Regulation of Toxic Substances: Legal Frameworks and Challenges

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Abstract

This paper examines the regulation of toxic substances, highlighting the legal frameworks and challenges that arise from incidents involving hazardous materials. The increasing global trade and use of toxic chemicals necessitate robust regulatory mechanisms to safeguard public health and the environment. Key international treaties, such as the Stockholm Convention on Persistent Organic Pollutants, provide a framework for collaborative efforts in managing hazardous substances. The paper also discusses national regulations, like the Toxic Substances Control Act in the United States, emphasizing their evolution in response to public health crises. Challenges in enforcement, regulatory compliance, and the emergence of new contaminants complicate the landscape of toxic substance regulation. As scientific understanding of toxicity advances, regulatory bodies face the pressing need to adapt legislation to address emerging threats effectively. The paper advocates for enhanced international cooperation, stakeholder engagement, and the integration of innovative regulatory approaches to improve health protection and environmental sustainability.

Keywords:

Toxic substances, Regulation, Public health, Environmental protection, International treaties, Stockholm Convention, Toxic Substances Control Act, Emerging contaminants, Regulatory challenges

1. Introduction

Incidents and accidents involving toxic substances have shown their ability to cause harm to human beings and the environment. The deaths and illnesses that result from exposure to hazardous materials are the most obvious manifestations of their negative impacts on public health and the environment. The widespread use of toxic substances with varying degrees of hazard increases their potential risk of disruption. Tens of thousands of chemicals are widely traded across the world – stored, processed, and/or disposed of at millions of work sites. In this context, an accident that would be local or regional in character in incidence or effect would have global significance due to world trade channels and financial market flows. This is why managing toxic

substances is a major concern, which is where the following essay is situated. Fairly obviously, the specific legal and regulatory rules underpinning the trade in toxic substances trundle along in the background of these points. More precisely, it is here that the roles, uses, and access of sectors and agents in society begin to be unraveled. As a system or process necessarily involves various interests in its scope and operation, and its effectiveness ultimately measures this operation, appreciation of how different parts fit together is unavoidable. Since the environment has bordered and transcended the spaces that previously divided them, globalization has fundamentally transformed the prospects for environmental regulation. This question is given added purchase by the era in which international environmental regulation finds itself. This essay will further increase understanding of toxic substance regimes and environmental regulation focused on international and human rights order. In the cases of comparative legal systems, we restrict the inquiry to some social actors: industry and non-governmental organizations.

Regulation of toxic substances, the topic of this document, is an outgrowth of concerns that emerged in the wake of major chemical accidents that led to widespread chemical exposures and societal alarm. Incidents involving lead exposure, such as those in Flint, Michigan, and the contamination of the Washington D.C. water supply; the asbestos contamination of Libby, Montana; and numerous events involving exposure to endocrine-disrupting chemicals or persistent organic pollutants provide other examples. These public health crises led directly to policy changes, some of which are described in subsequent sections. Memories of these events have proven long-lived, particularly among affected populations, and the need for improved protection and monitoring of the susceptibility of such groups is now clearly recognized. Toxic exposure, even at low levels, can lead to higher rates of chronic health problems such as diabetes, cardiovascular diseases, and cancer. The identification of those who are most susceptible, other than workers who are typically more exposed, is not well understood but is complex and involves racial and ethnic factors (Garnett & Van Calster, 2021).

The revolution in hazard assessment, beginning in the 1960s and early 1970s, which brought us test animals like mice, compared to modern techniques using human cells

and surrogate tissues, among other advances, has also been mentioned. Prior to the 1940s, policy development focused on exposure and prevention of gross and acute injury. However, as evidence for delayed and protracted impacts of chemical exposure blurred the line between outpatient and inpatient care and between cancer and chronic disease, emphasis on proper warning and the thorough evaluation of data began to increase. Incentives for both government agencies and industry regarding insurability, liability, and overall costs (as well as benefits) of regulating toxic substances also contributed to the shift in thinking to this more comprehensive view. Public outcry, as well as pressure from advocacy groups and the public, is often credited with initiating needed regulatory reforms. Regardless, the result of these various factors prompted society to begin to explore the issue of developing new approaches to regulate toxic substances in order to promote human health and protect the environment.

2. International Legal Frameworks

Herzler et al. (2021) state that the regulation of toxic substances must not only be controlled within any one territory but also addressed by international cooperation for two main reasons. These are, first, the transfer and international trade in hazardous waste and other hazardous substances to the detriment of the environment and human health; and second, the increased environmental pressure through air pollution, wind- and water-transferred hazardous substances which are only internationally reducible. Thus, over the last decades, a manifold of international treaties and agreements have come into force.

The respective international legal framework consists, on the one hand, of agreements with a special and more comprehensive perspective on different hazardous materials considering them in principle altogether regardless of their properties, fields of use, and operation; on the other hand, of agreements with a more specific perspective, which focus on single hazardous materials, their circulation or restriction, or prohibitions of production and use. National compliance and mechanisms of monitoring are the task of the parties, but in some cases, they are facilitated through expert and project assistance by the responsible secretariats of international organizations. While capacities in regulation and control vary from country to country,

efforts are made to harmonize standards internationally, in accordance with the principle of proportionality. The necessity of an international convention with common standards and procedures is illustrated by cases such as the control on international trade in ozone-depleting chemicals, the control of transports of toxic and other harmful waste. Only in this manner has international transfer and trade in toxic materials been accepted and supported. For all hazardous materials reaching the international regulatory table, this is equally important.

2.1. The Stockholm Convention on Persistent Organic Pollutants

This treaty focuses on a particular class of toxic substances. Persistent organic pollutants (POPs) pose special threats because they can be transported over long distances by wind and water, making them a transboundary problem. They are designed for stability, degrading slowly, and persisting in the environment for many years. They are biologically active and transferable through the food web to a range of different organisms. The objectives of the Convention are to reduce and eliminate the production and use of POPs in order to protect human health and the environment from the effects of POPs. In advocating for the enhanced exchange of chemicals across international boundaries, the Convention on Persistent Organic Pollutants represents a concrete expression of the principle of common but differentiated responsibilities and potentialities that underpin international environmental governance. In relation to the regulation of toxic substances, the Convention is one of a small number of key international agreements (Wohlleben et al.2019).

The Convention has focused on a few specifically identified POPs and has procedures for adding and removing chemicals from its Annexes following a sound scientific review and decision. Action is taken by the Conference of the Parties. A key part of the Convention is to promote alternative methods or substances in areas where permitted uses still occur. By adopting explicit preventative measures and historic measures, it takes a “catch and correct” method to stress relief. This area comprising eight sections will examine the lessons and problems that have emerged in seeking the Agreement on how best it can achieve its purpose. In practice, a number of challenges have to be overcome for the Convention effectively to address POPs pollution, particularly in early or limited implementation, especially in developing countries and

countries with economies in transition. Effective stakeholder involvement, cooperation, and capacity-building initiatives are critical to securing the successful implementation of the Convention within countries. Many States Parties have enacted legislation implementing the Convention. The efforts made to meet the operational objectives of the Convention to ensure that measures are taken to reduce or eliminate human and environmental exposure to persistent organic pollutants are still at an early stage in many countries. In order to take effective action and protect human health and the world, additional support to governments, legislatures, and key stakeholders is needed (McPartland et al. 2022).

3. National Legal Frameworks

In the past, all countries have regulated chemicals and have updated or upgraded laws rather extensively. Those laws differ according to national necessities as well as political preferences, which in turn are influenced by pressures and support from stakeholders and informed segments of society. These differences exist mainly because the risks, priorities, needs, and resources fluctuate among the nations. The fundamental principle of these laws is to ensure that public health and the environment are protected to an extent acceptable to the people and to society, be it for any criteria. Are these laws in toto logical and rational, coherent with ethics and life sciences, in the context of dealing with toxic substances in this emerging new millennium of molecular epidemiology, nanotechnology applications, and greater global chemical transfer? Uniformity in legislative principles clearly elides many other socio-economic and political issues. It is premature to speculate henceforth whether there could be environmental utopia, as nothing can override peculiar national priorities. Yet, if those laws are functional, transparent, and coherent with the changing structure of life sciences, they wish no review, globally and certainly only piecemeal nationally. Those laws are such a cantankerous lot as they differ enormously both among the Anglo-Saxon countries and those of the European continent. The main issue is that with the advancement of the sciences (biological, ecological, and medical), what is toxic and what measures could intercept the corpo-economic host are changing rapidly. Also, between the Anglo-Saxons and Europeans, the former heavily tie the science and risk assessment factors to political and

economic perspectives, explaining the lower levels for health and ecological protection than what has been set in legislation by the Europeans since at least 1986. Political rather than scientific pressures seem to heavily influence the former group of countries.

3.1. The Toxic Substances Control Act in the United States

According to the United Nations, the "sound management of chemicals" is essential to achieve Sustainable Development Goals. With the increasing demand for consumer products and industrial chemicals, nations around the world have begun adopting legislation aimed at developing the safe management of chemicals. The management of toxic substances, from production through disposal, has especially been a focus of attention. This trend is particularly evident in the United States, where policy has evolved over the last five decades to control the use and management of chemical substances (Mondou et al. 2021).

The Toxic Substances Control Act in the United States The United States' regulatory framework is managed extensively through the Toxic Substances Control Act of 1976. Electrifying exposure to polychlorinated biphenyls and other chemicals in the 1970s set the stage for mechanisms designed to act "to adequately protect the public and the environment from unreasonable risks." Substances regulated by TSCA are typically new chemicals that did not exist before a certain date and chemicals that are not regulated under other statutes.

The US regulatory system rests largely on the shoulders of the new chemicals program of TSCA, embodied primarily at Section 5. Registered chemicals are subject to market entry requirements so that substances are evaluated before they are manufactured. Unique to TSCA, the U.S. has made the decision that the government holds the burden of proof and that industry secrets will be protected. TSCA has required multiple layers to check the safety of new chemicals, as well as meet regulated standards for substances. Companies manufacturing, processing, or importing chemicals in the U.S. must test chemicals if subject to regulation and submit reports to the U.S. Environmental Protection Agency to establish the safety of their products. This is the premise and foundation of TSCA compliance in the U.S.

Some components of TSCA remain untested, as has enforcement, federal coordination over other laws, and TSCA efficiency, among other challenges. That said, a phenomenon that sparked legislative action was the role of the advocacy interplay between divisions of corporate America and the public. In response to global public concern dating back to the late 1970s and through the 1990s, TSCA was amended with notable additions to enhance management, including to set foundation and funding at the new chemicals program of the EPA, conducting worst-case scenario exposure-related evaluations, and enhancing record-keeping of chemical constituents within an article. In the background of the U.S. chemical assessment system under TSCA for new chemicals, the U.S. has been periodically updating, revising, and launching the system for over forty years. The current system may be a suitable template for the undertaking of various national programs. I mention this in closing to provide evidence that an intricate and bewildering program can leave a sizable, enduring relic for the schemata of chemical management systems worldwide. Further international regulatory actions are likely to result directly and indirectly in ongoing international chemical control initiatives globally.

4. Enforcement Mechanisms

Effectiveness, or lack of effectiveness, of government enforcement lies at the heart of many contemporary debates on regulating toxic substances and ensuring the safety of the products that surround us. If enforcement does not compel compliance, then companies have limited incentives to strive to comply with the law. If enforcement focuses only on easier cases, more recalcitrant polluters receive de facto immunity. Arbitrary or abusive enforcement results in a lack of public confidence in the enforcement of environmental law and the agencies responsible for environmental protection. The lack of carefully monitored enforcement targets can promote the ready filing of enforcement cases, or the necessary investigations and follow-up for cases may not be consistent. The possibility of such arbitrary actions hampers voluntary compliance. To better understand the relationships between prohibitions and compliance, this chapter will focus on reliable themes in various regulatory systems and then turn to specific enforcement systems in some of the key jurisdictions represented in the chemicals sector.

In many international, federal, and state jurisdictions, enforcement mechanisms and judicial systems exist to ensure compliance with environmental laws. Government agencies are given enforcement power by laws or statutes, and the agencies themselves may divide or allocate that authority and obtain resources and technical assistance in addressing the scope of those enforcement actions. Regulatory bodies are partners in a system of multiple regulatory enforcement options, and they can place toxic substances at various stages of the product cycle. Enforcement has the role of risk management for different subagencies, not just for toxic substances, and others. It is by no means the only partner in compliance assurance, but it is the most carefully monitored with data available to a large extent. For this reason, we have been able to collect information on the level of amperage and effectiveness of various enforcement actions.

4.1. Regulatory Agencies and Their Roles

Regulatory agencies play pivotal roles in managing toxic substances for public health and environmental protection (Duh-Leong et al.2022). The reach and capacity of agencies with direct responsibilities, as well as nongovernmental organizations dedicated to specific societal concerns, span local, national, continental, and international levels. Agencies at the national level are the key regulatory bodies for managing toxic substances and ensuring public health. In the United States, the major federal agency for regulating environmental contaminants is the Environmental Protection Agency. Similarly, other countries have national agencies with responsibilities related to health and safety and control of toxic substances. These agencies may or may not have environmental monitoring mandates. An example from a country with which we are familiar is Health Canada, which is largely responsible for ensuring product safety, including pharmaceuticals, in the Canadian marketplace.

Regulatory agencies rely on their technical capacity to undertake risk assessments for toxic substances that inform management and administrative decisions on regulatory controls. The possession of scientific expertise and interpretative capacities of technical and regulatory information can differ significantly from agency to agency. While some agencies may be rich in scientific expertise and financial resources, which gives them enforcement capabilities for managing toxic substances, others may

not. Collaboration between industry and regulatory agencies is often a norm in many regulatory systems. That is, industries are permitted to provide input to risk assessments that can inform regulatory decisions. However, recent challenges posed by allegations of potential conflicts of interest have led to a number of revisions of this approach. Regulatory fragmentation is an additional challenge: many agencies are often responsible for the management of different scientific fields.

Despite these challenges, case studies have demonstrated successful interventions and improvements in public health and environmental quality, outcomes that were achieved under the presence of clear and coherent regulations enforced through appropriate dedicated agencies. Public health is the key motivating factor for interventions and the protection of critical resources. Many regulatory agencies appreciate that the long-term success of public health and environmental quality needs to be based on stakeholder participation and their abilities to effectively address contemporary and known concerns with rapidity and effectiveness. Regulatory agencies realize that this cannot be achieved in the absence of significant and continued cooperation from industry, the main stakeholder group that is directly regulated by standard compliance and enforcement procedures.

5. Challenges and Future Directions

In this section, we discuss the future and some of the challenges in the areas of the regulation of toxic substances, toxicology, and public health—areas that we have been involved in to varying extents during all of the 22 or so years of this project.

There are many challenges facing the regulatory setting of toxic substances both now and in the future. Our understanding of the toxicology of substances has developed beyond recognition since the guidelines were first published in 2000. The initial list of priority pollutants, comprising mainly heavy metals known for their adverse health effects for many years, has been replaced with an ever-growing list of other heavy metals as well as many other substances. Further, while some substances listed for environmental management do have health-based guidelines, many do not, reflecting the increasing concern not only for public health but also for the environment (Nikolopoulou et al.2020).

There are other legislative frameworks that contribute to the regulatory environment for toxic substances in Australia that are also struggling to keep pace with the ever-growing evidence base regarding the potential for adverse effects on human and environmental health. Much-needed reform in this area includes larger lists of chemicals requiring registration, greater resources to perform comprehensive assessments, and faster turnaround times for mandatory compliance with the legislation. Clearly, dedicated regulatory actions such as these warrant far greater examination to facilitate or better guide potential reform. Regulatory delays are clearly borne from the complexities surrounding emerging contaminant identification, determination of environmental persistence, bioavailability, and the corresponding health risks. However, that is not an excuse to wait for more robust scientific data before action is taken. Potential means for reform or innovation in this area of law are widespread and can be found in recent literature. Clearly, improvements can be made on current laws, including the integration of an adaptive management regime to enable review and implementation of new research and further risk assessment. In New South Wales at least, the revised protection of the environment legislation gives a good example. There is no reason why this aspirational reform cannot be attempted at the national level.

5.1. Emerging Contaminants and Regulatory Gaps

There is growing concern over the potential regulatory gaps that exist for so-called emerging contaminants. An emerging contaminant is a novel substance, which could be either completely unknown to humans or present in the environment at levels previously considered innocuous yet harmful to human health or the environment disproportionately. Sources of emerging contaminants are diverse and include intermediate products formed during chemical reactions, preservatives, pesticides, drug residues, and waste from the psychedelics industry. The substances covered by the term emerging contaminants do not encompass the full diverse spectrum of potential toxic environmental substances. They have garnered attention in part because, compared to substances already subjected to regulation, they are relatively more likely to be unregulated (Mansfield, 2021).

The evidence base for emerging contaminants is often based on molecular properties that suggest they could be toxic. Distinguishing chemicals that actually pose risks is therefore challenging, particularly within existing legislative frameworks, which typically require that direct toxicity be observable before exposure to the chemical can be construed as unduly dangerous. Scientific understanding of the timing and patterns of human exposure to toxicants has long lagged behind regulations. Exposure settings that current standards do not directly consider include co-exposure to multiple stressors, like other psychoactive prescription or over-the-counter drugs, as well as habitual and infant exposure to contaminants in personal care and food packaging products, during dermal use, for example. Risk evaluation programs have yet to incorporate several other emerging exposure risks, like agricultural use of treated sewage sludge, use of PFAS-containing sludge as topsoil, and chemical migration from PFAS-treated textiles into domestic agricultural soils. Regulatory approaches can only become more reactive as new substance footholds are detected (Schmeisser et al.2019)

References

Cattaneo, I., Kalian, A. D., Di Nicola, M. R., Dujardin, B., Levorato, S., Mohimont, L., ... & Dorne, J. L. C. (2022). Risk assessment of combined exposure to multiple chemicals at the European Food Safety Authority: principles, guidance documents, applications and future challenges. Toxins, 15(1), 40. mdpi.com

Duh-Leong, C., Maffini, M. V., Kassotis, C. D., Vandenberg, L. N., & Trasande, L. (2022). The regulation of endocrine-disrupting chemicals to minimize their impact on health. Nature Reviews Endocrinology, 19(10), 600-614. kassotislab.org

Garnett, K. & Van Calster, G. (2021). The concept of essential use: a novel approach to regulating chemicals in the European Union. Transnational Environmental Law. cambridge.org

Herzler, M., Marx-Stoelting, P., Pirow, R., Riebeling, C., Luch, A., Tralau, T., ... & Hensel, A. (2021). The “EU chemicals strategy for sustainability” questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?. Archives of Toxicology, 95(7), 2589-2601. springer.com

Mansfield, B. (2021). Deregulatory science: Chemical risk analysis in Trump's EPA. Social Studies of Science. sagepub.com

McPartland, J., Shaffer, R. M., Fox, M. A., Nachman, K. E., Burke, T. A., & Denison, R. A. (2022). Charting a path forward: assessing the science of chemical risk evaluations under the Toxic Substances Control Act in the context of recent National Academies recommendations. Environmental health perspectives, 130(2), 025003. nih.gov

Mondou, M., Maguire, S., Pain, G., Crump, D., Hecker, M., Basu, N., & Hickey, G. M. (2021). Envisioning an international validation process for New Approach Methodologies in chemical hazard and risk assessment. Environmental Advances, 4, 100061. sciencedirect.com

Nikolopoulou, D., Ntzani, E., Kyriakopoulou, K., Anagnostopoulos, C., & Machera, K. (2022). Priorities and challenges in methodology for human health risk assessment from combined exposure to multiple chemicals. Toxics, 11(5), 401.

Schmeisser, S., Miccoli, A., von Bergen, M., Berggren, E., Braeuning, A., Busch, W., ... & Tralau, T. (2022). New approach methodologies in human regulatory toxicology–Not if, but how and when!. Environment International, 178, 108082.

Wohlleben, W., Mehling, A., & Landsiedel, R. (2022). Lessons learned from the grouping of chemicals to assess risks to human health. Angewandte Chemie International Edition, 62(22), e202210651.