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Scientific Rationale for Approaches to the Identification and Regulation of Chemicals of Concern in Plastics

Relevance of the Study

Plastics comprise a broad class of materials consisting of a high-molecular-weight polymer matrix and a complex mixture of chemical additives, including plasticizers, stabilizers, flame retardants, colorants, and other substances introduced to impart specific functional properties.

Plastics are among the most widely produced and extensively used materials worldwide. In 2019, global plastic production reached approximately 460 million tonnes and, if current trends continue, is projected to triple by 2060. Owing to their versatility, cost-effectiveness, low weight, durability, and resistance to external factors, plastics are extensively used in packaging, consumer products, healthcare, construction, transportation, electronics, and many other sectors. However, alongside these undeniable advantages, the rapid increase in plastic production has resulted in substantial environmental contamination and, consequently, growing concerns regarding the adverse effects of plastic-associated chemicals on human health and the environment.

One of the key characteristics of plastics is their long service life, which underlies their widespread application across numerous sectors of the economy. At the same time, plastic waste may persist in the environment for decades, undergoing slow degradation and accumulating in soils as well as freshwater and marine ecosystems. Plastic waste constitutes a significant source of chemical pollution, as chemicals incorporated into plastics may migrate into environmental media and adversely affect humans, flora, and fauna. Chemical additives introduced during plastic manufacturing to improve performance characteristics belong to diverse chemical classes and exhibit a broad spectrum of toxic effects on living organisms.

Accordingly, the international community has placed increasing emphasis on ensuring the chemical safety of plastics. In 2022, the United Nations Environment Assembly (UNEA) adopted Resolution 5/14, End Plastic Pollution: Towards an International Legally Binding Instrument. Pursuant to this resolution, the United Nations Environment Programme (UNEP) initiated the development of an international legally binding agreement aimed at preventing and reducing plastic pollution throughout the entire life cycle of plastics – from design and production to waste management and disposal. One of the central components of the future agreement is the management of risks associated with chemicals of concern contained in plastics.

Aim of the Study

To provide a scientific rationale for approaches to the identification and hazard assessment of chemicals of concern in plastics in support of regulatory decision-making.

Objectives of the Study

1. To analyze existing international and national approaches to the hazard assessment and regulation of chemicals used in plastics.

2. To provide a scientific rationale for the criteria used to identify chemicals in plastics as substances of concern due to their adverse effects on human health and the environment.

3. To develop a scientifically substantiated algorithm for compiling a list of chemicals of concern in plastics.

4. To develop a national list of chemicals of concern present in plastics.

5. To provide a scientific rationale for national regulatory approaches applicable to highly hazardous chemicals contained in plastics.

Scientific Novelty

1. Scientifically substantiated criteria have been developed for identifying chemicals in plastics as chemicals of concern.

2. For the first time, a scientifically substantiated algorithm has been developed for compiling a list of chemicals of concern in plastics.

3. A concept for a database of environmentally hazardous chemicals contained in plastics has been developed.

4. Scientifically substantiated approaches have been proposed for regulating chemicals in plastics that pose risks to human health and the environment, including prohibition of use, concentration restrictions, and the establishment of hygienic and environmental standards.

Theoretical and Practical Significance

1. A national list of chemicals of concern in plastics comprising 857 substances has been developed.

2. The database “Environmentally Hazardous Chemicals in Plastics” has been developed and registered under Certificate RU No. 2025622946 dated 10 July 2025.

3. Four industrial design certificates have been obtained:

3.1. Algorithm for the Hazard Classification of Chemicals According to the Persistence (P), Bioaccumulation (B), and Toxicity (T) Criteria, protected by Certificate RU No. 148667 dated 5 August 2025.

3.2. Algorithm for the Hazard Classification of Chemicals According to the Persistence (P), Mobility (M), and Toxicity (T) Criteria, protected by Certificate RU No. 148258 dated 9 July 2025.

3.3. Algorithm for the Hazard Classification of Chemicals According to the very Persistent (vP) and very Bioaccumulation (vB) Criteria, protected by Certificate RU No. 148668 dated 5 August 2025.

3.4. Algorithm for the Hazard Classification of Chemicals According to the very Persistent (vP) and very Mobile (vM) Criteria, protected by Certificate RU No. 148669 dated 5 August 2025.

4. The database “Chemicals of Concern in Plastics” has been developed and registered under Certificate RU No. 2025625939 dated 10 December 2025.

5. GOST 32424 “Classification of Chemical Products According to Environmental Hazards. General Principles” has been revised and updated.

6. Priority highly hazardous chemicals requiring regulatory action have been identified, including heavy metals, nitrogen-, oxygen-, and halogen-containing organic compounds, as well as per- and polyfluoroalkyl substances (PFAS).

Provisions Submitted for Defense

1. Scientifically substantiated criteria have been developed for identifying chemicals in plastics as chemicals of concern due to their adverse effects on human health and the environment, based on an analysis of existing international and national approaches to hazard assessment and chemical regulation.

2. A scientifically substantiated algorithm has been developed for compiling a national list of chemicals of concern in plastics. The algorithm is based on the sequential application of criteria confirming the use of a substance in plastics and evaluating its hazardous properties with respect to human health and the environment.

3. A national list comprising 857 chemicals of concern in plastics has been developed. The list includes 358 carcinogens, 71 mutagens, 229 reproductive toxicants, and 181 endocrine disruptors; 335 substances classified as acutely hazardous to the aquatic environment and 489 substances classified as chronically hazardous to the aquatic environment; 41 PBT substances, 89 vPvB substances, 37 PMT substances, and 40 vPvM substances.

4. Scientifically substantiated approaches to the national regulation of chemicals of concern in plastics have been developed. These approaches include the establishment of hygienic and environmental standards, prohibition of use, and restrictions on the concentration of such chemicals in plastic materials.