restrictions.

Restrictions on PVC additives

The information reported in this article was taken from the ECHA "Restriction List" [2] where data are reported on the non-use or maximum concentration that chemical substances must have in some products present on the market in Europe, but also many other substances of the same family (those known in the world of chemistry) not present on the market, but which could replace those subject to restriction. It should be noted that a restriction present in Annex XVII applies the same rules, even to imports from non-European countries. Polyvinyl chloride (PVC) is one of the most widespread and used plastic materials in the world in thousands of applications, from construction to food and pharmaceutical packaging, from medical-surgical devices to materials for civil protection, from paper to fashion and design. PVC additives that have been subject to a strong reduction in their presence in products on the market in Europe by ECHA under the Reach Regulation, the subject of this note, are plasticizers, heat and light stabilizers, while some flame retardants, at the moment, have only recently been proposed to be included in the "Restriction List". Furthermore, we will mention the restriction just published (the latest introduced in the "Restriction list") on the presence of micro-particles of synthetic polymers (micro-plastics) used alone, or as additives or that are formed by degradation of products containing polymers, limitations that could also involve PVC, but not directly. It is interesting to remember that the elimination of stabilizers based on Cd and Pb compounds had already occurred in PVC production in Europe a few years before the REACH Regulation was born: Cd, for example, through a European directive in the 1990s, while Pb had been voluntarily eliminated by European companies as part of the "Voluntary Commitment" of Vinyl Plus, the Association of European PVC producing industries. It is useful to underline that, even if the elimination of some toxic substances present in PVC produced in Europe occurred before the application of the REACH Regulation, PVC products arrived and still arrive in Europe from other countries with toxic additives that we then also find in recycled PVC; for this reason, a restriction by REACH was and is necessary also for

those substances. However, it may be surprising that there are no restrictions in the ECHA lists of some raw materials used for the production of PVC such as vinyl chloride and dichloro ethane, whose toxicity is well known, but this is due to the fact that the industry worldwide has almost reduced their presence in PVC to zero.

However, these two substances are present in the ECHA lists: vinyl chloride (PVC monomer) carcinogenic cat. 1A was the second chemical compound introduced in the "Restriction List" [2] (position 2), but only to prohibit its use as an aerosol propellant for any use, and 1,2-dichloro ethane carcinogenic cat. 1B, but there is no proposal for restriction in the products on the market and, therefore also on PVC, due to its non-presence in the products on the market because it is used as an intermediate. The absence of these chemicals, intermediates for the production of polymer PVC in products, is due to the fact that they have been subjected for years to safety rules related to the production phase such as, for example, worker exposure and emissions into the environment, which are systematically monitored and strongly reduced.

Restrictions and authorizations on plasticizers

Plasticizers are used to impart flexibility, deformability and mobility to PVC products [48]. Under restriction by ECHA are ortho-phthalates, i.e. low molecular weight alkyl esters of ortho phthalic acid. The restrictions by ECHA have eliminated some toxic ortho-phthalates, largely replaced by other non-toxic Ortho-phthalates, terephthalates and also by trimellititates, polymers, aliphatic esters and epoxy esters. Ortho-phthalates, depending on the number of carbon atoms in the alkyls, have different toxicity and also different types of application, and are reported below divided by type of restrictions, which depend largely on the number of carbon atoms in the alkyls. For di-n-butyl phthalate (DBP); di-isobutyl phthalate (DIBP); benzyl butyl phthalate (BBP); bis (2-ethylhexyl)phthalate (DEHP); in the "Restriction List" (pos. 51) [2] there is a limitation of their presence to 0.1% by weight in all products containing them with the exception of those used in industry, agriculture and aircraft. For C8, C9, C10 and C9-C11 phthalates in the "Restriction List" (pos. 52) [2] there is only the obligation.

Restrictions on stabilizers

Lead and tin compounds are used as stabilizers of PVC. In the Restriction List of ECHA [2,49] it is reported that the use of

lead compounds in PVC must be restricted and the placing on the market or use of lead in articles produced from PVC if the acceptable if concentration of lead is equal to or greater than 0,1 % by weight of the PVC material.

Organic tin compounds

Organic tin compounds have been and are still used as PVC stabilizers [50]. Today, some of these compounds are subject to restriction [2] (pos. 20) because they are not biodegradable and toxic to aquatic microorganisms. The "Restriction List" includes: tri-butyltin, tri-phenyltin, di-butyltin and diethyltin compounds that cannot be present in metallic tin concentrations >0.1% by weight in the products. Instead, dioctyltin oxide (DOTO) is used as a stabilizer for PVC, because it is not subject to restrictions, but it is under analysis because it seems to be an endocrine disruptor.

Flame retardants

On 15 March 2023, it was proposed by ECHA staff that brominated aromatics used as flame retardants in plastics and therefore also in PVC and, which are persistent in the environment and toxic to humans and the environment, should be restricted by ECHA [51] but now until October 2024 nothing has been decided.

Synthetic polymer micro-particles

Synthetic polymer micro-particles (excluding biopolymers and biodegradable ones), also called micro plastics, which are smaller than 5 mm, are produced to be used alone or to be added to some products as additives or are formed by degradation from polymer-based products (during their use or in their waste). This definition applies to all plastics and therefore also to PVC. It is necessary in the future to implement and improve technologies that minimize PVC micro-particle emissions especially at recycling facilities and landfills [52]. The release of PVC micro-particles contributes to plastic pollution. These micro-particles also contain harmful additives, and therefore, minimizing their releases would consequently reduce emissions of these additives [2]. These micro-plastics accumulate in the environment because they are not degradable and must be eliminated in the Circular Economy Action Plan and the Zero Pollution Action Plan, because they can accumulate in the human body. It is precisely the micro-particles of synthetic polymers, the latest chemical substances introduced on 17 October 2023 with this name in the "Restriction List" (pos. 78) [2], and it has been declared

that their placing on the market is not permitted, in the form of substances as such or, where the micro-particles of synthetic polymers are present to confer a desired characteristic, as components of mixtures, in a concentration equal to or greater than 0.01% by weight. These restrictions do not apply to micro-particles of synthetic polymers intended for use at industrial sites. Furthermore, it is necessary to minimize the emissions of PVC micro-particles, especially in recycled products sent to landfill [53].

CONCLUSIONS

Despite the fact that for years there has been talk of the Reach Regulation and the restrictions on the presence of toxic substances proposed by ECHA on products sold in Europe (produced or imported), the news arrived on 21 December 2023 that this Regulation has not been fully applied. This information had been reported on 13 December 2023 in a European inspection project document coordinated by the ECHA Forum active from 2022, which concerned the control of over 2,400 products present in Europe, in this control it was found that 18% of these inspected products largely presented excessive levels of lead and phthalates and cadmium, not compliant with the Reach Regulation, of course they were also present in 687 some soft PVC articles. This news tells us that in Europe there are products in many applications, plastic and otherwise, that do not comply with the Reach Regulation. The study also found, however, that the largest percentage of articles not complying with Reach were articles imported into Europe from non-European countries this implies the need for greater/better control of imports.

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