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Policy Analysis

Revisiting Chemicals of Concern in the PlastChem Report: Addressing the Challenges, Gaps, and Future Directions

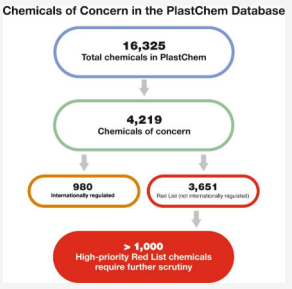
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ABSTRACT: Chemical compounds released from plastics are of great concern as some of them could be hazardous to the environment and human health. Recently, a hazard-based assessment was applied to an extensive data set of 16 325 known plastic chemicals (the PlastChem database). Using this approach, 4219 chemicals of concern were identified on the basis that they are persistent, bioaccumulative, mobile, or toxic. A small portion of the chemicals of concern (568) is already regulated globally; the rest of them (3651 chemicals) constitute the so-called Red List. Because of the enormous importance of the chemicals of concern, several articles published in high-impact scientific journals called for immediate action. They insist that the chemicals from the Red List should be regulated and curtailed within the scope of the forthcoming Plastic Treaty currently being developed under UNEA Resolution 5/14. Here, we report a critical overview of the Red List and show that about 30% of its entries appear questionable, which calls for further in-depth analysis and comprehensive revision of the list. Furthermore, we argue that the hazard-based assessment should serve only as an initial screening tool. The Red List of plastic chemicals of concern should also be subjected to risk-based assessment through tiered exposure filtering before adoption by any global regulatory framework.



KEYWORDS: *chemicals of concern, plastic waste, PlastChem report, plastic treaty, polymer science*

1. INTRODUCTION

The commercial success of synthetic polymers has placed plastics at the highest position in the hierarchy of modern materials. This success was strongly influenced by various factors, including the low cost of production, the lightweight nature, and their stable products that can provide a wide range of functionalities in material product design. It can be argued, however, that due to a combination of the low cost of virgin plastic production and the challenges of recovering postconsumer plastics, a significant financial barrier inhibits the implementation of robust management options for handling plastic waste. For example, the optimization related to the production of fossil-fuel-derived polymers enables their bulk production costs to be significantly lower than those related to postconsumer processing, resulting in recycled plastics costing more than virgin materials. There is thus a need for incentives and innovation that can strengthen the efficacy of recycling plastics, with the aspirational goal of supporting their use within a circular economy. Among the various concerns that can be identified as resulting from the mismanagement of plastic waste and its release into the environment is the environmental fragmentation of plastics that generate microplastics (MP)—small particles composed of synthetic polymers and measuring less than 5 mm. The issue of plastic pollution, particularly MPs, has attracted substantial public concern and has risen to prominence on the international agenda. According to the decision of UNEA Resolution 5/14 of March 2, 2022,[1] the International Intergovernmental Committee (INC) spent three years developing a draft international treaty aimed at reducing plastic pollution. As the Committee did not finalize the document by the end of 2025, its work must continue.

A key scientific challenge concerning both plastic waste and MP is the leaching of various chemical compounds.[2] Chemicals added to plastics, for instance, can leach into the surrounding environment during all life stages of the plastics. Various methods have been developed to measure the leaching of chemicals and to ensure compliance with safety standards, with regulatory instruments defining thresholds, including Regulation (EU) 10/2011 and the ISO 10933 standards for evaluating the biocompatibility of medical devices.[3] Assessing the leachability of chemicals thus represents an important source of information that can help better understand exposure in the context of both human health and ecology.[4] Understanding the environmental and human health risks posed by chemical additive leaching from all forms of plastics is therefore critical in helping to shape effective international

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policy, not only for managing existing plastic waste but also for guiding and supporting the sustainable development of the polymer industry in the future.

To better understand the implications concerning chemical additives in plastic products, it is first important to screen and prioritize their application in the production and subsequent service life of plastics. Currently, the most influential work for international policy on compiling a list of such compounds and identifying substances of concern is the study of Monclús et al.[5] In their work, the authors presented a summary of the PlastChem report,[6] which compiled the largest known list of plastic-related compounds to date. The main goal was to provide the scientific community with information reflecting the chemical complexity of plastics, although the list can also be used for further screening and prioritization purposes.[4]

For example, based on a hazard assessment approach, the PlastChem report identified a list of 4219 plastic-related chemicals of potential concern. Among these, 568 compounds are already regulated globally, while the remaining 3651 are flagged by the authors of the report in a prioritized 'Red List'. As we proceed to show, this list of chemicals requires additional scrutiny in the context of environmental and human health safety. One of the main ways that the identification and prioritization of chemicals of concern can be supported is through the collective evaluation of the Red List, which should hopefully help to guide the effective and efficient implementation of actions aimed at minimizing exposure to chemicals that represent the greatest risk to the environment and human health.

It is noteworthy that discussions regarding the problem of plastic waste and MP often ignore the opinions of not only polymer scientists but also organic chemists in general, which is already leading to significant errors and incomplete analysis in the field.[7−9] Thus, the identification of the prioritized list of chemicals used in plastics, as communicated in the PlastChem report, represents an opportunity for interdisciplinary dialogue and constructive insight from which a greater awareness of the use of chemicals in plastics and their safety implications can be more effectively articulated.

Due to the enormous importance of these chemicals of concern, a recent Nature editorial[10] as well as articles published in other high-impact scientific journals[11,12] called for immediate action. In particular, they insist that the chemicals of concern identified by a hazard-based assessment as the Red List should be regulated[12] within the scope of the forthcoming Plastic Treaty.[1] However, the following question is still open: is a hazard-based assessment sufficient to justify regulatory action for plastics-related compounds, as suggested by Hader et al.[12]

Here we take the opportunity to support the importance of interdisciplinary input by providing a constructive critical overview of the Red List of chemicals of concern,[5,6] which is given here from the perspective of chemistry, polymer, and exposure scientists. Furthermore, we argue that the Red List of chemicals requires a further risk-based assessment, including tiered exposure filtering; such an assessment should be plastic-specific. The objective of our study thus aims to ensure that the adoption of a prioritized list of chemicals used in plastics within any regulatory framework is based on a robust evaluation of the initial screening list, which we suggest would be greatly strengthened through the constructive input of interdisciplinary experts.

In this paper, we provide a detailed critical analysis of the development and content of the Red List, which constitutes the most essential part of the PlastChem report.[5,6] Our analysis indicates that around 30% of list entries raise concerns regarding their inclusion on the Red List. Furthermore, we propose additional risk-based assessment (including exposure filtering) to narrow the Red List to the chemicals that do show concern in terms of human health and environmental safety.

2. MATERIAL AND METHODS

2.1. Red List Composition

The following analysis of compounds included in the Red List refers to the PlastChem database and documentation[6] dated 14 April 2025 (plastchem_db_v1.01.xlsx). The list contains 3651 entries. The recent paper on mapping the chemical complexity of plastics[5] focuses on the brief description of the PlastChem report and this database.

According to the database information, the PlastChem database is built upon seven previously released data sets,[13−18] which were themselves derived from previous inventories focused on food safety, environmental protection, and occupational health and safety.[5,6] Notably, several of these foundational databases were developed directly by the authors of the PlastChem database.[14−18]

The methodology for building the PlastChem database was intended to synchronize and harmonize these seven primary sources with the inclusion of additional relevant information, mainly policy and regulatory data, as well as data from the US EPA CompTox Chemicals Dashboard, the European Chemicals Agency, the Australia Industrial Chemicals Introduction Scheme, and other similar sources.[6] Data from multilateral environmental agreements (MEAs): the Stockholm Convention on Persistent Organic Pollutants (POPs), the Basel Convention on Hazardous Waste, the Rotterdam Convention, the Minamata Convention, and the Montreal Protocol were also included. The authors state that, in addition to the project creators themselves, a number of experts in the fields of occupational health and safety, environment, and sustainable development, and regulatory bodies manually checked the database entries.[6] The database primarily consists of organic compounds, classifying a significant subset as chemicals of concern based on hazard traits, such as persistence, bioaccumulation, mobility, and toxicity.

The stated PlastChem's methodology clearly requires unambiguous identification, mainly by their active Chemical Abstracts Service Registry Numbers (CAS numbers) as the unique identifiers to annotate additional information; chemicals without valid CAS numbers are excluded, as these compounds cannot be traced across sources or deduplicated.[5]

2.2. Main Elements of PlastChem Database

Each compound in PlastChem has been assigned an Evidence Score based on the number of sources that classify the chemical as hazardous.[6] According to the PlastChem documentation,[5,6] the substances gathered from other databases are classified according to the Hazard Score, which contains the maximum scores for persistence, bioaccumulation, mobility, and toxicity. A hazard score is assigned to each chemical as follows: 1 or 2 for hazardous substances, 0.5 for less hazardous substances or those proposed for listing, 0.25 for substances with assessments under development or inconclusive findings, and 0 for nonhazardous substances. A blank entry indicates a lack of information.

An important issue is that some of the source data sets, developed by the same authors, now serve as screening and consultation databases to identify potential chemicals of concern or candidates for future detailed studies.[14−18] Nevertheless, the Red List, based on the compilation of the same data sets with the same level of (un)certainty and reliability, is designed to flag chemicals of genuine concern for immediate regulatory action[12] or consumer protection.

The analysis of the PlastChem report indicates that the majority (3618) of high hazard score values are attributed to toxicity scores alone, primarily driven by data on either aquatic toxicity or specific

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target organ toxicity (STOT) in humans. Furthermore, 1743 entries (48%) of the chemicals are included in the Red List based on a single hazard property from a single reference source (i.e., an evidence score of 1). An additional 27 entries are listed due to concerns regarding environmental mobility, which is derived from a list of chemicals compiled by the German Federal Environmental Agency (Umweltbundesamt, UBA).

The largest group of chemicals identified as aquatic toxicants on the basis of a single data source was most likely extracted from the European Chemicals Agency (ECHA) database. Specifically, 1205 chemicals are included in the Red List solely due to meeting aquatic toxicity criteria from one reference, while 294 are listed based on STOT and 114 are due to their classification as CMR (carcinogenic, mutagenic, and/or toxic for reproduction).

3. RESULTS AND DISCUSSION

3.1. Initial Evaluation

On the basis of our initial evaluation of the PlastChem prioritized list of chemicals, we identified numerous inconsistencies that are important to highlight. Most notably, for approximately 10% of entries (449 out of 3651 chemicals, see Figure 1), the name identifiers (PubChem_cid, PubChem-

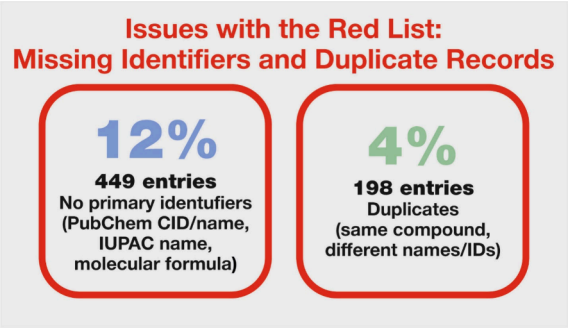


Figure 1. Issues with the Red List: Missing identifiers and duplicate records.

name, IUPAC_name, Molecular-formula, etc.) are blank, which makes it extremely difficult to identify as a chemical of concern. A spot check of one such entry (the compound with PlastChem ID {1171} and with CAS_ID 11141-16-5) showed that this entry corresponds to Aroclor 123 (or PCB 1232). Aroclor 123 is not a single compound but a blend of polychlorinated biphenyls (PCBs),[19] the use of which is already restricted and regulated due to their properties as known persistent organic pollutants (POPs) under the Stockholm Convention on POPs.[20] Therefore, this entry should not be included in the red list.

We also found other questionable entries in the list of chemicals of concern. For example, several salts, including common table salt (NaCl), which are ubiquitous in the environment and widely used in food, are included in the Red List. Salts are known to dissociate in aqueous solution and may thus cause adverse effects by altering the ionic strength of a test medium, e.g., in an aqueous ecotoxicological test system or an in vitro toxicity assay. This may be a reason for flagging salts as exceeding a toxicological threshold value. However, according to the EU REACH regulation, NaCl is an authorized active substance in plant protection products. It is considered unlikely to be carcinogenic, mutagenic, or toxic to reproduction or an endocrine disruptor and is a widely used high-production-volume chemical in Europe. To the best of our knowledge, NaCl is not a primary additive in plastics, and we are unaware of any study demonstrating that plastics are a major source of NaCl in the environment. Therefore, prioritizing NaCl (i.e., table salt) in the context of the PlastChem Red List (PlastChem ID {13652}) appears questionable and represents an example of a substance that could be deprioritized, enabling resources to be directed toward chemical additives whose use in plastics represents a significant source of concern.

The above examples stimulated us to more closely review the prioritized Red List of chemicals of concern. We also hope that this provides a source of motivation that will encourage a broader input by other experts. Below, we briefly summarize the outcome of our analysis; a more detailed description can be found in the Supporting Information. Overall, the issues found in the list of chemicals of concern can be grouped into five categories (see Sections 3.2−3.6 below).

3.2. Sample preparation and PlastChem Database Building Methodology

Inconsistencies with the methodology of data collection (sample preparation and experimental conditions vary for different compounds), technical errors in the composition, structure, or name of chemicals, and errors related to the properties of chemical compounds, including an incorrect classification of a compound as a "plastic chemical", significantly decrease the impact of the PlastChem database.

3.2.1. Sample Preparation. The sampling and sample preparation techniques are of the utmost importance in excluding any possible bias, especially survival bias-type errors of inclusion of secondary materials (such as minerals and the principal components of the environmental samples). For example, the authors in ref[21] claim that it remains unknown (and hence unproven) whether polymers such as PET or PP can be a source of inorganic compounds due to a limited number of selected samples. It is therefore doubtful that plastics may be a major source of substances such as principal minerals and soils in the environment. Nevertheless, the list includes calcium and magnesium carbonates, silicates, etc., and even natural soil-forming minerals like kaolin, plastchem_ID {2496}; kaolinite {16206}; other aluminosilicates {3060} and {15619}; hematite {2361}; as well as slaked lime {16198}, muscovite {1593}, and silicon dioxide {1305, 1307, 3141, 3270, 3461, 10534, 10773, 12459, 13623}, which are also major constituents of ordinary sand.

As a practical example, the state-of-the-art sample preparation methods for the isolation of microplastics are used to digest or remove organic matter or biogenic components. These methods include (i) chemical digestion-based methods (acidic, alkaline, and oxidative digestion) and (ii) enzymatic digestion and density separation (e.g., NaCl and $ZnCl_2$ solutions)[22−32] along with filtration and sieving (e.g., glass, cellulose acetate, polycarbonate, and other filter membranes).[33] All these methods are known to be subject to direct contamination of the sample.[34,35] Some treatments may retain inorganic components during the filtering. Compared with chemical sample preparation, enzymatic digestion introduces smaller amounts of inorganic components but may not remove all mineral particles, especially if no other separation is involved. After such a treatment, undigested minerals may be mistaken for microplastics if the separation is incomplete. Solid-phase (filter or membrane) materials may trap or react with inorganic particles, and there is little consensus on what is the best filter material to avoid inorganic

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contamination.[32,36] As a result, the level of inorganic components found in microplastics strongly depends on the sample preparation, that is, on the selection of a preparation method, digestion chemicals, the membrane material, and the washing steps following any selected treatments. All of these may result in various false positive results.

3.2.2. Database Building Methodology. To build up the database, a so-called conservative approach was employed when hazard information was collected from government regulatory sources and industry reports.[5] Essentially, the scientific literature was not considered, which constitutes a major drawback of the methodology used. As a result, there is no information about the methodology of experiments in which the chemicals were detected or quantified. Such information is crucial for understanding the possible limitations of each detection and quantification approach and the statistical treatment of chemical analysis. It could help to avoid bias and systematic errors, as well as the use of incorrect hypotheses. For instance, the PlastChem database shows many types of inorganic irons. However, the level of direct iron leaching from plastics is fairly low[37,38] and is not comparable to naturally occurring iron and iron leaching from other man-made sources, such as landfills[39] or battery waste sites.[40] The ratio of iron leaching from plastic to electronic waste/MSWI bottom ash and to battery/industrial waste is as low as 1:100:300000.[38,40,41]

The studies of metal leaching from environmental plastics have shown that a biofilm was observed on all particles under real-world conditions. This biofilm was mainly composed of bacteria, diatoms, and unidentified larvae of benthic organisms. It was suggested that the leaching of metals into the environment may be due to these biofilms and not due to polymers.[37] Another study showed that most of the metals present in real (environmental) microplastic samples were secondary, i.e., they were adsorbed on the biocorona of microplastics from all the sources, and most metal types from microplastics are not bioavailable.[38]

The next question is related to the fact that the source databases are predominantly derived from specific samples, and consequently, their unification requires profound efforts. As a result, the types of substances that may exist at the production stage are not stable in the natural environment or in living organisms. In fact, the list contains a large number of substances that cannot exist under any environmental conditions because of their high reactivity. These include sodium oxide {2315}, acetic anhydride {854}, metallic cesium {13319}, barium {13313}, lithium hydride {13571}, $KMnO_4$ {13757}, and many others.

3.3. Technical Errors, Duplicates, and Different Physical Forms of a Substance with the Same Composition Included As Separate Entries in the Database

The authors claim to have conducted a triple-check of the data throughout the PlastChem database: (i) a check of the initial databases; (ii) verification at the merging stage; and (iii) manual verification by the authors and external experts, mainly from regulatory agencies and specialists in occupational health and sustainable development (Appendix A4 in ref 6). However, we found many factual and technical errors related to both fundamental and applied chemistries.

3.3.1. Factual errors. Factual errors include the incorrect interpretation of the data, especially the CAS numbers. The Red List frequently does not distinguish among elements, molecules, and materials based on them. For example, the list contains both monomers and oligomers and often the polymers or resins themselves, such as diglycidyl bisphenol A resin {5698}, epoxy resin {8009}, epoxy resin {9886}, and possible types of their transformation, which are included in the same entry {9886}. The latter adds a lot of ambiguity to the database, as the list of possible transformation products takes into account the diversity of substances, conditions, and samples and requires a large amount of targeted information analysis.

The list also contains incorrect interpretations of data. For example, entry {2324} contains two unrelated compounds that clearly react with each other (Zn and H_2O_2). A check of the CAS number 1314-22-3 shows that it is in fact zinc peroxide.

Another case worth mentioning is Amphojel {4986}, which, according to CAS, is aluminum hydroxide AlH_3O_3 with a molecular weight of 78. However, in the Red List, it is listed as AlH_6O_3, with a molecular weight of 81 (with three extra hydrogens). This can be interpreted as aluminum plus three water molecules, which is incorrect.

Entry {11622} is a special case: it is a substance called bucelipase-alfa, which is claimed to be an enzyme drug, a recombinant human bile salt-stimulated lipase. However, no literature references can be found for this substance. The PubChem[42] database includes an almost empty PubChem entry with missing information for this substance; the database indicates that this compound is at the clinical trial stage and quotes chemically absurd information that this 'enzyme' is a heptamer of molecular hydrogen, H_{14}. At the same time, the corresponding CAS number 65997-06-0 shows that this Red List entry is a hydrogenated colophony (rosin), a modified-rosin technological and cosmetic product (which is in fact reflected in the ECHA field of the PlastChem database 'Resin and rosin acids and their derivatives'). As a result, the entry is simultaneously assigned to (i) a spurious enzyme, (ii) an absurd species of molecular hydrogen, and (iii) a hydrogenated natural resinous material.

Another problem is related to the presence of duplicates (for details, see Figure 1 and Section S1.1 in the Supporting Information).

3.3.2. Entries with No Primary Substance Names/Identifiers. As mentioned above, an analysis of all the database fields shows more than 449 entries (see Figure 1, 12% of the Red List) with no primary substance names/identifiers ("pubchem_cid", "pubchem_name", "iupac_name", "molecular_formula"). Although these entries have CAS numbers and secondary fields, verification of real substances under the CAS numbers is required to confirm these entries. Examples include ferrocene {289} and ammonium pentaborate {16188}. Some entries in this 'empty' list show barely identifiable materials with undefined properties, such as petrolatum jell {14174} and cresol mixture of isomers {2382}. The full list of these 449 entries may be found in the Supporting Information (see Section S1.2).

3.4. Widespread-Use Compounds and Compounds Broadly Distributed in the Environment, Including Minerals and Soil Components

3.4.1. Compounds That Make up the Geosphere and Biosphere. The arguments similar to those used in Section 3.2.1 can be applied to a rather broad set of substances that form the basis of the geo- and biosphere (see Figure 2). These include substances and minerals from the Earth's crust, silicon

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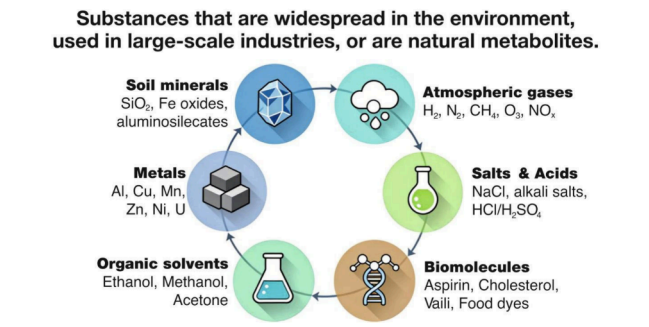


Figure 2. Substances that are widespread in the environment, used in large-scale industries, or are natural metabolites.

dioxide (SiO_2), amorphous species, and α-quartz {3270}, along with other silicon-based mineral compounds (repeated a total of nine times as various silicon dioxide-based minerals {1305, 1307, 3141, 3270, 3461, 10534, 10773, 12459, 13623}). The inclusion of these substances in the list requires careful verification from the perspective of chemistry and the reliability of chemical analysis.

In the polymer industry, under typical environmental conditions, silicon dioxide, when used as fillers, coatings, or silicone-based additives, can leach into the surrounding environment, although most SiO_2 remains bound in plastics within the polymer matrix. As an example, silicone rubber gaskets filled with fumed silica and untreated silica nanopowder release approximately 128 ± 3.3 mg Si/L and approximately 2.3 ± 0.2 mg Si/L for silicone formulations without a silica filler.[43] Similarly low values of amorphous silica migration into the environment were also found for starch-based biopolymers and polylactates.[44] However, these estimates are lower than the incidence of silicon from agricultural soils and the construction industry (within the range of 10^6 tons). Moreover, annual biogenic silica production by living organisms (mainly diatoms and higher plants) is in the gigaton range, i.e., 1000 times larger than the total industrial production and environmental anthropogenic release of amorphous silica,[45] which is many orders of magnitude higher than the amount of this substance arising from plastics (either as fillers or due to cross-contamination).

In addition to elements, the list contains oxides that make up the earth's crust, such as aluminum {2600}, titanium dioxide {2365}, and iron oxides ({2495} and {16199}). It also includes nearly every hydroxo and oxo species of ferric and ferrous iron. Key minerals are present as well: kaolin {2496}, kaolinite {16206}, other aluminosilicates ({3060} and {15619}), hematite {2361}, slaked lime {16198}, and muscovite {1593}.

On the organic side, the list features common alkanes (methane {13228}, propane {13238}, butane {684}, pentane {940}, hexane {1006}, heptane {3031}, octane {1110}, and nonane {1122}) and their isomers. For instance, heptane {3031} and 2-methylhexane are both present, with the latter recorded twice under entries {7217} (CAS number 31394-54-4) and {10335} (CAS number 591-76-4). Common unsaturated hydrocarbons such as ethylene {13230}, its duplicate {15008}, and propylene {1354} are also included.

Regarding biosphere constituents, the list contains numerous naturally occurring substances: caffeine {10173}, vanillin {1720}, retinol {11894}, and retinol palmitate {14049}. Also present are sucrose {10049} and ethanol {11245}; both are essential food components and natural products.

Additionally, the list includes endogenous human substances such as testosterone {10174} (the primary androgen), estradiol {9026} (the main estrogen during reproductive years), lactic acid {9023}, cholesterol {10055}, hydrochloric acid {13651}, and arginine {13227} (a conditionally essential amino acid). All of these substances can enter plastics via contamination or through biofilm development on microplastics in the environment.

The presence of all of these chemicals in the list may be due to the abundance of these substances in the environment. They can accompany or pollute environmental samples at the stage of primary sampling or sample preparation, as mentioned in the previous section. Some extra work is needed to understand the presence of these substances at hazardous or alarming concentrations and to estimate the risk arising from such concentrations. According to the Paracelsus principle, all chemicals are hazardous, but it is the dose that makes the poison. Therefore, additional exposure screening is of tremendous importance to flag a chemical as a chemical of concern.

Very important examples for this part are also metals (see Sections S2.1−S2.3 in the Supporting Information) and carbon (see Section S2.4 in the Supporting Information).

3.4.2. Natural Gases. The Red List also contains natural gases that are not plastic components but rather represent cross contamination or environmental background. These include molecular nitrogen {13768} (the atmosphere's main component) as well as molecular hydrogen {2510}, ozone {81}, methane {13228}, propane {13238}, butane {684}, carbon monoxide {11068}, sulfur dioxide {13349}, hydrogen sulfide {13868}, NO {189}, N_2O {68}, and ammonia {13679}.

3.4.3. Compounds that are widely used in various industries. The Red List encompasses substances that are mass-produced in the chemical, coal, and petrochemical industries in much larger amounts than in the plastics industry. Many of these substances are constituent parts of the Earth's core.

The most notable examples are sodium metaborate {13832}, borax {2220}, sulfur dioxide {13349}, sulfur trioxide {13351}, hydrochloric {13651}, sulfuric {13681}, and nitric acids {13715} (the list contains almost all inorganic acids, including those that exist in nature), potassium hydroxide {2291}, ammonia {13679}, benzene {12865}, methanol {11719}, acetone {11721}, dimethyl sulfoxide {11723}, hydrazine {6993}, caprolactam {573}, melamine {882}, and sodium EDTA {2868}.

The list contains fully approved synthetic and natural dyes that are used in the food industry. An example is Sunset Yellow FCF {6579}, which does not have genotoxicity, carcinogenicity, or developmental toxicity in the amounts or concentrations at which it is used,[46−48] with some controversial opinions on its effects.[49] Sunset Yellow FCF is generally not used as a standard additive in plastics; if present, it is considered a contaminant or residue arising from recycling, coloring, or contact with dyed materials and not as a deliberate ingredient. No specific industry standards or typical concentrations for Sunset Yellow FCF in plastics have been published, while in food, animal feed, and cosmetic products, the use of Sunset Yellow FCF and its concentrations is strictly regulated, with well-documented maximum and

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typical values. Potential hazards are only meaningful in the context of dietary or cosmetic exposure, governed by specific regulatory limits.[50]

Other examples include colorants widely used in clinical practice (e.g., Evans Blue {7218}) or for dyeing fabrics for domestic use, clothing, and similar tasks (e.g., indigo {8930}). In the latter case, the toxicity of indigo is a matter for debate and appears only at large concentrations and physical properties of insoluble dye particles.[51]

Evans Blue has limited use in clinical practice, and its main use is in analytical chemistry and histology.[52] Evans Blue is not a commercial pigment in any type of plastic, though it may be accumulated in laboratory experiments; otherwise, concentrations are negligible. Usually, Evans Blue is used to model generic azo dyes in waste and wastewater,[52] and it may be the reason for the presence of this dye in the Red List. Also, exceedingly high concentrations of Evans Blue may be attained in clinical experiments, but they can also appear in the natural environment. As such, the question of Evans Blue appearing in the PlastChem database should be carefully analyzed and clarified.

3.4.4. Pharmaceuticals in the Red List. The Red List contains medicinal substances produced on a large scale in the pharmaceutical industry (e.g., cortisone {9468}, aspirin {9030}, vitamins (retinol {11894} and retinol palmitate {14049}), as well as hydrogen peroxide {13759} and calcium glycinate {7784}). All of these substances are widespread in pharmaceutical production rather than in polymer materials.

For example, while the major hazards of cortisone are linked to its potent pharmacological effects at high or repeated medicinal doses, it is not intentionally added to plastics. Its primary route into the environment is via discharge from pharmaceutical manufacturing and healthcare waste.

Once in the environment, cortisone binds to sediments, organic matter, and other absorbent materials. For instance, polypropylene, polystyrene, and high-density polyethylene can retain 0.25 to 0.6 μg of cortisone per gram under ambient conditions.[53] However, sorption to organic matter—which is at least 1000 times stronger than to microplastics—is the dominant retention process in most natural soils.[54] Therefore, the relevance of cortisone as a chemical of concern in plastics requires further studies.

3.4.5. Entries Related to the Food Industry. The Red List contains compounds that represent the principal manufactured products of the food industry. The examples include sucrose {10049}, saccharin ({2144} and {14260}), and sodium chloride {13652}.

The inclusion of sucrose in the list seems unproven, as this chemical has an extremely high oral LD50 (~29.7 g/kg in rats) and correspondingly very low acute toxicity relative to its consumption levels.[55] The hazard associated with sucrose as an environmental contaminant is minimal, as sucrose biodegrades rapidly. Furthermore, there are no reports regarding the use of sucrose in plastics. A deeper examination of the PlastChem database reveals an unexpectedly low value for stated sucrose production of 1000 tons per year, which should be carefully checked and corrected. In addition, in Nordic countries, what is called "sucrose" is probably another sugar, fructomaltose, so this is one of the hidden technical errors, see Section 3.3.

3.5. Most common polymers with large-scale production

The duplicates discussed above often involve one entry being a low-molecular-weight compound and the other being a polymer. For instance, ethylene appears twice ({13230} and {15008}): the second entry has CAS 9002-88-4, which is polyethylene (generic for all PE types) and not the monomer. Similarly, vinyl chloride ({13451} and {15007}) is duplicated by PVC (CAS 9002-86-2) and styrene ({11} and {15039}) by polystyrene (CAS 9003-53-6).

Other examples include formaldehyde ({7054} and {9020}), where the second entry is paraformaldehyde (CAS 30525-89-4); acrylic acid ({15014} and {14032}), duplicated by poly(acrylic acid) (PAA, CAS 9003-01-4); and tetrafluoroethylene ({1392} and {15005}), where the second entry is a technical PTFE dispersion (CAS 9002-84-0). Note that polyethylene, polystyrene, and PVC alone account for over 40% of the world's synthetic polymer production.

It is also worth noting that the database contains a dedicated polymer indicator column ("other_groups, polymers"), which is set to 1 for 255 entries.

3.6. Degree of Leaching or Release of Chemicals from Matrices as a Function of Concentration, Time, Conditions, and Polymer Type

As shown above, a considerable number of entries on the Red List raise questions, which call for further scrutiny. In particular, there is a need to assess the leaching of Red List chemicals from plastics under realistic conditions. Recently, such an approach was used by the government of Canada: after the initial screening of chemicals in plastics, they applied a stepwise examination to evaluate exposure of the chemicals.[4] We will discuss this approach in more detail in Section 4. Below, we present additional considerations regarding the need for the leaching assessment of chemicals of concern from the Red List.

3.6.1. Hazard of Chemicals As a Function of Concentration Level. Another very relevant issue is that the primary, mainly chemical information, that proves the presence of chemical compounds (extracted from materials or detected in migration experiments) is incomplete. The most important information that the PlastChem database lacks is the concentration of the substance detected as this concentration is critical for assessing the risk level. Most likely, this is the reason why sodium chloride {13652} was included in the Red List. Sodium chloride may affect human health and environmental samples (water and soil) when it is present or used technologically in large concentrations. However, the effect of NaCl salt that is released from plastic materials is not as adverse as that from other sources. To assess this effect, it is necessary to indicate the hazardous concentration of NaCl in plastics and the possible one-time presence of NaCl during leaching into the environment. Due to the widespread nature of plastic waste, the release of NaCl salt from plastics into the environment can hypothetically have negative consequences only if large amounts of plastic debris are spread uncontrolled, and the corresponding substance can be released quickly in dangerous quantities. Moreover, sodium chloride is not inherently present in common plastics, nor is it released from the polymer matrix under environmental conditions (it could occur only from certain polymers like PVC under very harsh conditions[56]). Without information regarding the concentration, the inclusion of any chemicals similar to NaCl salt in the Red List does not make sense.

A set of similar examples includes strong inorganic electrolytes that cannot be components of plastics or polymer composite materials (most salts of ammonium, sodium, and

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potassium). First of all, some of these salts are natural compounds: the above-mentioned NaCl {13652}, Na_2CO_3 {8995}, Na_2SiO_3 {2599}, KCl {13361}, and KNO_3 {13787} are the main components of seawater. Second, their existence and release from plastics are minor compared to other sources such as the construction industry, pharmaceuticals, agriculture, etc. ($NaNO_3$, {13628}, NH_4HCO_3, {721}, NH_4NO_3, {11482}, and NaF, {13696}).

3.6.2. Chemical-Related Hazards Depending on the Type of Polymer, Particle Size, and Use Conditions. Another important piece of information that is lacking in the Red List is the degree of leaching or release of substances from plastics depending on the type of polymer, particle size, and the conditions under which the leaching occurs. It is noteworthy that both existing regulatory conditions (e.g., EU Commission regulation 2016/1416 sets the reference temperature for refrigerated storage at 5 °C, and for frozen storage at −18 °C in compliance testing for migration from packaging materials)[57] and changing operating conditions should be taken into account. Without such data, it is impossible to evaluate any actual hazard. In addition, such data should be compared with the same chemicals of concern in other widespread materials, particularly in cellulose-based materials, as these are often considered the main alternatives to plastics.

A more detailed description of some important examples for this part can be found in the Supporting Information (see Sections S3.1−S3.3).

4. DISCUSSION AND FINAL REMARKS

Overall, our evaluation raises significant questions for about 30% of 3651 compounds included in the Red List. This substantial fraction of uncertain classifications is a matter of serious concerns regarding the reliability of the methodology used to generate the list. Such methodological shortcomings can propagate large-scale errors, undermining the list's utility for science and policy. The automated approach used to create the list is akin to the misuse of artificial intelligence, which has been recognized as one of the three most significant scientific crises of modern times.[58] Therefore, our critical assessment shows that the list of chemicals of concern has to be carefully re-evaluated and revised.

On top of that, all entries in the Red List should pass through an additional specific filtering, which ensures that each chemical of concern is relevant to plastics. In particular, a simple analysis of UPR (use/presence/release) fields of the Red List shows that 2132 chemicals (58.4%) have blank entries in all the use, presence, and release columns. This fact makes it difficult to understand why these chemicals were included in the PlastChem database in the first place. Furthermore, it is of tremendous importance to prove that each chemical on the Red List is leaked from the polymer matrix in an amount that makes it dangerous for human health and the environment. Without such leaching screening, no chemical should be flagged as a chemical of concern in plastics.

The need for additional filtering after a hazard-based assessment has become increasingly evident nowadays. As a recent example, one can mention the prioritization approach for chemicals in plastics, which was presented by the government of Canada in December 2025.[4] This approach employed a hazard-based assessment at the first stage of prioritization of plastic-related chemicals, followed by a risk assessment approach at the second stage; the latter involved a tiered exposure evaluation. It is worth noting that the initial list (16 441 entries) included all 16 325 chemicals from the PlastChem database.

According to the approach adopted by the government of Canada, the chemicals that are not in use in Canada were excluded. Then, after a hazard-based evaluation, each chemical of concern was subjected to a tiered exposure screening based on the production volume, the relevance to human and environmental exposure, the function of the chemical in plastics, and the diffusivity of the chemical from the polymer matrix. This tiered exposure screening reduced the number of chemicals of concern in plastics to just ∼7.5% (159 compounds out of 2129 chemicals flagged by a hazard-based assessment).[4] This is an excellent illustration of the importance of plastics-specific tiered filtering, which we propose to apply to the red-listed chemicals after the hazard-based assessment has been performed.

The screening of the diffusivity of a chemical in plastics mentioned above can be performed using different approaches. For instance, the release of a chemical from plastics can be treated as being diffusion-controlled, and the corresponding diffusion coefficients can be evaluated through the Piringer/Brandsch model, which is widely adopted in EU regulations.[2] The leaching score can be then defined as a ratio of the released mass of a chemical and the specific migration limit (SML) set by the EU regulation (or the overall migration limit, OML, if SML is not available).[2] Such an approach is described in detail in Section S4 of the Supporting Information. As an illustration, we applied this leaching filtering to two chemicals from the Red list (bisphenol A and Chimassorb 944) and demonstrated that one chemical passed the screening (Chimassorb 944), while another (bisphenol A) did not, see Section S4.

It is also noteworthy that the issue of leaching from plastics can be more involved as degradation of plastic waste results in the formation of microplastics. For microplastics, the rate at which chemicals leach turns out to be faster than that for macroscopic plastics, influenced by the small size of MP particles and a larger surface-to-area volume ratio;[59] this aspect should also be properly accounted for.

Furthermore, based on our preliminary analysis, only ∼10% of the chemicals of concern are inorganic compounds, with the remainder being organic. For many organic compounds, plastics are not necessarily the main source of environmental release, as the functionalities associated with the properties of organic chemicals lend them to a wide range of applications. There are both national and international chemical regulations that currently exist that aim to restrict the use of hazardous chemicals. These include the EU REACH legislation that restricts the use of chemicals identified as being persistent, bioaccumulative, and toxic and more recent initiatives to target chemicals identified as mobile. At the international level, the well-functioning Stockholm Convention on POPs would represent an important instrument to limit the use of plastic additives identified as POPs. This would negate the need to duplicate this effort within the context of a future Plastics Treaty. Overall, inclusion of any compounds in a plastics-specific list of chemicals of concern should be scientifically justified. Otherwise, upon adoption of the list by global regulation, one could impair polymer production without rationale.

While we share the concerns of the authors of the Red List[5] regarding hazardous chemical additives in plastics, we have to emphasize that plastics are not the only source of chemicals.

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Other industry sectors should be treated on the same footing as the production of plastics, and similar material-specific exposure filtering can also be applied to evaluate the chemicals of concern in other sectors. This is especially important, given the slow release of chemicals from plastics compared with other materials such as paper. We recall that the need for global regulation of chemicals became the basis for the adoption of the Bonn Declaration[60] and the Global Framework on Chemicals[61] in 2023. These initiatives should be supported and given a new impetus for development and implementation. By identifying systematic flaws in data harmonization and pointing out the need for an evaluation of the release kinetics of chemicals, we highlight a critical risk of overregulation through hazard-based assessment that could destroy polymer production without any meaningful environmental benefit.

■ ASSOCIATED CONTENT

Supporting Information

The Supporting Information is available free of charge at https://pubs.acs.org/doi/10.1021/acs.est.6c05309.

Additional examples for degree of leaching or release of chemicals from matrices as a function of concentration, time, conditions, and polymer type brief description; technical errors, duplicates, and different physical forms of a substance with the same composition included as separate entries in the database; widespread-use compounds and compounds broadly distributed in the environment, including minerals and soil components (PDF)

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Notes

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