

Chemical Regulation in the Middle East

Executive Summary

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Many developing and emerging countries have implemented or are working diligently to implement chemical substance management programs. Examples of such programs include the development of a Restriction of Hazardous Substances (RoHS) regulation in Brazil, a bill that would establish criteria for the progressive and voluntary provisions for reduction of single-use polymers and their derivatives in Peru, and a draft technical regulation for food contact plastics in Vietnam.

The Middle East has been perceived to be at a relatively nascent stage of developing a comprehensive program for managing chemicals. There may be a variety of reasons for this perception, ranging from a lack of fluency in Arabic, Hebrew, or Urdu, to a somewhat insular culture within the region, and to the tendency to focus on geographic regions with more robust commercial and business operations. There are, however, emerging chemical regulatory initiatives underway in the region, and a thorough understanding of these programs and those agencies and entities involved, the legislation in force, and the key areas of concern is vital for compliant and commercially successful operations across the region.

Whether you are a seasoned regulatory compliance professional or a newcomer to the industry or the region, John Wiley and Sons, Limited's recently published and first of its kind book, *Chemical Regulation in the Middle East*, is an invaluable resource to help navigate the complexities of chemical compliance across a myriad of countries. Organized by country, and as outlined below, *Chemical Regulation in the Middle East* guides the reader through multiple key topics for each country. The book helps familiarize readers with the key chemical control programs and enables readers to anticipate associated issues that may arise in legal and commercial settings. Each chapter of the book is presented in the same format, making it quickly searchable for the applicable regulations. In addition, a detailed index minimizes search times.

Each chapter begins with a "National Overview," providing a brief history of the country to establish a sense of context for the items that follow. Next is "Governmental Structure," detailing the function and structure of the country's executive, legislative, and judicial branches, giving the reader a firm understanding of the process for proposing, considering, and enacting legislation within each country. Following that section is "Key Chemical Regulatory Agencies." This section provides a holistic view of the major and relatively major Ministries, Authorities, National Bodies, Organizations, and others who have various responsibilities relating to the management of chemical substances. The section also details situations where multiple agencies share jurisdiction, helping to guide the reader in situations where a single regulatory submission may not be appropriate.

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The final section of each chapter, “Key Chemical Substance Regulations,” provides a comprehensive examination of the main chemical substance laws in force in the country at issue, including the name of the statute, the responsible Authority (ies), and a detailed examination of the requirements, including particular aspects to pay attention to, through a section-by-section walk through of the regulation. “Key Chemical Substance Regulations” is divided into the following subsections:

- Chemical Control Regulation;
- Pesticide Regulations;
- Occupational Safety and Health Regulations;
- Waste Regulations; and
- Safety Data Sheets and Labels.

Chemical Regulation in the Middle East focuses on eight countries that have fairly well developed chemical regulatory schemes in place: Bahrain, Egypt, Israel, Kuwait, Oman, Pakistan, Saudi Arabia, and the United Arab Emirates. While each is part of the geographic region collectively known as the Middle East, there are both many similarities and multiple differences among the regulations in each country. For example:

Bahrain: The country of Bahrain imports a considerable volume of chemicals from around the globe, including pesticides, cleaning materials, pharmaceutical drugs, and food additives. The country is similar to many of the others in the region in that it presently has no national inventory or new chemical notification scheme in force. The country does, however, have specific regulations in place with respect to pesticides, fertilizers, industrial chemicals, consumer chemicals, hazardous materials, and hazardous waste, among several others.

Egypt: One of the relatively more progressive countries in the region with respect to chemical legislation, Egypt has had such laws in place since 1958, but undertook a concerted push in this area beginning in 1991. Egypt has issued a large number of environmental legislations governing importing, manufacturing, trade, and use of chemical substances across different areas. Uniquely, the country also has legislation in force addressing Integrated Pest Management. Egypt has seven different Ministries with varying roles and responsibilities for issuing chemical substance permits, which may make obtaining such clearances challenging and time-consuming. Similar to Bahrain, the country has neither a chemical inventory nor new chemicals notification requirements.

Israel: Perhaps along with Saudi Arabia, Israel is the country with the most thoroughly developed chemical substance regulations in the Middle East. The Ministry of Environmental Protection has been the authority responsible for hazardous substances regulation since 1993, although over time, other government agencies and Ministries have gained increased authority and influence. The most significant segment of the Israeli chemical industry is the pharmaceutical business, which is a world leader in the manufacture of generic drugs. As such, there is extensive chemical product regulation here. Currently, registration and licensing is required for pesticides, pharmaceuticals, cosmetic preparations, and food additives. There is no legal framework for the licensing of industrial chemicals (e.g., a national inventory of existing or new chemicals), nor is there presently a new chemical notification scheme,

although a licensing framework exists for chemicals used in agriculture. Israel primarily regulates chemicals through a permit licensing program.

Kuwait: As early as 1987, Kuwait had implemented a national monitoring system for chemical substances. In 1995, it introduced the concept of “polluter pays” into national law through passage of Law No. 21, and in 2001, it promulgated Decision No. 210/2001 “Pertaining to the Executive By-Law of the Law of Environment Public Authority” that requires the provision of specific data by importers and/or exporters of such substances to the Environment Public Authority (EPA). While not a chemical substance notification law per se, these entities must submit information such as a list of ingredients and the “serial number” (Chemical Abstracts Service Registry Number (CASRN)) of the products at issue. Kuwait also has a pesticide registration law that requires prior approval from the authority before importing or manufacturing a pesticide product.

Oman: While Oman may have relatively few distinct chemical substance management regulations in its national law, those that exist are fairly comprehensive. The Basic Law of Oman (RD 101-1996) considers the protection of the environment and prevention of pollution a social principle and the responsibility of the State, through the Department of Chemicals (Department). Oman’s Royal Decree No. 46 of 1995 established a wide range of requirements for chemical substances, including authorizing the Department to conduct tests on substances to determine their toxicity, preparing inventories and registers for both the substances and their users, issuing usage permits, and establishing a database of substances. Oman also has substantive pesticide registration laws and, largely unique to the region, wide-ranging occupational safety and health regulations. Oman also has a Safety Data Sheet (SDS) regulation in force.

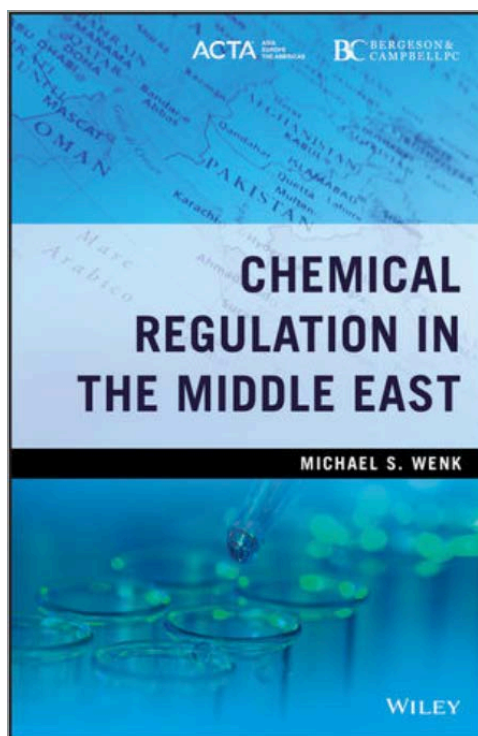
Pakistan: Pakistan presents an unusual regulatory situation, and one that often challenges compliance staff, as relevant Ministries and organizations maintain their data with respect to chemical substances under their purview, and no central database of such exists. Moreover, a national information system regarding chemicals and related safety and security aspects does not exist. As such, it can be challenging to understand which entities regulate a given chemical substance. Additionally, the province of Sindh has its own expansive regulations, which do not necessarily align with national regulations. As with Israel, Pakistan tends to regulate many chemicals by the issuance of permits. The country has an extensive pesticide Ordinance, dating to 1971, which (among other aspects) contains a list of 26 active ingredients that are banned from use.

Saudi Arabia: The Kingdom of Saudi Arabia is particularly interesting from a regulatory perspective as the country has delegated to the Saudi Arabian Standards Organization (SASO) the authority to promulgate a wide range of (enforceable) standards relating to chemical substance regulations. Most recently, SASO maintained a library of in excess of 20,000 standards. Similar to Pakistan, six different Ministries have responsibility for chemical management, under the auspices of the “Law of Chemicals Import and Management.” Also similar to Pakistan, Saudi Arabia has two cities, Jubail and Yanbu, that have their own regulatory systems in place to manage chemicals.

United Arab Emirates (UAE): The UAE has a strong interest in chemical substance management, with specific attention given to hazardous chemicals administration. Uniquely, the UAE also codifies a form of cost-benefit analysis within its Federal Law No. 24, “Development and the Environment.” Pesticides are highly regulated in the UAE, requiring registration for virtually all end uses, establishing a list of pesticides prohibited from use or import due to their dangerous effects, and outlining a substantial data set required for approval. Additionally, the country’s occupational safety and health regulation is highly protectionist in its language, limiting the areas in which non-citizens may work, and the processes by which they may apply to do so. The UAE also has promulgated a specific regulation (Decree No. 37) addressing SDS.

Each of the focused chapters in the book, through detailed commentary on the regulations, listed resources and citations, and critical evaluation, will help guide the reader through the myriad of regulatory environments in the region. The text will prove to be an invaluable resource for strategic planning, hands-on regulatory work, and providing a nuanced understanding of what has historically been an unfamiliar region to many industries.

Chemical Regulation in the Middle East is available for purchase via the [John Wiley and Sons Ltd. website](#).



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