Hebrew University of Jerusalem
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# Regulation in an Era of Global Governance -

# Israel's Chemicals Regulatory Regime Following the Accession to the OECD

Final Research Paper for a Masters in Public Policy

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7 October 2010

# Acknowledgements

Completing this thesis was a challenge.

I would like to dedicate this project to my beloved son Ariel Matan, whose bare existence motivated me to work harder to complete the assignment.

Professionally, I would like to express my great gratitude to my supervisor, Prof. David Levi-Faur, whose expertise, understanding, and patience, added considerably to my graduate experience. This work could not have been accomplished without him.

Deepest gratitude are also due to Ofra Toren-Commere, without whose motivation and encouragement I would not have finished the challenge that I took upon myself.

A very special thanks goes out to Galia Moldavsky (Yavilevich) for her profound and careful editing of the text.

Last but not least, I would also like to thank my family for the support they have always provided me. Thank you mom, dad and my dear brother Daniel. In particular, I must acknowledge my husband, Moran, without whose love, encouragement and editing assistance, I would not have finished this thesis.

# Abstract

The Organization of Economic Cooperation and Development (OECD) is an international platform for policy discussions and the setting of "best practices". Up until recently, it was comprised of 30 member countries, all of which are liberal democracies with open market economies. On May 16th 2007, the OECD Council invited Israel, alongside Chile, Slovenia, Estonia and Russia, to start negotiations on the terms of their accession. Israel's process of negotiations reached its peak on September 7th 2010, when it became the 33rd member country.

This 3 year long process, involved an in-depth analysis of Israel's legislation and policy in various fields. One of the major policy gaps between Israel's existing legislative framework and the OECD's requirements lies in the field of chemical regulation. Currently, Israel has no coherent and comprehensive regulatory regime governing the production, marketing, transportation and authorization of chemicals.

This research traces the process of Israel's accession to the OECD with respect to the establishment of a chemicals regulatory regime. It is expected that this policy lacuna is set to undergo a major change in order to comply with the OECD's set of core legal documents and requirements.

The theoretical framework, upon which this research is based, is policy change and policy transfer (Bennett & Howlett, 1992; Wolman, 1992; Dolowitz & Marsh, 2000). The specific context in the case under study is the growing role of international players in shaping national policies. It was previously recognized that the agents of change are not limited to government officials, and the industry can play a vital role in policy transfer.

Analysis of the initial stages of the agenda-setting process outlining the establishment of a chemicals regulatory regime is focused on the forces, considerations and expectations that shape the process of change in regulation. The interests and strategies of industrial groups are important determinants of policy outcomes. Moreover, since the industry ultimately bears the implementation cost of most environmental policies, it is crucial to assess the interests which

will influence the future compliance and effectiveness of chemical management standards as well as the voluntary adherence to stricter policies.

This research addresses the question of the extent to which these changes reflect not only policy learning and policy transfer, but also potential changes in the structure of power between state agencies regulation and civil regulation.

Two contradicting hypotheses are debated: the neo-liberal top-down approach, which emphasizes the role of the OECD and the government bureaucrats as policy transfer agents; and the pluralist bottom- up approach, which examines the role of non-state centred actors in shaping this process. The proposed answer is that the potential power shift will likely occur, not only according to the bottom-up approach, which empowers the industry and civil society organizations, but also according to the top- down approach stipulated by the OECD itself.

The policy outcome shifts from a state-centered regulatory regime to a more complex structure of civil regulation models. These complimentary regulation models may vary across a continuum; starting with voluntary self regulation by a company or an industry, through third party regulation, moving towards a more hybrid form of co-regulation and ending with meta-regulation. Conclusively, in situations where the interests of the industry do not fully align with the obligations made by the government, self regulation is unlikely to be an effective instrument.

In the context of this research, when establishing a chemical regulatory regime, Israel should bear in mind that when economic motivations are not strong enough, co-regulation or meta-regulation would be a better model for regulating chemicals.

# Table of Contents

## List of Figures



## List of Tables:

# Chapter I. Introduction

## I.1 The Scope of the Research

On 27 May 2010 the Ministerial Council of Organization for Economic Cooperation and Development [hereafter, OECD] adopted a resolution to invite Israel to join the organization. This decision was the closing chapter after an intense three-year-long process of negotiations and policy reviews. The above mentioned review process began on 16 of May 2007, when the council approved to open discussions with Chile, Estonia, The Russian Federation, Slovenia and Israel on terms of entry to the organization. This research examines Israel's accession and the obligations arising from such a review process in one particular case study of policy setting.

Following the Council's resolution back in 2007, the Secretary-General had set out the terms, conditions and process for the accession of these countries to the OECD. Few days earlier, the Council set up a procedure for future accessions known as a "Roadmap". According to the Roadmap, the initial requirement for OECD membership is commitment of the countries to common values and standards, which serve as the foundation of the like-mindedness of OECD members and have been expressed in various OECD Ministerial Communiqués. Accepting these values, along with the established body of OECD legal instruments, standards and benchmarks, is a requirement for membership. Each acceding country was requested to position itself vis-à-vis all the legal substantive instruments adopted within the OECD prior to joining the organization. This research examines the processes of change in the Israeli chemicals regulatory regime in the context of the accession process to the OECD.

The OECD, which was established in its current form in 1961, is an international organization that acts to facilitate reforms and where governments can compare policy experiences, seek answers to common problems, identify good practices, and coordinate domestic and international policies (Bayne, 1987). The mandate of the OECD is broad, ranging from economic and social to

environmental issues (Woodward, 2007). Initially, The OECD evolved from the Organization for European Economic Co-operation (OEEC), which was founded in 1948 to help administer the Marshall Plan for the reconstruction of Europe after World War II (Hahn, 1962). As the Marshall Plan faded, the OEEC focused solely on economic questions. In the 1950s, the OEEC provided the framework for negotiations aimed at determining the conditions for setting up a European Free Trade Area, to bring together the Common Market of the six and the other OEEC members on a multilateral basis (Camps, 1975; Mahon & McBride, 2009; OECD, 2004a)

The OECD can be seen as an instrument for safe-guarding the economic equilibrium in Western Europe and North America and, due to that impact of these regions on worldwide economic development, for the maintenance of economic growth generally (Ostry, 1984). Therefore, a realistic assessment of the political merits of the OECD may, therefore, recognize the new venture as an acknowledgment by the member states of their responsibilities vis-a-vis other nations, especially those which depend for their economic development on aid from Europe and North America (Hahn, 1962; see also Ohlin, 1968; OECD 1984; Camps, 1975; Wolfe 2007)

Over the years to come, the organization has grown and expanded its activities dramatically. Global reach has been an integral part of OECD's mission from the beginning. Article 1 of the OECD Convention states that members "should contribute to sound economic expansion in member as well as non-member countries in the process of economic development." At that time OECD economies comprised a vast share of the world's production and trade. But as more countries have embarked on integration into the global economy that share is steadily diminishing. In order to remain an influential voice in the world economy the OECD must strengthen its links with other countries through policy analysis, dialogue and rule-making.

Today, the OECD plays a key role in managing globalization – understanding it, explaining it, analyzing its effects, and making policy recommendations in order to maximize its benefits and to tackle its challenges. This is achieved by various means: peer reviews and surveillance, such as country studies; benchmarking, i.e. the students exam- PISA study; and by the negotiation of instruments, such as the Anti-Bribery Convention. Israel's accession serves to strengthen the fulfillment of the OECD mandate to become more global and will significantly contribute to the geographical diversification of the organization, as well as ensuring the policy - making process becomes more relevant to different and perhaps smaller economies.

The OECD engages with a large number of economies outside its membership. Many are actively involved in core OECD activities, for example as observers or participants in OECD Committees, and main Working Groups or Expert Groups, where representatives of each of the member countries review progress and discuss policy in specific areas. Currently this is the case for 25 non-members sitting on 43 Committees and main Working Groups.

Prior to its accession, Israel had participated in various forums and committees of the organization, looking forward an invitation to join. Entering the OECD is a matter of importance in positioning the Israeli economy among the advanced economies of the world, and being able to take an active and significant part in shaping global agenda. OECD membership will support Israel's goals of further enhancing structural reforms and implementing social and economic policies.

This research is set within the OECD influence framework. The general scope of the research is to identify the shaping forces and major players in the regulatory process the goal is to explore processes of policy change (Bennett & Howlett, 1992; Wolman, 1992; Dolowitz & Marsh, 2000), in the context of the growing role of international players in shaping national policies (both state-centered and non-state organizations and frameworks), the accession seen as an agenda setting leverage. At the same time, it explores not only the policy problems and issues involved in policy globalization, but also the potential power shift from a state-centered regulatory regime to a more complex structure that includes self- and third-party regulation.

The scope of this research, namely the setting of regulatory regime for chemicals in Israel derives from the doctrine of Risk Regulation (Breyer, 1993; Hood, Rothstein & Baldwin, 2001; Vogel, 2001), which can be defined as governmental interference with market or social processes in order to control potential adverse consequences to health. In modern human activity and technology with risks that require special expertise to understand, it is extremely complicated to set forth regulation that is not based on in-depth analysis of the risk the potential regime holds. Hood, Rothstein and Baldwin (2001) use the term "regime" to denote the complexities of institutional geography, rules, practice, and animating ideas that are associated with the regulation of a particular risk or hazard. Regimes, be they managerial or regulatory, tend to break down into components: first, the methods of collecting information concerning issues to be

controlled; second, the means of policy or rule-making so that targets or goals can be set, and third, the systems for enforcing and securing compliance (Hood at al., 2001). Traditional regulation of risks is characterized by the use of rules which are reinforced by legal sanctions. Required behavior is stipulated, standards are fixed, unacceptable actions are defined and outlawed and penalties for noncompliance are set out (Dimitrov, 2003; Jensen & Sandoe, 2002). However, risk regulation is not limited to the command and enforcement approach and in recent years we witness more and more hybrid modes of regulation in that field.

Israel's accession to the OECD sets forth various regulatory reforms Israel will have to undergo, one of the major ones is in the field of regulating chemicals. The existing cluster of legally binding regulations by the OECD does not call upon a particular set of rules when establishing a registration mechanism in the member countries (OECD, 2008b). The recommendations are guideline-prescribed activities that are presumed to be applicable to a range of registration and authorizations regimes, leaving the interpretation to the member countries themselves.

Currently there is no coherent, formal, comprehensive and elaborate regulatory regime for the governance of the production, marketing, transportation and authorization of chemicals in Israel (Zimend, 2010). It is expected that the issue of regulatory policy is set to undergo major change following events and processes in international organization and via the creation of global best practices for this field. It is important to note, however, that the policy problem here is not necessarily the weak regulation and dangerous situations in controlling chemicals in Israel, but instead the need to adapt to the regulatory framework coherent with the rules of the OECD.

It was previously recognized that the agents of change are not limited to government officials, and the industry can play a vital role in policy transfer. The interests and strategies of industrial groups are important determinants of policy outcomes. Moreover, since industry ultimately bears the implementation cost of most environmental policies, it is critical to understand the interests for assessing the level of future compliance and effectiveness of chemical management standards. Market-driven economic rational considerations are a key factor in the industry's level of participation in policy-shaping phase, as well as adhering to sticker policies voluntarily.

This research strives to make three contributions: First, to map out the characteristics of the Israeli chemical regulatory regime, and the changes it may have to undergo in order to comply with international standards. Second to shed light on the relationship between domestic and international factors and the way these shape national environmental regulation in general and chemical regulatory regimes in particular. Third, to add to already existing literature on policy transfer, especially in inter-governmental and state-centered perspectives, by extending the analysis to the role of industries, international norms and domestic civil society intuitions, bringing together international and domestic politics.

Accordingly, this research raises three questions:

1. What are the current characteristics of the Israeli chemical regulatory regime and in which ways does it differ from the legal documents, guidelines and expectations inherent to the OECD recommendations?
2. Looking at the very first steps of the agenda-setting process, what are the forces, considerations and expectations that shape the change in regulation of the Israeli chemical regulation regime?
3. To what extent do these changes reflect not only policy learning and policy transfer but also potential changes in the structure of power between regulation by state agenciesand between the business and civil society organizations?

## I.2 **Methodology and Arguments**

This research focuses on the tracing process of policy shaping in the field of chemical regulation in Israel in light of the accession to the OECD. Though earlier usage of such a technique can be traced back to the 1970s, one of the earliest explicit definitions of process tracing was provided by George and McKeown (1985), who defined it as a method of within-case analysis to evaluate causal processes.

More recently, Bennett and George wrote: “In process tracing, the researcher examines histories, archival documents, interview transcripts, and other sources to see whether the causal process a theory hypothesizes is in fact evident in the sequence and values of the intervening variables in that case” (Bennett and George, 2005: 6).

The accession to the OECD has only just been completed, so there is not enough sufficient data for complete analysis, thus several obstacles might arise due to unforeseen shifts of power, or perhaps major changes in the process. At the core of this research lies the degree of involvement and the strategies of the stakeholders in the regulatory process.
The regulatory regime for managing chemicals is due to be changed in the foreseen future. The regime will be based upon risk regulation. However, science cannot solely dictate policy since politics intervenes in knowledge and action, and the transition from information to interest formation is shaped by values, power, and institutions (Dimitrov, 2003).

Government officials are the most trivial agents of policy change, however they are not the exclusive agents. I shall first strive to examine how the coercive application of the legal requirements of the OECD will influence the future developments. Israel will have to adopt the relevant rules and make adjustment to its policy as forced by the OECD thresholds. If a more decentralized structure of power exists in the OECD guidelines, adopting such an empowering approach could be a reasonable outcome.

I will then examine the participation of non-state actors in the regulatory process and their role in the policy outcome, focusing on a pluralistic hypothesis, which empower non-state actors. This approach focuses on groups of interest that strive to promote their agenda, this “clash of interest” between the industry in Israel and its eco-friendly ("green") non-governmental organizations will determine the regulatory regime in chemicals. It is worth noting that though this approach highlights the domestic players, those domestic players frequently adapt themselves to external norms and interests.

# Chapter II. Theoretical Framework

This chapter delimits the theoretical discussion of the regulatory process for setting out a chemicals regime. The general context of the discussion will be held within the framework of the policy transfer doctrine. Two explanatory approaches will provide contrasting arguments of "top- down" and "bottom- up" forces that shape regulatory processes.

## II.1 Setting the Background

The questions posed in this research are set in the general context of the manner in which policy change in the era of global policy. Various players participate in the regulatory process. The issue at hand, chemical regulation, is part of the global environmental governance scheme.

### II.1.1 Global Governance

Governance, according to the Commission on Global Governance, is the sum of the many ways that individuals and institutions, both public and private, manage their common affairs. Since world politics is characterized by governance without government, the process of governance encompasses a broad range of actors (O'Brien et al, 2000).

Through the last decades, there has been considerable increase in the number and importance of international institutions, regimes, laws, organizations, and networks; and the Westphalian principle of non-intervention in internal affairs has been eroded by interventions in the name of dispute resolution, economic stability, and human rights. Simultaneously, international agencies of different types (whether governmental or non- governmental) increasingly became recognized as official stake holders and representatives of public interest (Burris et al., 2008). As a result, complexity, diversity, and particularity all can be used to describe the drive accounts of governance today. The structure of governance is most commonly described in networks, both state-centered and non-state centered (Sperell, 2007).

### II.1.2 State- Centered Actors

International organizations, such as the United Nations, World Trade Organization, International Monetary Funds, World Bank, World Health Organization and others, are examples of international alliances between countries, emphasizing the export study and recommendations on best policies for the member countries.

From a legal point of view, international intergovernmental organizations are the products of treaties; the purely voluntary character of participating sovereign countries in international organizations and international cooperation efforts need not to be emphasized. In fact, the majority of countries continue to emphasize the paramount value of the state, and obstacles to any larger role for international organizations are not diminishing (Schiavone, 2001).

One such example, the organization being examined, is the Organization for Economic Cooperation and Development – OECD, one of the major players in the contemporary global world. Prior to enlargement and accession there were 30 member countries[1], all democracies that espouse free market economies, the largest part are high-income economies and are among the most developed countries in the world (Porter & Webb, 2007).

### II.1.3 Non- State Players

Various regulatory agencies, executives, corporations and even legislators – are networking with their counterparts abroad, creating a dense web of relations that constitute a new global order (Slaughter, 1997). As Levi-Faur (2007) rightfully notes, stakeholders are becoming increasingly important and through the diffusion of regulatory capitalism we see the growth in the influence of experts and stake- holders.

[1] The OECD's 30 members (prior enlargement) are: Austria, Australia, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, the UK and the US; now joined by 4 more countries: Chile, Estonia, Slovenia and Israel.

Non-state actors are all those players that are not (representatives of) states, yet they operate at the international level and are potentially relevant to international relations (Biermann & Bauer, 2004). Generally, four groups of non-state can be distinguished in literature: (1) Non-Governmental Organization (NGOs); (2) Industry Groups and Multinational Corporations (MNEs); (3) Epistemic Groups and (4) an additional category, which includes terrorist networks, professional organizations, scouts, religious establishments, etc. (Schneider and Hyner, 2005).

This research examines the role of state-centered actors and non-state centered actors in policy shaping process, namely the establishment of chemical regime. The case that was selected is a single aspect, perhaps less commonly recognized as a leading global environmental issue, is the chemical regulatory regime.

## II.2 Regulating Risk

Modern governments are involved in a wide range of regulatory activities, reflecting the public's desire for adequate public services and protections in a wide range of policy domains. As the demand for public regulatory initiatives grows, political pressure for these regulations to become as efficient and effective as possible also increases.

One such new aspect of regulation is regulating risk, or in the context of this paper, setting up a sufficient chemical regulatory regime. According to Beck, unlike the risks of the industrial age, contemporary nuclear, chemical, ecological and biological threats are "(1) not limitable, socially or temporally; (2) not accountable according to the prevailing rules of causality, guilty and liability; and (3) neither compensable nor insurable" (Beck, 1999: 2).

In general agreement with this conceptualization, Shackley and Wynne (1995) have argued that regulatory science should be seen not just as a "sort of hybrid of science and policy" but as part of a larger process of "mutual construction". According to this perspective, in risk regulation - science and policy do not simply interact on occasion, but instead build upon one another so that political assumptions form a key but unacknowledged element within scientific risk assessment, and scientific assessment in turn serves to frame policy.

The task of environmental risk management is highly complex. There are more than 150 Multilateral Environmental Agreements (MEAs) forming a complex web of international regimes varying in scope, membership, and degree of effectiveness (Biermann and Bauer 2004; Durant, 1999).

New technologies and risk threats are constantly on the rise, as pointed out by Levi- Faur at al.: "The abundance of risk and – perhaps more important – the growing intolerance of the costs of risk on the part of society led to the invention, promotion and institutionalization of social, economic and political instruments that are meant to tame risks so as to maximize the efficiency of production and the allocation of resources" (Levi- Faur & Comaneshter, 2007).

Scientific evidence and evaluation seem to offer not only a rational basis for harmonization but also a policy foundation that applies across nations, so in this sense it is universal. However, such a generalized attitude towards of the relationship between science and regulation tends to ignore the local negotiations, institutional structures, social relationships, and professional judgments that lie at the heart of contemporary regulatory science. (Rotshtein et al, 1999; Andonava & Levy, 2003)

## II.3 Complementary Approaches for Setting up a Regulatory Regime

Traditionally, compliance assurance was considered a crucial element of the iterative, cyclical process of chemical regulation. It links legislative requirements of policy implementation assessment and feedback, thus allowing to adjust laws and policy instruments. Successful policy implementation depends upon the effectiveness of each element in this regulatory cycle (Dimitrov, 2003).

The traditional approach to regulation focused on the enforcement element of regulatory agencies. Compliance, as part of the regulatory formalism, was yet another layer of hierarchies, command and control approach to regulating risk. Yet, through the last several decades non-governmental players called upon the involvement of muliti-stakeholders in the regulatory framework.

This new approach became latter known as Civil Regulation. Civil regulation differ from other forms of cooperative business-arrangements, such as industry associations, production alliances, and cartels, in terms of the breadth of their activity, often incorporating less institutionalized forms within their scope (Cutler 2002: 28-29).

Civil Regulation which is rules created outside the statutory realm, is a broad concept comprised from a range of forms of regulatory governance that will be discussed below.

## II.4 Explanatory Framework - Policy Transfer

Globalization has become a buzz word in any household across the globe. Not only are we now aware and have access to information about different parts of the world, but we tend to share a great amount of similar policy problems. In this "shrinking world" policy lessons are increasingly drawn from a cross-national basis rather than from specific national experience and are less and less constrained by cultural and geopolitical boundaries (Levi-Faur & Vigoda-Gadot, 2004). National governments can compel different sectors or lower levels of government to follow the practices of others. The common theme among studies in this field of policy transfer is the concern with "knowledge about how policies, administrative arrangements, institutions and ideas in one political setting (past or present) is used in the development of policies, administrative arrangements, institutions and ideas in another political setting" (Dolowitz & Marsh, 2000: 5).

The general theory of policy transfer in the global world focuses on the dynamic whereby knowledge about policies, administrative arrangements or institutions, and it is used across time and space in the policy development practicies, administrative arrangements and institutions elsewhere. A wide range of proliferation of labels in this field was introduced in the last few decades, apart from "policy transfer" and "policy diffusion": "lesson-drawing" (Rose, 1991), "policy band-wagoning" (Ikenberry, 1990), "policy borrowing" (Cox, 1999) or "policy shopping" (Freeman, 1999) and "systematically pinching ideas" (Schneider & Ingram, 1988). These are terms that convey a sense of transfer is a voluntary activity. Penetration, or what is

also known as "external inducement" (Ikenberry, 1990) and "direct coercive transfer" (Dolowitz & Marsh, 1996: 347), are terms that convey a compulsion to conformity.

Diffusion, a relative approach often intertwined with the analysis of policy transfer, has been defined as “the process by which an innovation is communicated through certain channels over time among members of a social system” (Berry and Berry 1999: 171). Diffusion describes a trend of successively or sequentially adopt a practice, policy or program. The “diffusion” literature suggests that policy percolates or diffuses; something that is contagious rather than chosen. It connotes spreading, dispersion and dissemination of ideas or practices from a common source or point of origin (Stone, 2004; Levi- Faur, 2005).

The policy transfer literature assumes that transfer results from a rational process by decision-makers of imitation, copying and modification (Evans, 2004). Positive lesson drawing occurs in cases where entities search for solutions in places where a problem has been dealt with successfully (Rose, 1991). Rather than bilateral horizontal transfers between states, policy transfer can occur vertically between states and international organizations, or between transnational non-state actors. It is also possible to learn from more than one jurisdiction at a time, and to take away a multiplicity of lessons. It results in selective borrowing that leads to hybrids and adaptive innovation to make policy development fit local conditions (Stone, 2004). However, lesson drawing does not require policy adoption or behavior change. Negative lessons are drawn when an entity decides not to adopt a particular policy or program after reviewing what has been done elsewhere (Dolowitz, 1998; Rose, 1991; Bennett & Howlett, 1992).

It is important to note that lessons can be drawn to varying degrees. Rose classifies these as follows: copying, emulation, hybridization, synthesis and inspiration (1991; see also Dolowitz and Marsh, 1996).

Copying involves adopting existing policy without alteration. It may involve using the exact wording of legislation in developing policy and assumes consistent institutional and contextual variables. Emulation assumes a standard starting point for best policy, but it allows for adjustment to suit the varying needs of the adopter. It may also involve subtle improvements in the original program or policy. Hybridization involves merging two components from different places. Rose offers the example of using a program from one place and employing different administrative means to suit an adopter with a different political system. Synthesis is similar to

hybridization but involves elements taken from three or more different places. It often involves combining a number of components into a new setting. Inspiration stimulates the creativity of policy after examining problems in a different setting or context (Rose, 1991; Hulme, 2005).

Policy transfer literature has been focusing on the decision making dynamics internal and political systems and defining the role of agency in transfer processes. Policy transfer involves various actors and stakeholders, inter alia international organizations, non- governmental associations, industries, academia and bureaucrats (Evans, 2004). However, it is important to emphasize that the government regulators are the immediate agents for transferring the policy and implementing lesson drawing from international context (Jacoby, 2001). It has been proposed that organizations that have reached consensus on a general direction for change (like joining the OECD) are more likely to adopt foreign models. For example, Knill and Lehmkuhl (2002) suggest that one important mechanism of Europeanization is change through cognitive pathways, when national governments have reached internal consensus, an EU proposal can serve as a focal point around which secondary aspects of the proposal are organized.

## II.5 Top Down (Neo-realist) Approach

This approach builds upon the use-of- power element and coercion in the context of international relations in general, and policy shaping in particular. basedon theories of international relations neo-realism focuses power and coercion in the relations between states and international organizations. Neorealism was initially set as a theory of international relations, outlined by Kenneth Waltz in his 1979 book "Theory of International Politics". Waltz argued in favor of a systemic approach: the international structure acts as a constraint on state behavior, so that only states whose outcomes fall within an expected range survive.

The neo-realist approach suggests that the economic might and political power of states, as well as international organizations, is the principal force in setting the agenda and determining success in international policy setting (Witold et al., 2004).

Diffusion of policy lessons from the international level, whether countries or organizations, to the domestic policy shaping sphere occurred when specific or implied power is used. This theory refers to the exertion of pressures for homogeneity by the state and other powerful actors as a coercive isomorphism. International coercion occurs when powerful actors, mainly international inter governmental organizations, influence the policy choices of governments directly, or when such actors alter the outcome of a domestic policy struggle by favoring the domestic coalition supporting a given policy. The former concept of direct coercion implies that domestic groups or parties that set policy simply acquiesce to international pressures.

Some empirical studies focus on the direct coercive influence of specific powerful organizations. For example, the signing of International Labor Organization conventions enhances subsequent welfare spending (Strang and Chang 1993). Guler et al. (2002) found that the presence of the state and foreign multinationals in the economy accelerates the rate of diffusion of quality certification among local firms. The literature on IMF lending practices argues that intervention by external actors, who provide short-term resources conditional to the implementation of a reform, and threaten subsequent direct or indirect punishments if that reform is not implemented, may alter the domestic political balance of power in favor of reform (Boughton 2003; Dixit 1996, Henisz et al., 2004)

The case under study, i.e. Israel's accession to the OECD, does not involve a borrowing of resources, thus the coercion element of the process is weakened (as opposed the coercion element that the IMF, ILO or WB may poses). The OECD defines a set of threshold, adjustments and benchmarks. Thresholds are qualitative and subjective judgments about minimum standards that new formal structures must meet to qualify the acceding country for membership in the international organization. Adjustments guide relatively small correctives to some larger institutional scheme (OECD, 2002). Due to the organizations' monitoring, these adjustments tend to even less voluntary than templates (Jacoby, 2001).

According to the Neorealist hypothesis, the international organization, namely the OECD, uses direct and indirect power in order to coerce the desired outcome in terms of adopting the regulation scheme accepted and guided by the instruments of the organization. Israel will have to adopt the relevant rules and make adjustments to its policy as outlined and enforced by the OECD thresholds. Bureaucrat officials are the leading force behind the process of setting up a

chemicals regulatory regime, thus emphasizing even further the role of state and the top-down regulatory process.

Changes in the structure of power are feasible if the organization sets a preference to a certain balance of power within the regulators and the regulatees. Provided that a more decentralized structure of power exists in the OECD guidelines and most of the regimes studied by government officials, adopting such an empowering approach could then be a reasonable outcome. Yet, if this isn't the case, the policy transfer could result in the adoption of strict regulatory rules based on command and control.

## II.6 Bottom Up (Pluralist) Approach

Pluralism, deriving from the literature on political science, centers on the power of groups and the conflicts between various domestic interests. This approach strives to highlight the impact of domestic actors on shaping policy, even in a globalized world. International trends and flows of power mostly empower existing domestic groups, but still leave the process of designing the required regulatory regime in the hands of local interests.

Pluralism sees the political system as reasonably open to multiple interests, if proponents of these interests feel strongly enough about an issue to mobilize pressure. The power system is, to be sure, untidy, but the pulling and hauling of diverse groups promotes "polyarchy". "Polyarchy" is Robert Dahl's and Charles Lindblom's term for systems run according to putative democratic rules of the game (Dahl & Lindblom, 1976: 277.)

Sullivan (2003) refers to interest groups (also advocacy groups, lobby group, pressure groups or special interest groups) as organizations that seeks to influence political decisions. Usually these are private organizations that try to persuade public officials to act or vote according to the group's interests. The political theory of pluralism holds that political power in society does not lie with the electorate, nor with a small concentrated elite; but is distributed between a wide number of such interest groups. These groups may be trade unions, interest groups, business organizations, and any of a multitude of formal and informal coalitions. The pluralistic approach suggests that many non-governmental groups are using their resources to exert influence, while groups of individuals try to maximize their interests (Hirst, 1989; Stirling, 2008).

Pluralism assumes that groups of interest strive to improve their position on every section of policy setting and implementation, including the drafting of legal norms. Bottom-up transnational lawmaking is a soft, sometimes unchoreographed and spontaneous, normative process that produces hard, legal results (Levit, 2007). The process of norm creation begins with the informal, day-to-day experiences and concerns of practitioners who, in grappling with the technicalities of their trade, seek standardization and harmonization as a means to anchor and promote their business. The group then translates these practices into organicnorms, which, in turn, govern such practices. The lawmaking group also establishes interpretive, procedural, and remedial rules designed to maintain their flexibility and proximity to actual group practice (Papadopoulos, 1995, Levit, 2007).

According to the Pluralist hypothesis, the accession process is an important leverage for agenda setting and a chance to promote the interests of various internal actors. This hypothesis argues that the decision making is driven mostly by a clash of interest between the industry (whether organized or not) and eco-friendly ("green") non-governmental organizations. The compromise and the balance between those two will eventually define Israel's regulatory regime in chemicals. The government is a mean for the interest groups, at times playing a technical role in the regulatory process.

Changes in the structure of power are the core outcome of the process. The various lobbying groups use the accession process as a leverage to promote their concerns and values to influence the central government. Such a process is bound to shift power from state regulation to a range of ways of civil hybrid regulation.

## II.7 Summary

To sum up the theoretical analysis suggested in this chapter, the two explanatory theories discussed offer different expectations as to the process that will shape the new Israeli chemical regulatory regime. This conceptualized framework can be outlined in the figure:

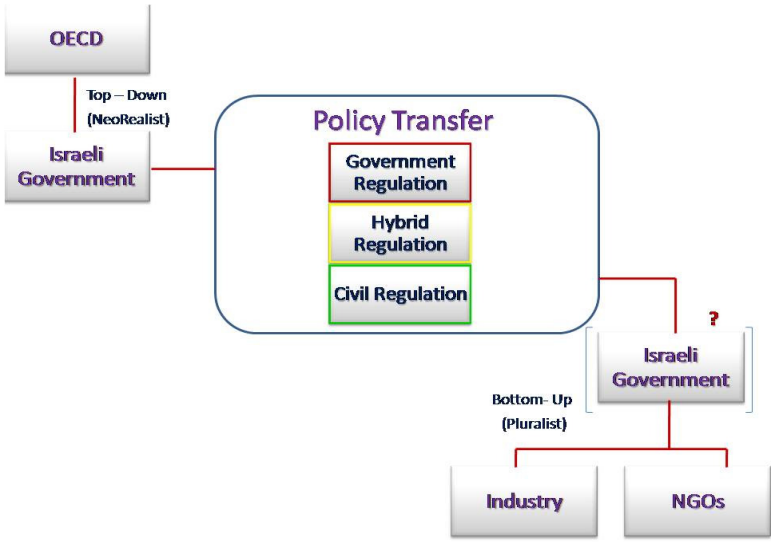


**Figure 1**: The conceptualized framework outline

Both of the hypotheses assume some form of policy transfer, and at first glance they only differ in the leading forces towards this policy shaping. Yet, I maintain that the level of involvement of the pluralistic agents, such as the industry and the NGOs, will ultimately have a direct impact on the scope of the policy itself. The regulatory regime can be viewed as a continuum, government enforcement being on one end and total self regulation on the other. The potential shift of power discussed under section VI might influence the nature of the regime established in Israel. In other words, the greater the level of the involvement of the non- state oriented policy agents in the agenda shaping process, the more decentralized the regime is expected to be.

# Chapter III. The Israeli Regulatory Regime and the OECD Requirements

This chapter explores the various characteristics and actors in the Israeli chemicals regulatory regime. It focuses on: (a) the characteristics of the industry; (b) the players (market players, including producers and importers, government agencies and their interests and functions as well as on non-governmental organizations; (c) the normative regulations and the legal framework; and (d) function of the regime.

## III.1 The Israeli Chemicals Industry

The Israeli chemical industry includes the production, transporation, processing, import and export of industrial chemicals (e.g., fertilizers, pesticides, petrochemicals and synthetic fibers), and chemical products (including paints, soaps and toiletries, drugs, food additives and pharmaceuticals). The industry is a major supplier of materials to other industries and other segments of the economy, including agriculture, plastics, textiles, metals, and pharmaceutical industries (Gabbay & Barzilay, 2008). It supplies performance chemicals for high-tech industries such as the electronics and microelectronics industry, Israel's largest growing sector (Orenshtein, 2009). Israel's chemical industry is based largely on those fields in which it has a relative advantage, such the products based on minerals found in Israel (magnesium, bromide, phosphates, potassium), a petrochemical industry which is based on oil refining in Israel, and a pesticide industry and organic intermediates based on local research and development (Dreazen, 2009). The most significant segment of this industry is the pharmaceutical industry, which is a world leader in the manufacture of generic drugs. Most notable is Teva Pharmaceutical Industries Ltd., a global pharmaceutical company specializing in the development, production and marketing of generic and proprietary-branded pharmaceuticals, as well as active pharmaceutical ingredients. Teva is the largest generic pharmaceutical company in the world and

as such enjoys a high lobbying status among the decision makers and cannot be disregarded when planning a regulatory reform.

Most of the inorganic chemical industry is either owned by the Israel Chemicals conglomerate or by Haifa Chemicals Ltd. The sector is based on two principal natural resources: (1)The Dead Sea-source of potash, bromine, magnesia, magnesium salts, various fertilizers and other inorganic salts like polybrominated compounds (flame retardants), and (2)The Negev mines-sources of phosphate rock, some exported as is, while others undergo further processing to phosphoric acid and its derivatives to be used primarily as fertilizers and as food and animal feed additives (Levinson, 1993 (Hebrew)). The petrochemical industry draws upon the oil refineries in Haifa for its basic raw materials. This industry has grown and based on these these refineries and manufactures' it developes a range of organic chemicals, including aromatics (principally benzene, toluene and xylene), formaldehyde and polymers such as polypropylene and polyethylene. Pesticides and herbicides production for agricultural use is an industry, which is largely dominated by the Makhteshim-Agan group, who use the advanced agricultural infrastructure in Israel as a convenient testing ground for new products. Over 95% of their production is for export (Dreazen, 2009; 12). Chemicals are also used as intermediates and raw materials by some chemical companies as well as by a variety of other industries, in particular electronics, textile, and metalworking industries. Most are based on organic synthesis while some are inorganic in origin, such as fire retardants based on bromine compounds (Orenshtein, 2009; Dreazen, 2009)

In 2008 the chemical, life science and pharmaceutical industry sales mounted to over 20 billion U.S. dollars, of which about 50% were exported (around 30% of the total industrial export of Israel, by value) (Orenshtein, 2009). The Israeli chemical sector can be divided into five major products of the Industry- basic inorganic chemicals, organic chemicals, biologically active chemicals, consumer chemicals and other chemicals used as intermediates and raw materials (Gabbay & Barzilay, 2008) The main chemical industries are concentrated in three areas: Haifa-Akko in the north of the country, Ashdod in the center and Beer-sheba, Dead Sea, Mishor Rotem and Ramat Hovav in the south. The chemical and pharmaceutical sector is the only industrial

sector that did not suffer a slow-down due to the global economic crisis, and its exports are expected to continue to grow (Kantor, 2009; Orenshtein, 2009).

## III.2 Existing Regulatory and Legal framework

The chemical regulatory regime in Israel is not mature enough and not fully developed to this date. No well-structured policy on the general chemical regulation exists in Israel thusfar, and the matter is handled in a way patches drawn together from various areas of regulation. The environmental aspect of risk regulation is the leading regulatory approach. Environmental policy has been rooted in the conviction that it is far more effective to identify potential environmental conflicts, simulate or forecast their extent or severity and incorporate appropriate environmental management measures in the planning process than to repair damages after they have occurred (Kornfeld, 2008 (Hebrew); Covarsky, 1983 (Hebrew)). Environmental measures are most frequently determined based on ambient, emission and design standards derived from the results of national and international research. Standards for pollutants are revised and updated based on evolving research in economic, technological, health and agricultural effects (The Ministry of Environment Protection, 1992b).

Israel's environmental legislation is wide-ranging: it seeks to prevent environmental deterioration on the one hand, and to stop, abate and clean-up existing pollution, on the other hand. It includes environmental provisions in the general body of law, specific laws that deal with such environmental issues as air, water, marine, waste and noise pollution, nature protection, and more general laws, such as planning and building and business licensing, which serve as the legal base for resource management and sustainable development (Gabbay & Barzilay, 2008). National legislation is complemented by a wide range of environmental bylaws on the local level and by an increasing number of international conventions on a global scale (Levinson & Dror, 2006 (Hebrew)).

Alongside legislation dealing with specific environmental issues, whether conservation of environmental resources or prevention of nuisances and pollution, the regulation of chemicals in Israel falls mainly under two comprehensive laws, such as the Licensing of Businesses Law, 1968

(and various regulations under the law) and the Hazardous Substance Law, 1993. The regulation of pharmaceuticals and cosmetics chemical preparations is regulated under the Pharmaceutical Ordinance, 1981.

**The Licensing of Businesses Law (1968)**

The law provides efficient administrative and criminal enforcement tools for the supervision of industry, by stipulating, *inter alia*, special conditions in business licenses including use of best available techniques (BAT).

Business licenses are granted by the Israeli Ministry of the Interior, and in consultation with relevant ministries. Special environmental conditions may be imposed by this license among which are air quality, solid waste, hazardous substances management and water and sewage (including industrial effluents). Numerous regulations have been promulgated pursuant to the law, including regulations on the disposal of hazardous waste, hazardous industrial plants, and transfer stations for waste (Bar-Tov, 2009).

In the last decade intensive efforts have been invested in making the system more efficient. An important step was the classification of all businesses appearing in the Business Licensing Order into three levels (A to C) according to their potential environmental risk, where the A level represents industrial plants with the greatest potential for environmental pollution (Bar- Tov, 2009). Local environmental units and associations of towns for the environment were then authorized under the law to deal with C level businesses, including preparation of conditions and enforcement of their implementation.

**The Hazardous Substances Law (1993)**

The management of hazardous substances in Israel is carried out by the permitting and supervising operators of facilities dealing with hazardous substances, rather than permitting the hazardous substances themselves. The law provides the Ministry of Environmental Protection, with the authority to control hazardous substances, including licenses, regulations and supervision of the various aspects of their production, use, handling, marketing, transport, import and export (Dreazen, 2009).

Licenses are required for any premise selling hazardous materials, and permits are required by any business dealing with hazardous materials. Regulations under the law classify hazardous substances according to their use, degree of toxicity and risk, and relate to various aspects of treatment, production, import, export, trade, transfer, storage, maintenance and use of hazardous materials. The law obligates anyone dealing with a hazardous substance to apply for a Hazardous Materials' Permit (Levinson, 1993). The law also provides various enforcement tools such as Removal Orders of hazardous materials and hazardous waste and high penalties (Bar- Tov, 2009; Dreazen, 2009). Hazardous Substances Regulations on the import and export of hazardous wastes were promulgated in 1994 and provide the legal basis for implementing the Basel Convention on the Trans Boundary Movement of Hazardous Wastes and their disposal (Orenshtein, 2009).

**The Pharmaceutical Ordinance (1981)**

According to the Pharmaceutical Ordinance, the Ministry of Health's Institute for the Standardization and Control of Pharmaceuticals is yet another component in Israel's environmental health and safety infrastructure. The Institute, which consists of a number of laboratories, is primarily responsible for quality assurance of pharmaceuticals marketed in Israel- whether imported or locally produced (Dreazen, 2009: 41). Each application is accompanied by detailed documentation that relates to the results of a wide array of clinical and other experiments. Registration is only granted by the Ministry of Health. The Institute of Standardization and Control of Pharmaceuticals carries out work in the following fields: (1) Evaluation and control of medicines intended for human and veterinary application, in order to enshure quality, safety and efficiency of pharmaceuticals; (2) safety of cosmetic products; (3) Efficiency and safety testing in pesticides; (4) toxicological and analytical evaluation of files of human and animal drugs; (5) development and improvement of quality control methods for the measurement of pharmaceuticals.

**Information and Response Center for Hazardous Substances**

To implement the wide range of tasks required during emergencies involving hazardous substances and to facilitate enforcement of laws and regulations, up-to-date information must be available on hazardous materials that are used, produced, imported, exported, transported and disposed of in Israel. Such data must relate to quantities, types, characteristics and concentrations

of materials found at all levels—industry and institutions on the local, regional and national levels. For this purpose, the Ministry for Environmental Protection established an Information and Response Center for Hazardous Substances Incidents (Bar-Tov, 2009). The Center collects both quantitative and qualitative data on hazardous materials in every sector, as well as data on safety, detection, identification, treatment and neutralization procedures, for chemical accidents (Dreazen, 2009). No assessment is carried out and the objective of the center is limited to hazardous substances, thus excluding industrial, pharmaceutical and agricultural chemicals.

**Safety research on new substances: complies with GLP principles**

An agreement on the Mutual Recognition between activities according to the OECD principles of Good Laboratory Practice (GLP), was signed with the EU on 1999 and ratified in Israel in 2000. As a consequence of the recognition that Israeli monitoring authority complies with the GLP principles, the Israel Laboratory Accreditation Authority (ISRAC), which serves as the monitoring authority, was invited to join the OECD GLP Working Group.

The acceptance of Israeli monitoring program affirms the need to ensure the high quality, validity and reliability of the safety, in vitro analysis and environmental data generated by testing of the industrial chemicals, pharmaceuticals, food additives, animal feed additives and pesticides.

## III.3 The Actors

The Israeli chemical regime includes state and non-state actors who are acting according to their respective interests.. In the context of risk regulation, the chemical regime is based on the path between the regulator and the regulatees. The regulatees of the chemical regulatory regime are the industrial plants discussed in the previous section.

About 150 companies are members of the Chemical, Pharmaceutical and Environmental Society, one of six societies comprising the MAI (Manufacturers' Association of Israel)[2]. The society is responsible for all environmental issues and activities in MAI. The field of pharmaceutical

[2] www.industry.org.il/eng

chemicals the Manufacturers' Association covers only a fragment of the Life Science companies, who are incorporated separately under ILSI (Israel Life Science Industry)[3].
Market forces play a major role in the structure and redeployment of the industry. Environmental legislation and regulation abroad are monitored closely, and at times the industry chooses to implement a stricter standard than enforced by the government. Those market incentives will be discussed in greater length in the chapter regarding the participating actors in the accession process.

On the regulator's side we will traditionally find the government, or more precisely the Ministry of the Environmental Protection. The ministry is responsible for formulating an integrated and comprehensive national environmental policy, the legislation and for developing specific strategies, standards and priorities for environmental protection (Donagi, 1983 (Hebrew)). At the national level there are over thirty divisions that deal with the wide gamut of environmental subjects. An important element in national environmental policy is inspection and control. To strengthen environmental law enforcement, the ministry has reinforced national inspection units in such areas as pesticides in the agricultural sector and has established a national inspection patrol that focuses on such areas as hazardous waste disposal and solid waste disposal (The Ministry of Environmental Protection, 1992b (Hebrew)).
On the local level, 36 municipal environmental units and associations of towns for environmental quality operate throughout the country. These environmental units operate under the administrative jurisdiction of their respective municipalities but under the professional authority of the Ministry of Environmental Protection. They play an essential part in the provision of environmental services on the local level (Gabbay & Barzilay, 2008; Dreazen, 2009).
Other government agents are increasingly gaining power in the area of environment regulation. The Ministry of Industry, Trade and Labor and the Ministry of Agriculture and Rural Development are becoming more and more involved in regulating chemicals. The Chemical and Environment Administration in the Ministry of Industry, Trade and Labor is responsible for industrial waste management as well as representing the industrial aspects in any regulatory forum. The Ministry of Agriculture's Plant Protection and Inspection Service is in charge of the registration and regulation of pesticides for plant protection- the major part of pesticides used in

[3] www.ilsi.org.il

Israel. National Maximum Residue Limits have been established for all pesticides in Israel that are based, whenever appropriate, on the Codex Alimentarius Limits. The Ministry of Agriculture supervises and regulates quality and health requirements of exported agricultural produce and cooperates with international bodies on standardization of pesticide tolerance regulations (Dreazen, 2009: 49). Those governmental agencies also take an active role in the OECD accession process, including, among others the formulating of the obligations Israel takes upon itself in the field of chemicals regulation. The Ministry of Finance, which leads the accession process, is also the authority concerning the allocation of an additional budget for the implementation of policy adjustments of the regulatory regime.

Environmental movements and NGOs currently don't hold major role in the existing regulatory regime. They tend to criticize both the industry for not being environmentally cautious and the government for not implementing stricter policies and enforcing "green" standards on the chemical industry. The various NGOs in Israel are also active in the field of private legislation process in the Knesset, striving to introduce environmentally-friendly policies and thresholds through private legislation. The framework of the participating actors can be outlined in the figure:

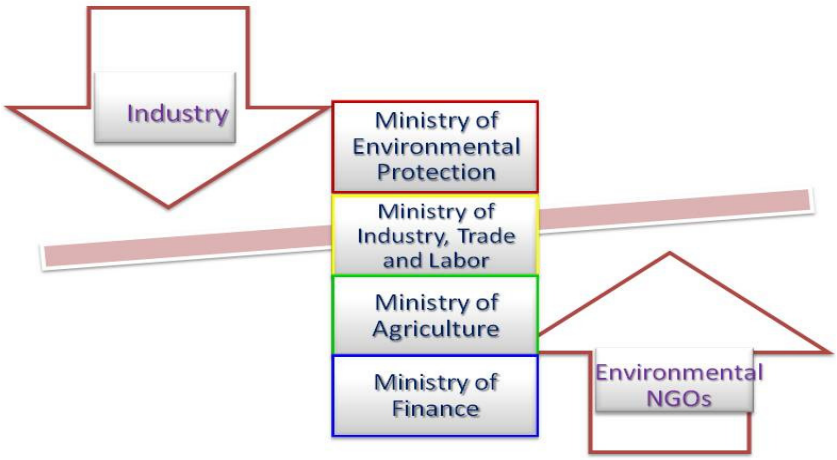


**Figure 2**: Participating actors in the Israeli regulatory regime

## III.4 The OECD Regulatory Requirements

The work of the OECD which relates to industrial chemicals and pesticides is carried out by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, with Secretariat support from the Environment, Health and Safety Division of the Environment Directorate. The Environment, Health and Safety Division pursue work in the various chemical related spheres: testing and assessment; Good Laboratory Practice and compliance monitoring; pesticides; risk management; harmonization of regulatory Oversight in biotechnology; PRTRs (pollutant release and transfer registers); and chemical accidents (OECD, 2008b; Turnheim, 2009)

The OECD Chemical Program was launched In 1971, aiming at developing harmonized tools and policies for chemical safety, which would allow countries and industry to increase efficiency, reduce non-tariff barriers to trade, and improve the policies aimed at protecting man and the environment from the risks posed by chemicals (Diderich, 2010).

With respect to chemicals produced by the chemicals industry, all OECD governments follow a similar process. First, the government collects information on specific chemicals from environmental monitoring equipment, literature and industry (e.g. exposure estimates, animal test data, environmental or health effects data predicted by models). Based on this information, the government can determine which actions, if any, are needed to manage the risks posed by the substances. For new chemicals and pesticides, governments collect and assess information from a prospective manufacturer before a chemical is placed on the market (Diderich, 2010). Unlike new chemicals, the large number of existing industrial chemicals already on the market – and the general lack or transparency of information on them - pose a primary environmental and health challenge for the industry and regulators (OECD, 2009c; OECD 2008b). Current efforts to fill this information gap have focused primarily on high production chemicals, with limited success to date.

Over the years, a number of significant OECD legal documents have been adopted in order to facilitate cost-effective chemicals management, mostly promoting systematic investigation of new and existing chemicals (Visser, 2009). Since the beginning of the 1990s, health and safety

data on high volume chemicals produced in the OECD countries have been generated and assessed as part of the OECD's Existing Chemicals High Production Volume (HPV) Program (determining the bar at minimum 1,000 tones production or import to an OECD country)[4].

A 1995 OECD Council Recommendation calls on member countries to "carry out, early in the regulatory process, an informed comparison of a variety of regulatory and non-regulatory policy instruments, considering relevant issues such as costs, benefits, distributional effects, and administrative requirements" (OECD, 1995; OECD 1997).

Many of the national data requirements for new industrial chemical notification and assessment schemes are based on the OECD minimum premarketing set data, which defines a base set of data for an initial assessment of the potential effects of chemicals on man and the environment (Diderich, 2010). This set includes recommended data elements and additional information, which should to be considered before a decision is taken to put a chemical on the market. It includes information on those physical/chemical properties which can be used to predict how the chemical will behave in the environment, toxicological and ecotoxicological effects, as well as how and to what degree the substance is likely to spread and concentrate in the environment and in biological systems. The MPD also includes information on intended use and estimated production (Turnheim, 2009; OECD 2008a).

Furthermore, information on chemicals scattered among websites hosted by organizations around the world, was brought together by a joint OECD and BIAC[5] initiative by establishing a database portal on chemicals. Launched in May 2007, The Global Portal on Information on Chemical Substances (aka ChemPortal), hosted by OECD, offers a single free of charge point from which to facilitate and enhance public access to information about chemical hazards. Thus, databases is accessible free of charge from a single web location (Diderich, 2010). Users are able to simultaneously search and query multiple sources of information on health and environmental effects data without initially having to go to different sites, where the data is stored. Search results provided by the Global Chemical Portal link directly to the relevant information within each site. Further, the Global Chemical Portal provides access to information in a transparent way, indicating clearly whether and when the accessed data was assessed by competent authorities or whether they were submitted by the industry.

[4] http://www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html
[5] BIAC- The Business and Industry Advisory Committee to the OECD

As described above the OECD operates a vast variety of programs in the chemical regulation area, some of which are on of a voluntary basis, while others are legally binding (OECD, 2009c). The OECD Council Decisions and Council Recommendations are known collectively as Council Acts. Bellow is a table summarizing the major issues tackled by the OECD Council Acts, that are relevant to the work of the Chemicals Program[6]:

| | |
|---|---|
| Environmental Economics | • Recommendation on the Application of the Polluter-Pays Principle to Accidental Pollution [ C(89)88]<br>• Recommendation on Integrated Pollution Prevention and Control [ C(90)164] |
| Good Laboratory Practices | • Recommendation of the Council of the Determination of the Biodegradability of Anionic Synthetic Surface Active Agents [ C(71)83]<br>• Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals C(81)30l and C(89)87 [ C(97)114]<br>• Decision on the Mutual Acceptance of Data in the Assessment of Chemicals [ C(81)30l] [C(97)186]<br>• Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [ C(89)87] [ C(95)8 |
| Specific Chemicals | • Decision-Recommendation on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls [ C(87)2/Final]<br>• Recommendation on Measures to Reduce all Man-Made Emissions of Mercury to the Environment [ C(73)172]<br>• Recommendation on Measures to Reduce all Man-Made Emissions of Mercury to the Environment [ C(73)172] |
| Regulatory Regime | • Decision-Recommendation on the Systematic Investigation of Existing Chemical [ C(87)90]<br>• Decision on the Minimum Pre-marketing set of Data in the Assessment of Chemicals [ C(82)196l]<br>• Recommendation on Guidelines in Respect of Procedures and Requirements for Anticipating the Effects of Chemicals on Man and the |

[6] http://www.oecd.org/document/47/0,3343,en_2649_34365_1817647_1_1_1_1,00.html

| | |
|---|---|
| | Environment [ C(77)97]<br>• Recommendation on the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [ C(83)96/Final]<br>• Recommendation on the Exchange of Confidential Data on Chemicals [ C(83)97]<br>• Recommendation on the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [ C(83)96l]<br>• Recommendation on the Exchange of Confidential Data on Chemicals [ C(83)97]<br>• Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [ C(90)163] |
| Accidents | • Decision of the Council on the Exchange of Information concerning accidents capable of causing Trans frontier Damage – [C(88)84]<br>• Recommendation on the OECD List of Non-Confidential Data on Chemicals [ C(83)98]<br>• Decision-Recommendation concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances [ C(88)85]<br>• Recommendation concerning Chemical Accident Prevention, Preparedness and Response [C(2003)221] |
| Pollutant Release and Transfer | • Recommendation of the Council on Implementing Pollutant Release and Transfer Registers [ C(96)41] [C(2003)87]<br>• Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [ C(90)163] |

## III.5 The OECD and Israel's Accession

The OECD accession Roadmap promulgated the conditions and standards to be examined in each area, specifying all the 21 legal instruments in chemical management (the Roadmap, OECD, 2007c: 17)

In addition to the firm decisions calling upon member countries to establish a regulatory regime of registration and assessment of chemicals, the following issues are dealt with in the legal acts of the chemical committee in the OECD: accident prevention, preparedness and response, good laboratory practices, polluter pays principle, measures of reduction of specific chemicals, pollutant release and transfer register and integrated pollution prevention and control. The Roadmap calls upon Israel to make a commitment to harmonizing its chemicals regulatory regime with those of OECD countries in order to ensure that the instruments used to protect man and the environment are of comparable quality to those in the member countries, and promote an OECD-wide system of chemicals management, thereby contributing to creation of a level playing field. Israel has committed to meet those requirements, stating it is "able and willing" (Israel's Initial Memorandum, Environmental Chapter).

A large group of the above listed OECD acts calls upon the establishment of a comprehensive regulatory regime that will register, evaluate and authorize all chemical production in the country together with its function of a transboundary export and import supervision, collaborating with parallel regulatory agencies abroad[7]. **The establishment of such regime is in fact the main gap between Israel's environmental legislation and OECD requirements** (Zimend, 2010).

As mentioned previously, the management of chemicals in Israel is performed through the Hazardous Substances Law and the Business Licensing Law. In practice, the supervision is on enterprises which deal with hazardous materials, rather than on the substances themselves, as required by the OECD framework. Thus, assessment of the environmental, licensing and health implications of chemicals is only undertaken for a limited number of chemicals: pesticides, pharmaceuticals, cosmetic preparations and food additives (Dreazen, 2009).

Implementation of the regulatory regime obligations will require new legislation and establishment of a new unit or an independent agency, with scientific, legal and administrative services, and inter-ministerial steering committee. It will be responsible for the registration and licensing of new and existing chemicals in Israel in accordance with the principles and the guidelines of OECD's decisions, and in coordination with the existing committees for registration

[7] Decisions and recommendation C(90)163, C(82)196, C(83)97, C(83)96, C(77)97, C(74)215, C(84)37

and licensing of pesticides, pharmaceuticals, cosmetic preparations and food additives (Hirshler,2010).

## III.6 Summary

The patches structure of the existing Israeli regulatory framework, results in the lacking of a coherent regime that assess, analyses and regulates all of the spectrum of industrial and pharmaceutical chemicals (neither risk regulation in terms of toxicity, nor in the area of policy harmonization in the international arena). Assessment of the environmental, licensing and health implications of chemicals is only undertaken for a limited number of chemicals: pesticides, pharmaceuticals and cosmetic preparations, as discussed above.

The nature of the existing framework is based on the traditional approach to of government enforcement of the regulation, and little, if any, cooperation and consultation with the industry is carried out on an ongoing basis in the existing regime.

The existing legal and administrative framework lacks the coherent structure and wide scale of chemicals regime required by the OECD legal acts. In this context, policy learning and policy transfer of some nature is inevitable. Policy transfer is a conceptual framework broad enough as to account for voluntary and coercive transfer, positive and negative lessons, transfer of wholesale policies and more limited transfer of instruments. The OECD does not set forth regulatory framework imposed on the Israeli regulator, it suggests a list of recommended guidelines, mainly in the field of registration, evaluation and authorization of chemicals that are suppose to help Israel develop its own regulatory regime for chemicals.

The following table summarizes the main principles in the OECD recommendations:

| **The OECD** | | **Israel** |
|---|---|---|
| Goals - protection of human health and the environment | | yes |
| Registration | Scope- all chemicals | narrow (only pesticides, |

| | | |
|---|---|---|
| of Chemicals | | pharmaceuticals and cosmetic preparations) |
| | Burden of proof in information generation- both government and industry | government agencies |
| Evaluation of Chemicals | Prevention of risk (ex- ante) | no |
| | Cost- benefit evaluation | no |
| | Substitution of safer alternatives | no |
| | Conformity Assessment- by accredited bodies | only government |
| Transparency | the right to know | no (except the general provisions of the Freedom of Information Act) |
| | International Cooperation in Data | no, except for GLP |
| Authorization of Chemicals used | | Authorization of the facility using the chemical (except pesticides and pharmaceuticals) |

# Chapter IV. International Perspective- Competing Regulatory Regime: The US vs. EU

This chapter attempts to suggest models for establishing a coercive global regime for regulating existing and new chemicals. As discussed in the previous chapter, The OECD guidelines **do not specify the exact scope of the desired regulatory regime**, but rather propose the principles and core values, allowing each member country to implement the requirements in a slightly different way (Visser, 2009). This section will focus on two major competing models for chemical regulation in the world, namely the US and the EU models.

## IV.1 The Toxic Substances Control Act in the US (TSCA)

The United States Toxic Substances Control Act of 1976 confers the Environmental Protection Agency (EPA) manifold rights to require testing or reporting activities for new and existing chemicals and to regulate them. The main goals of TSCA are to receive adequate data about the negative effects of chemical substances and regulating such substances, which present or will present an "unreasonable risk of injury to health or the environment Negative impacts for the economy and innovation should be avoided by using the ''least burdensome [regulatory] requirements" (Porter at al, 1995).

Under TSCA, testing for existing chemicals is required by the establishment of testing rules for as many as 50 chemicals per year following recommendations by the Interagency Testing Committee (ITC). According to this, EPA requires tests from industry or EPA has to justify why tests are not necessary from their prespective. In practice, a relatively small number of those rules were actually promulgated. In the first 15 years of TSCA, the ITC proposed tests for 175 chemicals to EPA, but EPA thereupon required testing from industry for only 25 chemicals. For

34 other chemicals, EPA and the industry agreed on voluntary testing, and for 8 other chemicals, tests were only proposed (Koch & Ashford, 2006).

Preliminary work toward TSCA's enactment began in 1971 after the Council of Environmental Quality (CEQ) issued a report which found that existing regulations to control the potential toxicity of chemical substance were "inadequate" and that there was a "high priority need for program of testing and control of chemical" (CEQ Report, as quoted in Bergeson at al, 2000). Both Congress and the Senate heeded the message and, in a spectacularly productive legislative session, passed TSCA and Resource Conservation and Recovery Act (RCRA) within a few weeks of each other.

The central regulatory standard for determining the acceptability of a chemical's toxicity level is "unreasonable risk," which appears in section 6 (dealing with TSCA's basic regulatory authorities) and in varying forms in the other operational sections of the statute, such as testing requirements and imminent hazards. "Unreasonable risk" is undefined in the statute, but the legislative history and subsequent judicial interpretation consistently interpret it as a greater-than-zero level that is determined by reference to health, benefits, and costs (Sachs, 2009).

To effectuate CEQ's goal for obtaining more chemical information, TSCA includes a menu of data-gathering provisions. New chemicals are subject to a notification process, called Pre-Manufacture Notification (PMN), which gives EPA an opportunity to examine existing data on new chemicals or new uses of existing chemicals and to object if it finds an unreasonable risk or believes that additional data are needed (Art. 5). Existing chemicals are subject to reporting requirements for studies that show adverse effects (Art. 8), and EPA is authorized to require testing of existing chemicals upon certain preliminary findings (Art. 4).

However, TSCA has not been the comprehensive and aggressive regulator of industrial chemicals that was recommended by CEQ, feared by industry, and predicted by both. Rather, its actual performance reflects the important legislative compromises that were necessary to enact it (Applegate, 2008). If EPA wants more information, then it must take the initiative and assume the burden of proving need when it seeks to restrict a new chemical or new use. EPA's experience under PMN has been pretty much what one would expect from this structure. In sharp contrast to the expectations of "careful premarket scrutiny," EPA's own website acknowledges that, "because many PMNs include little or no toxicity or fate data, the program uses several risk

screening approaches to facilitate assessment in the absence of specific data" (S. REP. NO. 94-698, at 3 (1976), as cited in Applegate, 2008)

The weak PMN screening system receives little support from the information gathering about existing chemicals, which constitute the vast majority of chemicals in commerce. EPA has the authority to require manufacturers to submit a variety of environmental and health effects data under section 8 of TSCA, however, it encounters several procedural and definitional barriers in the statute itself. EPA also has the authority under section 4 to require manufacturers to test existing chemicals, but in each case EPA must first make several formal findings which are subject to judicial review under the demanding "substantial evidence" standard (Applegate, 2008: 13). TSCA's PMN neither allocates the burden to the applicant nor requires any minimum set of toxicity information – with the above results. Instead, the burden of demonstrating *un*safety is allocated to EPA.

TSCA has not changed substantially in this regard since its first implementation (In contrast to the European attempts to improve the legal procedure for existing chemicals, as will be shown in the next session). However, in the late 1990s, EPA did implement its High Production Volume (HPV) Challenge Program, under which chemical companies have begun to voluntarily provide test data for 2800 chemicals, which are produced in amounts greater than 1 million pounds per year, although they have not agreed to test 300 of the chemicals originally on the HPV list (US GAO, 2005).

## IV.2 Registration, Evaluation, Authorization of Chemicals Regulation of the EU (REACH)

This ambitious legislative process started with the publication of the whitepaper in 2001 focusing on strategies for a future chemicals policy. The new system is called REACH -Registration, Evaluation and Authorization of Chemicals. The system's focal points are uniform procedures for the registration and evaluation of new and existing chemicals in place until 2012, and the transfer of responsibility for producing and assessing data to the industry, as well as the expansion of

responsibilities to the downstream users. As for new chemicals, the required data set depends on the amount produced annually (Fuhr & Bizer, 2007).

Generally, the system is three-tiered. All chemicals produced in higher amounts than 1 t/y have to be registered without any further evaluation (ca. 30,000 substances). A safety assessment report is necessary for substances produced in amounts over 10 t/y (ca. 15,000 substances). This report contains not only data about substances' properties and exposure profiles, but also data about necessary risk reduction measures that need to be taken to assure safe application/use from the producer to the downstream users. A safety data sheet that also contains information about necessary risk reduction measures has to be submitted, and if necessary modified, by the actors in the supply chain. All substances produced in higher amounts than 100 t/y (ca. 10,000 substances) and the substances that are produced in lower amounts, but are suspected to be hazardous, will be evaluated by the authorities after registration (ca. 5000 substances) (Konar & Cohen, 1997).

In contrast to the well-defined data requirements for risk assessment, the responsibility for risk management is defined only cursorily and superficially in REACH (Article 13, 6). Every manufacturer or importer shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 29.

Chemicals with certain hazardous properties must be separately authorized. The objective of the authorization is to ensure their progressive replacement, and so at the center of the process is analysis of substitute substances. This includes substances, which can cause cancer or mutations or are toxic to reproduction, or are either persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative (vPvB). For these substances the burden of proof shifts from the authorities to the producers, who are now in charge of demonstrating the safety of a substance to get the authorization. The authorization in turn does not automatically take place for all, but only for safe applications. An authorization (for production and use) is possible if the risks of an application can be "adequately controlled" or if the producer is able to prove that the socio-economic benefits exceed the risks.

A new European Chemicals Agency (ECHA), headquartered in Helsinki, was created to manage and coordinate all of the aspects of the process. Its regulatory decision making authority is quite

limited, however, as such authority is reserved to the Commission and the member states acting in concert.

The main motivation in revising the European chemicals policy is the past failure in mitigating the information deficit with existing chemicals. Despite the planned modification to the new system, this approach basessentiallyically follows the path of first solving the risk information problem, before risk management can take place. Nevertheless, due to the shift in responsibility for the risk assessment to the industry this system is argued to be more feasible than the regulation that was previously in place. Moreover, the testing demands are more flexible in comparison to the previous regulation that demanded a very comprehensive risk assessment. Identifying risk reduction measures is also integrated into the responsibility of the producers and users of chemical substances. But so far, however,this responsibility is described only very vaguely in contrast to the detailed requirements of reporting data about risk information.

In principle, the authorization system could establish a new form of regulatory risk management, based on reversing burden of proof for substances with certain properties. The system can be seen as the embodiment of the precautionary principle, because substances are to be screened for their possible potential effects and not only because risk has been scientifically validated (Sachs, 2009).

REACH Regulation shifted responsibility to producers and importers and requires them to assess risks and develop risk minimization strategies. The intention of this change-over is captured in ambitious objective of risk prevention on a high level is unambiguously maintained (Art. 2.6). To meet this objective with a policy of self-responsibility is quite a challenge to legislators: if the state intends to intervene, it must adopt an approach which takes into account the incentive situation of the relevant actors and design a regulatory platform, which makes it reasonable for them to comply. REACH is attempting such an approach by carefully framing responsibilities and demanding information as well as requiring the adoption of self-responsible risk reduction policies of firms. Generally speaking, REACH places all major responsibilities with firms rather than on administrative bodies.

At the same time, this policy is far from undemanding: companies marketing substances falling under REACH must ensure that dangers to health and environment will be reduced along the production chain throughout all intermediate and final users of the substance or the product containing the substance. In other words, producers of REACH chemicals must start information

and communication processes along the entire value chain to meet the requirements of the directive (Führ & Bizer, 2005).

The state is no longer trying to collect all relevant information, to process it according to risk assessments, and to design appropriate reactions, but it is shifting such responsibilities to firms that are much more likely to have access to such information, will be able to design appropriate communication and information processes, possibly even at lower costs, and have an incentive to reduce risks connected with their substances.

## IV.3 Comparative Analysis of the EU and US Regimes

REACH adopts several techniques that tacitly reverse the TSCA approach, the most important of which are eliminating the distinction between new and existing chemicals, and shifting the burden of proof for producing information and demonstrating safety. The following table summarizes the main provisions of REACH and TSCA and compares them:

| | | | **The EU - REACH** | **The US- TSCA** |
|---|---|---|---|---|
| Goals - protection of human health and the environment | | | yes | yes |
| Registration of Chemicals | Scope | All chemicals | yes | yes |
| | | New chemicals | yes | yes |
| | | Existing chemicals | yes | no (with a narrow exception) |
| | burden of proof in information generation- both government and industry | | the industry | the government (EPA) |
| Evaluation of Chemicals | Prevention of risk (ex- ante) | | yes | no |
| | Cost- benefit exam | | yes | yes |
| | Suggestion of safer alternatives | | submitted by the industry | proposed by the government |
| | Conformity Assessment- by accredited bodies | | By the industry and private accredited bodies | By private accredited bodies |
| Transparency | the right to know | | strong | weak |

| | | | |
|---|---|---|---|
| | International Cooperation in Data | yes | yes |
| Authorization of Chemicals used | | yes | partial (from a certain volume used) |

As mentioned earlier, the OECD does not give preference to any of the competing models. In fact, the narrow approach is also common in other OECD member states, such as Korea, (Diderich, 2010). In the framework of this research, the international arena doesn't offer a clear guidences for copying and mutual learning, while the transfer of policy principals is occurring among major regulators that are normally perceived as policy pioneers.

It is interesting to note that recent developments have increased the possibility that we will see a legislative makeover of the 33-year-old Toxic Substances Control Act (TSCA) during the current Congress. A diverse cross-section of stakeholders, including both industry and environmental groups, now share the view that TSCA is in need of an update to reflect new trends in international and domestic chemicals regulatory mechanisms (Auer, Biles & Culleen, 2009). Further, US Environmental Protection Agency (EPA) Administrator Jackson recently announced the Administration's "Essential Principles for Reform of Chemicals Management Legislation".[8]

REACH is likely to cause spillover effects to the regulatory system in the US. According to Noah Sachs' (2009) analysis, four major explanations can be offered as to the policy change in the US. First, U.S. chemical companies may incorporate EU toxicity testing and information disclosure norms into their own internal practices. Second, REACH toxicity data will increasingly shape the chemical purchasing decisions of U.S. manufacturers, retailers, and consumers. U.S. manufacturers may begin to require REACH compliance (or equivalent disclosures of toxicity data) as a condition of their purchases from chemical suppliers in the United States. The third informational spillover effect from REACH is that U.S. federal regulators can use the toxicity data from Europe in existing regulatory regimes, including TSCA and other environmental laws. Finally, information disclosure under REACH is likely to have significant impacts on sub-national environmental regulation in the United States. As states consider bans or restrictions on certain classes of chemicals, the toxicity data from Europe - as well as EU decisions on which chemicals are of "very high concern" - is likely to be influential. Already, in the past five years, several U.S. states have enacted legislation to address chemical

[8] http://www.epa.gov/oppt/existingchemicals/pubs/principles.html

hazards, an area of environmental law traditionally under federal authority (Sachs, 2009: 1862-1864).

# Chapter V. Participating actors in the regulatory process and their respective interests

The following chapter provides an analytical discussion on the forces, considerations, and expectations that shape the process of change in the guidelines of the Israeli chemical regulation regime as affected by the process of accession to the OECD. It analyzes the nature of state- and non-state- (business and civil) actors' involvement in the policy process by looking at the initial steps of policy change, and examining the driving forces behind both the governmental and non-governmental actors participating in the regulation process. It proposes a characterization of the procedure that includes the empirical considerations related to the various actors in the policy domain and analytical elements related to the narrative of the field's development as well as its theoretical background. It likewise examines the hypothetical expectations that shape the process of change that has occurred in this realm, specifically as it relates to the parameters of the Israeli chemical regulation regime.

As previously discussed, voluntary transfer usually occurs when a policy-maker proposes to remedy a problem by looking outward for alternative solutions, and tentatively prepares to emulate policies that have proved successful elsewhere. There is a number of factors which facilitate policy transfer, including: relationships between policy-makers, common contexts, languages and ideologies, the existence of think-tanks, non-governmental international groups, and regional organizations. Coercive transfer, on the other hand, occurs when the political actors of a particular state or international organization, such as the IMF or World Bank, impede upon, or in some way intervene in the policy-making of a country through measures such as aid conditionality. In contrast to the processes of both voluntary and coercive transfer, "policy convergence," or "diffusion," is usually deemed to occur as a result of overarching structural forces, and thus imputes a less active role to policy-makers. These varying models of policy

calibration are the prototypes upon which the following discussion of Israel's accession process to the OECD is based.

## V.1 The State- Centered Policy Setting

Derived from the Top-Down hypothesis (see chapter II.3) that stipulates the exertion of pressures by the state and other powerful actors such as international inter-governmental organizations which influence the policy choices of governments or affect the policy-setting process, the immediate claim is that the policy transfer process vis-à-vis the Israeli chemical industry's regulatory regime is primarily determined by the conditions delineated by the modus operandi incumbent in the state's accession to the OECD. That is, the leading, if not sole, actor in this proposition is the government of Israel, as the agent that initiated the process and that is liable to the OECD for their compliance with the organization's norms.

In examining the OECD's role as an actor in relation to the state policy-setting process, it must be acknowledged that the OECD does not conventionally operate through aid conditionality, yet has been recognized by the global community as a transfer agent and therefore it does act in this capacity (Henisz et al., 2004). One example of their activities in this role is the dissemination of information by the OECD's Public Management Program (PUMA)[9]. This forum has established and maintains a number of mechanisms – publications, networks of senior officials, conferences, etc., through which it distributes information and induce "forward thinking" on matters such as national accounting standards and human resources management. The organization's recommendations in this sphere are put forth in their publication, "OECD Best Practices for Budget Transparency" (2002).[10] A joint initiative of the EU and the OECD entitled: "Support for Improvement in Governance and Management in Central and Eastern Europe" (SIGMA) likewise advises transition countries on methods for improving public governance at the level of central government (OECD, 2007a; OECD, 2006a).

[9] http://www1.oecd.org/puma
[10] http://www.oecd.org/dataoecd/33/13/1905258.pdf,

As suggested, most of the literature on policy transfer focuses on the nation state, with public officials normatively considered the key agents of transfer (Evans, 2004; Bennett, 1991; Eyestone, 1977; Boughton, 2003 and Finnemore, 1993). Senior bureaucrats in the Ministry of Environmental Protection are thus the primary official agents for activities in the realm of regulation of the Israeli chemical industry. The Interministrial Committee, as a steering group for implementing the commitments made by the professionals in the Ministry, comprises the second echelon of policy transfer agents. Several government ministries take part in the Inter-ministrial Committee, though they collectively act in the name of the common good and the state of Israel, concomitantly protecting the particular interests of their respective ministries.

The roles and interests of the diverse governmental ministries among the actors participating in the process Israel's accession to the OECD a propos its chemical regime are varied. The Ministry of Environmental Protection sees the bureaucratic framework as an opportunity to better position itself and acquire additional resources for implementation of "green" programs (Brachia, 2008). The Ministry of Finance, though eager to accessed the regulations of the OECD, is predominantly concerned with maintaining the government budget. The commitments prescribed by the OECD documents will ultimately require the establishment of auxiliary authorities, the requisition of more manpower, and primarily, with regard to the concerns of the Ministry of Finance, the allocation of an additional budget for the implementation of the aforementioned measures. The Ministry of Industry, Trade and Labor is the government body in charge of protecting the interests of industry, striving to limit the burden on the plants and promoting the comparative advantages of Israeli industry and trade (Hirshler, 2010). The Ministry of Agriculture focuses on the obligations incumbent upon companies in relation to pesticides, while the Central Bureau of Statistics must attend to implementing the overall data analysis and adaptation to OECD standards that they will be responsible for overseeing, a mission very hard to achieve without, the aforesaid, additional resources.

In line with the neo-realist top-down hypothesis of this research, the obligations made by the government to the OECD are the key elements of policy learning and transfer that is about to occur when the regulatory regime in Israel will be established. The starting point of the technical discussions concerning the terms and conditions of accession was the submission of an Initial Memorandum by Israel to the Secretary-General of the OECD (2008). This document specifies

to the extent to which Israel accepts the legal and political obligations resulting from each of the substantive OECD Acts and legal instruments, as well as the compatibility of OECD obligations with Israel's own governmental legislation and policies with these obligations. The Memorandum outlines Israel's reservations concerning these matters, briefly explains and stipulating their justification. Various commitments have been initiated in numerous sectors in relation to this initial step, including in the field of chemical management. On the subject of the obligation to establish a chemical regulatory regime, there are several OECD documents that call for a concrete commitment[11]. Implementation of these Decisions and Recommendations will require new legislation and establishment of a new unit or agency with scientific, legal and administrative services, to be established over several years (as indicated below). It will be responsible for the registration and licensing of new and existing chemicals in Israel in accordance with the principles and the guidelines of OECD's decisions, and in coordination with the existing committees for registration and licensing of pesticides, pharmaceuticals, cosmetic preparations and food additives.

Israel's Initial Memorandum specifically states that said obligations:
" will require additional legislation and [the] establishment of a new administrative unit. The anticipated time frame for implementation is as follows:

> a) 2010: Selection of the preferred mechanism for chemical management in Israel, following completion of a tender for comparative analysis of chemical management systems.
>
> b) 2011: Presentation of draft legislation to Parliament.
>
> c) 2012: Establishment of a new administrative unit, to implement the chemical registration system.
>
> d) 2013 onwards: Staged implementation of chemical management mechanism." (Israeli Initial Memorandum, 2008)

[11] Including: C(90)163, C(82)196, C(83)97, C(83)96, C(77)97, C(74)215, and C(84)37

The first step in deciding upon the best policy for establishing such a regime is based on a tender to study and examine the various factors in the chemical regulatory regimes of other nations, predominantly those in the EU and the US, as well as in a selection of other relevant countries. Studying those regimes will position the Israel officials in the classical site of policy learning and transfer, and thus emphasize both the government's involvement and supremacy in the regulatory process. A tender was indeed published and the Ministry of Environmental Protection is currently examining the applicants for the initial assessment and consulting process for the establishment of the regulatory regime for chemicals.[12]

On June 8th 2009, Israel underwent its "examination review" in the chemical committee at the headquarters of the OECD in Paris. The national delegation, headed by the Director General of the Ministry of Environment Protection, presented the strengths, deficits and weaknesses incumbent in the process, and the obligations that Israel is willing to take upon itself to fulfill the OECD requirements in the field of chemical regulation. The official position of the committee was summed up in a "formal opinion" and transferred to the OECD Council, adjacent to the occasion of the general discussion on Israel's accession. According to the opinion Israel was requested to sign a "Side Note" to the accession, obligating it to report back to the committee regarding a process of reformation of Israeli legislation. Such a commitment grants the OECD additional reviewing power and concede to it the possibility of coercing the adoption of OECD norms and legal Acts.

From the OECD's perspective, the expectations from the acceding country, in this case Israel, are that it will implement all the obligations that the country took upon itself upon initiation of the accession process. The operational tool the OECD is likely to use is peer review and monitoring. Such instruments are a reasonable outcome of Israel's examination in the committee, and a mechanism that the OECD uses rather frequently. Peer review aims at examining a country's compliance with international guidelines, standards, and principles (OECD, 2002). It consists of the assessment of the policies and performances of a country by other countries. The goal is to help participants to improve their policies vis-à-vis OECD norms and to comply with its established standards; it is, in fact, often through this process that optimal practices are

12 http://www.sviva.gov.il/bin/en.jsp?enPage=BlankPage&enDisplay=view&enDispWhat=Zone&enDispWho=michraz&enZone=michraz

identified. This policy instrument poses a clearly coercive characteristic, which falls in line with the top-down hypothesis claiming the norms are imposed on the countries (Porter & Webb, 2007).

From an international perspective, the "soft law" quality of the peer review can prove more effective in encouraging compliance with recommendations rather than traditional enforcement mechanisms such as courts or other judicial bodies (Abbott & Duncan, 2000 ; Simmons, 2000). A peer review can only function properly, however, if there is mutual commitment to act upon its findings by all the participating countries. This requirement requires not only supplying the necessary monetary resources to carry out the findings of the reviewers, but also that the participating countries be fully engaged at every stage of the process.

The effectiveness of peer review relies upon the influence and persuasion exercised by the peer countries during the process, an effect widely known as "peer pressure". In the context of setting international standards for chemical regulation and environmental performance, the peer review process can give rise to such peer pressure through, for example: a mix of formal recommendations and an informal dialogue among the peer countries; public scrutiny; comparisons and, in some cases, even ranking among countries; and the impact of the above on domestic public opinion, national administrations, and policy makers. The influence of these factors will be greatest when the outcome of the peer review is made available to the public, as is usually the case within OECD (Woodward, 2007a). When the press is actively engaged in transmitting the story, peer pressure is most effective. Indeed, public scrutiny often proves to be most effectively where the media is involved (Pagani, 2002).

## V.2 Non-State Actors in Policy-Setting

Policy transfer is not only influenced by governmental agents, but can also be facilitated by organizations operating outside of and between components of the official state apparatus (Dahl & Lindblom, 1976; Sullivan, 2003). In other words, policy transfer is just as likely to be achieved by bottom-up mechanisms, such as those embedded in markets and other networks, as

the hierarchies of the state. Non-state organizations provide essential services for decision-makers by acting as resource banks, advocating policy ideas, developing discourses of transfer, as well as spreading ideas and information through their professional networks and those of the media and civil society.

An instance of these mechanisms in action can be seen in the case of Israel's accession process. As part of this procedure, mirror working teams were established to work in tandem with the OECD committees. The Manufactures Association and "Adam Teva V'din", Israel's union for environmental defense, were invited to be permanent members of the Interministrial Committee working group as representatives of relevant stake holders. The following section focuses on the level of involvement by the non-state centered players in the decision-making progresses; the actors which will be examined are the industry and organizations referred to as "green NGOs".

### V.2.1 The Industry

The function of businesses in the setting of industrial standards is well established. In the area of environmental governance, especially in Europe, both green and business interest groups have played prominent roles in the advocacy and dissemination of voluntary ecological agreements, ecolabels, and ecological tax reforms (Jörgens, 2000; Andonova 2003; Lober n1997). Since industry ultimately bears the cost for implementing many environmental policies, understanding industrial environmental strategies and the industry's involvement is critical in order to assess the level of compliance with and the effectiveness of regulations concerning environmental standards.

The Manufacturers' Association of Israel (MAI) is recognized as a central force in the Israeli economy as a whole, and in the industrial sector in particular. It is extremely aware of its obligation to promote national goals such as economic independence and security.[13] The president of the MAI serves also as Chairman of the Federation of Israeli Economic Organizations (FIEO), a body comprised of fifteen commercial and trade associations that together represent virtually all of the country's business sectors. According to the MAI, in the

[13] http://www.industry.org.il/Eng/

past four years 250 million US dollars have been invested each year by industries (predominantly by the chemical industry) for prevention and reduction of toxic and otherwise harmful emissions and for landscape treatment (Kantor, 2009). This effort is part of an ongoing commitment that will be continued in the future, and an indication of the measures that the chemical industry in Israel, through MAI, has initiated in order to adopt a civil regulatory mode prior to the implementation of the OECD accession.

One program that represents this trend and commitment is the Responsible Care Initiative. During the 1980s, public confidence in chemical companies steadily eroded; from 1980 to 1990, favourable opinion about the chemical industry fell from 30% to 14% (King & Lenox, 2007). Responsible Care was created in order to mitigate the increasingly negative public opinion about the chemical industry (Prakash, 2000). A voluntary initiative of the global chemical industry Responsible Care works to promote safe handling of their products from inception in the research laboratory through manufacturing and distribution until ultimate reuse, recycling, and disposal. It also encourages public involvement in decision-making processes for environmental regulation. Inaugurated in Canada in 1987, Responsible Care has quickly spread to 53 countries.[14] This group sets a global standard for the chemical industry, of which most members are large MNEs, companies that together account for nearly 90% of global chemicals production.

The reporting system of self-regulation that the industry employs under the auspices of Responsible Care is rather broad; it includes ten guiding principles and six codes of management practices (Karsten, 2001). Signatory firms must annually self-assess their progress toward code implementation and then submit their findings, signed by the CEO, to the Chemical Manufacturing Association (CMA). "Companies...move at the pace that's right for them," explains a CMA publication, "but they are expected to report continued progress" (CMA, 1993). Though the CMA has not expelled any of its members for failure to meet the requirements of Responsible Care, recently it began to initiate contact with and offer assistance to members whose progress implementing Responsible Care standards appears to be unduly delayed.

[14] http://www.responsiblecare.org/page.asp?n=membersupport&l=1

In accordance with the bottom-up approach previously described, the industry seeks to take an active part in the regulation setting process, and thus to have first-hand input on the policy outcomes. A short while after the official decision to begin negotiations to join the OECD had been made, MAI created an experts' forum in order to study the potential consequences of such a move on the Israel chemical industry. The forum presented an initial policy brief stating that the prospective regulatory requirements, if adopted as strict enforcement tools, are "changeable and difficult" (Kantor, 2009). In an interview (Arie, 2009), a representative of the industry went one step further and claimed that the regulations would be administered by bureaucrats with personal agendas and without a sufficient basis in scientific analysis or independent review, if no action would be taken to prevent such an occurrence.

MAI indeed operates and promotes an "agenda", one directly related to the policies of the Ministry of Environmental Protection. Yet, this is only the beginning of the process. MAI, together with Israel Institute of Energy and Environment, which has not been directly involved with the OECD accession process up to this point, has called upon the Ministry of Industry, Trade and Labor to take a more active part in the proceedings and to vocalize their initiative to establish a regulatory team (comprised of governmental bodies, economic organizations, and "green" NGOs) to consider a range of possible alternatives to be considered when setting the regulatory regime (Arie, 2009). A draft action plan for the establishment of such a multi-stakeholder committee is currently under preparation. In fact, representatives from both government ministries and from economic associations traveled to Brussels in order to actively launch the policy-learning process[15]. The formation of such a committee would most definitely bring about a power shift between state-centered regulation and complementary approaches.

In regulatory politics, the interests and strategies of industrial groups are important determinants of policy outcomes (World Bank, 2000). The bottom-up hypothesis of this research suggests greater involvement of the regulatees is a derivative of the OECD accession process. There are various rationales for encouraging the industry's more active involvement in the regulatory process in light of the OECD accession. Industrial interests link the international and domestic realms of environmental politics, as both arenas are affected by international trade and investment. They offer special incentives to ensure that domestic and international environmental

[15] *www1.moital.gov.il/.../221E3DEF-60E6-4469-84F0-D411F31D3221.htm*

standards are set up in such a way as to not diminish companies' international competitiveness (Andonova, 2004). That follows the major driving forces behind the industry's high involvement in environmental standard-setting is detailed, highlighting the bottom-up notion of the regulatory process that is the result of the strong incentives for industry and other (such as "green") organizations using the accession process as a leverage to affect proposed legislation and policy shaping. Such non-governmental participation in the regulation process is discussed below, as well as the phenomenon of the industry adopting stricter standards in a relatively voluntary manner.

The relationship between international markets and environmental norms within the OECD countries is one of the main mechanisms of trans-national influence on the politics of environmental policies in accession countries such as Israel. In a closed economy, industrial preferences for environmental regulation are determined solely on the basis of the immediate costs and benefits of regulatory compliance (Zywicki, 1999, Andonava 2004). With access to the international markets of the OECD countries that have set forth an array of environmental standards, however, business groups in accessing countries have additional factors to consider. The addition of this factor means that they add to their environmental calculations the gains and loses from free trade with the now-accessible markets within the union, which results in a newly formulated economic paradigm.

As theories of trade and political economy have shown, international trade redistributes resources domestically as well as internationally, resulting in predictable divisions between winning and losing firms, sectors, and classes (Andonava, 2004). Corporations and businesses, that produce primarily for the domestic market or that compete within a field dominated by imports, stand to gain little or even to lose from integration with OECD. For exporters, however, the adoption of standards of the OECD countries can improve their access to OECD markets, and thus their economic standing. Compliance with the organization's product standards and processing criteria is often a precondition for subcontracting to firms located in the countries that are full-fledged OECD members. Some member countries have moved even further, deciding that chemicals that underwent the HPV evaluation program of the OECD will be exempt from national compliance requirements (the US being a leading example) (Diderich, 2010).

Harmonization with common OECD standards assures that firms are working according to the accepted codes, and so builds trust and allows for more efficient systems of production, while at the same time achieving an internationally accepted level of environmental responsibility. This removes potential barriers to trade for export-oriented firms and wards off accusations of ecological dumping. Moreover, the adoption of OECD norms may even open new "green niche" markets and opportunities for Israeli products that supply an additional realm of differentiation in environmentally sensitive markets (Inbar, 2010). This provides commercial incentive to Israeli firms to support the "ratcheting up" of domestic standards to the environmental level adhered to in the large, regulated markets.

Of course, exporters could also improve both their access to OECD markets and their market share by seeking to avoid costs associated with environmental abatement and by offering reduced prices. This may be a particularly attractive solution for small enterprises, for which the relative cost of regulation is proportionally higher (Andonova, 2004). However, in many cases the practical success of such a strategy is limited by consumer preferences, subcontracting requirements, or pressure from industry and consumer organizations to conform to more stringent environmental standards.

An additional incentive for the adoption of OECD standards is that they serve to reduce transaction costs for exporting firms. This is especially true for large firms with extensive international operations (Andonava & Levi, 2003; Lober, 1997). As the representative of the Manufactures Association has noted, the chemical sector in Israel has a preference for the stable and uniform regulations associated with the OECD accession process rather than weaker, less demanding but more uncertain systems (Kantor, 2009).

Multinational enterprises, which are among the beneficiaries and supporters of accession to the OECD, have similarly distinct incentives to support the adoption of OECD environmental standards. Multinationals, the majority of which are at any rate located in the OECD countries, worry less than exporters in accession countries about access to OECD major markets, a factor that is typically ensured by their already-established production networks and marketing strategies. However, multinational enterprises have recently come under increasing scrutiny from consumer unions, advocacy groups, and even stake holders, to apply environmental standards in host countries that are compatible with those required in their home countries

(Graafland et al., 2003). Moreover, similarly to exporters, multinationals reap benefits from such harmonization in terms of reduced transaction costs, greater regulatory stability, and the advantages they already enjoy over domestic firms and new entrants to the market.

Accession to the OECD, together with economic integration and harmonization with the OECD standards, influences the environmental position of internationally oriented industries in the accession countries. In addition to the requirements of conformation to the organization's criteria is the invisible hand of the market, and pressure, as well as assistance, from transnational business organizations. The Business and Industry Advisory Committee (BIAC) is anticipated to take a major role in the coming months in working to increase the involvement of accession countries' industries in the accession process. BIAC, founded in 1962 as an independent organisation, is the officially recognised representative of the OECD business community; BIAC's members are the major business organisations in the OECD member countries. Via its 32 standing committees and task forces, BIAC mirrors all economic policy issues that the OECD covers, as well as their impacts on both member and an increasing number of non-member, especially accession, countries. Israel's MAI joined BIAC as an observer in 2005 in order to align its practices with those of the business organizations of OECD countries, and to have access to OECD policies that might have an influence on the industry. The BIAC forum can also serve as an empowering leverage for Israeli industry to take upon itself a more active role and participate in the reform process of establishing a regulatory regime for chemicals in Israel.

The analysis of the driving forces of Israeli industry can benefit from an international perspective and comparison. A parallel example of business harmonization is the case of EU enlargement, and the role that transnational business organizations have played in the integration process. The European Chemical Industry Council (CEFIC) provided the acceding countries during the EU enlargement information about relevant EU standards to non-member countries and businesses, increasing the environmental sensitivity of East European exporters as well as their awareness that EU standards can be used as requisites for, and so barriers to, trade (Andonova, 2004). Driven by the motivation to avoid competitive disadvantage, EU business organizations also exerted direct pressure for the adoption of EU standards and policies upon those desirous of a commercial association, making it clear that their support of EU integration was contingent on universal compliance with EU norms by all prospective members. In the EU context, while

domestic chemical associations typically gave weight to the interests of large export-oriented members, they also sought to establish compensation mechanism for smaller firms and to strengthen the overall support for integration. Intra-industry compensation schemes include free training and subsidized auditing and consulting services for smaller companies, and in some cases lobbying for a more gradual schedule of compliance for small and medium-size enterprises (Compagnon, 2008; Andonova, 2004). Though potential parallels are evident, it is still too early in the current phase of the OECD accession process to determine the exact level and mechanism of involvement by transnational business associations. It is, however, safe to declare, even at this early stage, that such involvement will indeed take place.

As discussed previously in chapter III, the Israeli chemical industry is not homogenous, but rather includes various firms in different areas of chemical production, with dissimilar ranges of enterprise sizes and notably divergent marketing strategies and ties with OECD markets. The adjustment of national environmental policies to align with OECD chemical regulations is not entirely unidirectional in cases when the OECD instruments affect multiple sectors having different positions with respect to accession and indeed impose costs on actors that do not benefit from the accession and greater harmonization. In such instances, OECD commitments affect the strategies of domestic actors subject to regulation, as in their strategies of opposition these actors respond to international pressure for policy reforms either by seeking to block change or to gain compensation and extended time periods for compliance.

### V.2.2 Environmental ("Green") NGOs

The organizational and political strength of domestic environmental movements is another important factor for the success of environmental reforms and the implementation of international commitments in the chemical regulatory regime. One such organization is Adam Teva V'din (IUED), the NGO invited to participate in the Interministerial Committee for OECD accession. This membership-based organization with over 4,000 members, and a staff of 27 that includes lawyers and scientists specializing in a range of environmental spheres, was founded in 1990. There are dozens of other NGOs with environmental agenda, but the uniqueness of Adam

Teva V'din is the legislative approach of the group and the way in which it does not limit its involvement to mere protest but is actively involved in the process of policy regulation.

Through the last decades there has been a significant increase in awareness of and concern about the not unsubstantial, and occasionally dramatic environmental impact of the chemical industry (and other industrial) operations upon the environment. A change in public attitudes has occurred concurrently with these developments. Industrial behaviour that was complacently accepted a few short decades ago is now widely and vocally opposed (Borzel & Buzogany, 2009). Communities are wary of and concerned about the dangers they may encounter from nearby industrial facilities, and they do not hesitate to question and criticize the parties that are responsible for such developments. Workers now demand to know the dangers of and environmental implications for the substances they are required to handle, both on and off the job (Miller, 2003). At present, these and other non-management personnel who have historically not had a say in corporate environmental policy are suddenly contending that they are indeed stakeholders and that their concerns must be considered, thus in the analytical framework of this research, contributing to the bottom-up approach with higher degree of involvement.

Adam Teva V'din is one body that pressures the government ministries, through formal complaints and in court, to enforce environmental safety regulatory requirements and adopt stricter policies. The legal status allowing an NGO to bring its case to court is an important element of the "educational strategy" and one of the roles played by non-state oriented policy agents in shaping the regulatory regime (Winston, 2002). This realm is based on an international comparison model. In some countries (e.g. Finland, China, and Russia), citizens have direct access to courts only if they are personal victims of industrial environmental negligence in terms of the adverse effects of their products and/or manufacturing practices. In other cases, they have to complain to official environmental authorities. A further model is one such as the United States adopted, where most major environmental statutes include provisions which allow private citizens to bring legal suits to enforce federal environmental (OECD, 2009b)

There are numerous benefits to providing opportunities for the public, through NGOs, to participate in environmental enforcement of protection against chemical hazards. First, local citizens directly affected by a violation are often better positioned to detect and evaluate the impact of the infringement on the environment and upon their specific community. Citizen

enforcement also saves resources for enforcement authorities and bolsters the government's position against the sometimes inordinately powerful political influence of offenders, and thus can empower the government official in command and control of regulation.

Despite what the bottom-up hypothesis suggests, the NGOs' strategy throughout the process of Israel's accession to the OECD can be described as merely responsive. A position paper was issued concerning all environmental issues, stating that Israel falls behind the OECD standards.[16] With regard to chemical regulation, the paper only stated that no regulatory regime for assessing and authorising industrial chemicals was in place. No suggestions concerning how a proper risk-regulatory regime should be determined have been offered to date; though this is the most relevant and necessary field of expertise, it seems to have been missing since the first formulation of the original position paper. Yet, as the culmination of the legislative process towards an establishment of a chemicals regulatory regime approaches, the role of "green" NGOs, that may in some sense help to address this gap, especially that of Adam Teva V'din, should not be disregarded.

[16] *www.adamteva.org.il/*

# Shift in the balance of Power ?

To what extent do the changes foreseen in the Israeli chemicals regulatory regime, and the policy process leading to it, entail potential changes in the structure of power between state agencies / business and civil society? To what extent does the accession to OECD mean not only policy learning and the creation of hybrids regime of regulation, but also a shift in the way power is distributed among different actors?

As presented in the previous chapter, a comprehensive regulatory regime that will register, evaluate and authorize all chemicals, both existing and new, is Israel's biggest obligation under the chemical committee Roadmap of the OECD. Such a regime will be based on the risk regulating.

The assumption that lies in the basis of the process is that obligations will be taken by the government officials, yet an in depth analysis might suggest that the "private" non-state centered interest play a vital role in shaping the policy to establish a regulatory regime. The growing interest in socially responsible activities in the global era is understood. As Shamir puts it "The more the public domain is privatized, the more that the private becomes a matter of public concern. The naked logic of the market also breeds the naked logic of corporate social responsibility". (Shamir 2002)

Governmental risk regulation in Israel nowadays is changing as a consequence of deregulation, privatization, outsourcing of public services, and a shift in regulatory style. These shifts have led to the manifestation of a new institutional and policy style, in which the government's role as a regulator is expanded, while its role as direct provider and employer has declined; the regulatory state (Majone, 1998). This means that we live in a world, where many sources of power can be identified and government is an object as well as a subject of regulation (Braithwaite, 1999).

In accordance with the bottom-up approach presented in the research, we witness a great interest by the industry, and slightly less so by the civil society organizations in shaping the regime. The

vivid participation in the regulatory process is not limited to providing information and input on suggest policies, rather a collaboration between the regulators and the regulatees striving to work together to establish a proper regime. The extent to which the regulatory regimes are equitable and fair will depend upon how they are developed and administered by the industry or relevant association in collaboration with the governmental regulatory authority. Transparency will be maximised when there is an open process for the development of the regime – with the opportunity for relevant stakeholders to participate and express their views.

In the area of environmental policy, complementary approaches of civil regulation are commonly used as part of the regulatory regime. Indirect regulation refers to promoting behaviour change through means other than inspection and enforcement, i.e., by using economic instruments, information- based instruments and education, providing financial incentives, etc. While civil regulation, as discussed in the background chapter, refers to a spectrum of regulatory regimes, including voluntary changes in the behaviour of the regulated community, accreditation by a third party – scheme put forward by civil organizations or acombination of the above with governmental regulatory tools.

The regime is not yet established, nor has a final decision on its scope and structure has been reached. The government, however, seems to realize that the sole enforcement approach will not suffice in this case and collaboration with the industry is more than desired in order to implement the obligation Israel took upon itself during the accession process. The government does not "shake off" its responsibility; rather enable the relevant stake holders to take an active role in shaping the process.

The feasibility and applicability of various forms of civil regulation depends to a large extent on the dependency relationships and the constellations of interest among the actors involved with the risks to be managed (OECD, 2006c). When the regulatee has a direct interest in managing a risk, that is when there is the greatest chance of self-enforced regulation and reliable, effective internal assurance systems. The previous chapter examined the strong interest that lead to a greater interest of the industry in implementing the OECD norms, basing this assumption on economical factors of the Israeli chemical industry (Konar and Cohen, 1997; OECD, 2009a).

In the context of establishing a regulatory regime in Israel, the shift of responsibility (and accordingly some shift of power) is warranted. Industry has a greater role to play in providing and assessing data, and in managing chemicals. To help fill the information gap on existing chemicals, procedures could be developed to give industry full responsibility for generating all the necessary data on all chemicals on the market (i.e. more than just for high production volume chemicals). Industry could also assume a greater role in preparing assessment reports (based on guidance developed by governments with involvement of all stakeholders) that governments would then make widely available. Industry could also be obliged to provide information on the uses of the chemicals they produce, not only so that they can be managed better, but also to help set priorities for assessment. This wide contribution and reliance of the regulatee, namely the industry, contributes to the potential power shift in accordance with the bottom-up hypothesis.

The degree of the potential shift in the balance of power also relies on the power of the actors participating in this particular process of agenda setting. The Ministry of Environmental Protection is generally referred to as both politically and financially "weak ministry", while the chemical industry in Israeli (including Chemicals for Israel, Agan Machtashim and Teva) has substantial political power and influence over decision makers. This particular scenario encourages a synergetic relationship between the government and the industry in shaping the regulatory regime.

The political implications that encourage introduction of civil regulatory regimes can be summed up as an “economization” of regulatory politics (Morgan, 2003). Civil regulation excludes competing ways of understanding regulatory policy choices, causing bureaucrats to “translate” aspects of social policy that previously may have been expressed in the language of need, vulnerability or harm into the language of market failures or market distortion and thus implement economic tools for regulation.

Recognizing that a true change cannot be achieved without collaboration of all stakeholders involved serves as an additional catalyst for creating a regulatory regime which is not solely based on enforcement; rather some sort of civil regulation is desirable (Parker, 2006). The best model for such a structure of power will perhaps be the meta-regulation model, which enables

the state to keep it authorization and supervision, while delegating some responsibilities to the regulatees, namely the industry itself.

There is no set recipe for a successful regulatory regime; there may be government involvement in the development of self-regulatory arrangements without necessarily implying government support or official backing for the scheme. A self-regulatory scheme could be developed with government assistance in the form of advice or government officials participating in the discussions establishing the scheme, but with no formal legislative backing or government responsibility for the scheme (Parker, 2006; OECD, 2009a).

The presence of a certain degree of organizational and self-regulatory capacity in a sector or organization seems to be a minimum requirement for meta-regulation. Those conditions are not met by the Israeli industry; the MAI is lacking both in legitimacy and in power to implement such a task. But as argued by Honingh et al. (2009) meta-regulation can make sense even under sub-optimal conditions. The main added value of meta-regulation is that it affords the authorities a better understanding of the dependency relationships and the constellation of interests, which contains the risks to be managed.

**OECD as a Platform for Civil Regulation**

Civil regulation, whether self, co-regulation of the meta model, may arise not just due to the necessity of power shift in the Israeli context given the political forces shaping the regime. The potential also lies in the core values of the OECD itself. Stake holder involvement and consultation, together with self-monitoring techniques are popular policies among OECD members, thus leading to the assumption that the accession process should be seen as more than just an agenda setting incident. Thought this chapter focuses mainly on how the non-state oriented actors may affect the policy outcome, the OECD itself promotes two mechanisms that can influence the power shift and result in a more hybrid form of regulation, involving the relevant stake holders.

Two recent OECD publications (OECD, 2008a; OECD 2009b) have touched upon a shift in environmental enforcement and regulatory requirements, stating that although regulatory

agencies have historically undertaken compliance monitoring, it is a growing practice to require operators to track and report data on their environmental performance, including the chemical regulation. The emphasis on self-monitoring and self-reporting is regarded as a possible means of substituting government compliance monitoring efforts by passing some of the monitoring responsibility and cost onto the firm without decreasing deterrence. It allows the competent authority to reduce the frequency and sometimes the duration of inspections and increase their efficiency (assuming that related cost reductions would not be overweighed by costs of processing and verifying operator reports). Self-monitoring also gives the industry more ownership of compliance. In some countries (e.g. in Finland and the UK), self-monitoring and reporting requirements of different complexity cover practically all installations regulated by environmental authorities.

As demonstrated in chapter IV dealing with the international perspective of regulating chemicals, the European REACH regulation takes a clear stand by shifting major responsibilities to the industry. Following the implementation of REACH, industry is responsible for assessing and managing risks posed by the chemicals that they produce and for providing appropriate safety information to their users, according to the slogan "no data – no market"![17]

Self-monitoring in various OECD countries is done either by the operators themselves or is outsourced to third parties with appropriate accreditation. The frequency of emissions monitoring (usually defined in the permitting documentation) depends on the sampling methods and priority of individual parameters and varies widely from continuous to monthly to once in several years (OECD, 2009b). Competent authorities produce guidance documents for operators which describe sampling and analysis methodologies, provide emission factors and other supporting material for the evaluation, and explain appropriate data management and reporting practices.

Within the scope of this research, this trend falls under meta-regulation at a conceptual level, meta-regulation has considerable appeal in that it provides the regulated organization with a considerable degree of freedom to meet its regulatory obligations, should it prove trustworthy and genuine in its processes and practices when dealing with its regulatory responsibilities.

This approach claims to lead to "better regulation", while adopting a more consensus-oriented and participatory style, taking economic aspects more seriously, allowing for more flexibility and autonomy for the private sector and the governments alike, mobilizing a broader knowledge base

[17] http://ec.europa.eu/environment/chemicals/reach/2008_reach_workshop/index_en.htm

or adopting more integrated and holistic approaches than previous sectionalized and compartmentalized policies (Hey et al, 2007).

Yet another tool provided by the OECD itself, that could lead to a potential power shift towards some sort of civil regulation model is the OECD Guidelines for Multinational Enterprises adhered to by all OECD members and 12 additional countries, including Israel. The guidelines are supposed to be promoted by the adhering governments, thus blurring the line between the two explanatory approaches of this research, namely the top-down and the bottom-up approaches.

The guidelines are a set of voluntary recommendations, principles and standards that assist in establishing responsible behaviour in the business sector. They intend to guide companies in every important aspect of their social behaviour (including employment and industrial relations, human rights, the **environment**, information disclosure, combating bribery, consumer interests, science and technology, competition, and taxation)[18]. The aim of the guidelines is to promote contributions to economic, environmental and social progress. The aim is not to override existing laws, but to supplement them.

Although the name OECD Guidelines for Multinational Enterprises implies that the guidelines are focused on MNEs, they are applicable to companies of all sizes and bear great importance to them. The guidelines are implemented in the adhering countries by National Contact Points (NCPs), a government office representative. The NCP for Israel is located in the Foreign Trade Administration in the Ministry of Industry, Trade and Labor. In addition Israel has created an Advisory Committee to the NCP comprised of representatives from various Ministries.

The Israeli NCP has recently initiated a re-thinking progress regarding the advisory committee, striving to bring together more stake holders from the non-state centred sector, namely the industry and social NGOs, in order to promote a more collaborative approach in promoting the guidelines and encouraging the businesses to take up more voluntary mechanisms. Though the coordinator of the action plan is the government, the regulatory form inspires to spread beyond

[18] http://www.oecd.org/topic/0,2686,en_2649_34889_1_1_1_1_37461,00.html

legislative obligations and shift the power of the regulatory responsibility and enforcement, leading us, once again, to suggest that a meta-regulation is perhaps the best solution is setting up the regulatory regime. The NCP could in turn promote a more hybrid form of regulation, "educating" the Israeli industry to take upon itself a more significant role in monitoring and regulating the chemical sector.

# Chapter VI. Concluding Remarks

Voluntary action and coercive pressure are present in different proportions in all processes of policy transfer. Policy transfer is more than 'learning' it also entails at least in some cases, a change in the power relations between policy actors and in the balance of power and the structure of relations in established policy networks. This is indeed what was expected and explored in this thesis following the accession of Israel to the OECD. The import of regulation is expected to be augmented with a power shift from state-centered regulation to some form of a hybrid regulation based on the involvement of stake holders. While the new regulatory regime for chemicals in Israel is still in its initial stages and while it is rather early to predict the various features of the emerging regulatory regime be, it is safe to suggests, even in this early stage, that certain changes, not only in the regulations but also in the way government and civil society actors interact, is inevitable.

In environmental governance, it is possible to observe all kinds of experiments with civil-regulation by businesses, target groups policies, co-governance in professional networks, tradable emission permits, exo-taxes, law enforcement and soft rules, open coordination mechanisms, regional contracts and green alliances between business and NGOs (Meidinger, 2002; Schneider and Hyner, 2003). This makes the case study so peculiar.

The first part of the paper analyzed the existing chemicals regulatory framework in Israel. The policy currently in place lacks coherent and comprehensive rules that would satisfy the OECD mandatory requirements in establishing a registration regime for chemicals (chapter III). As discussed previously, the OECD regulations are rather flexible and do not present concrete ground rules for such a regime, but a scheme of recommendations for the member countries to interpret and implement. Two different modes of regulation were presented as potential "instructors" for policy learning and transfer into the Israeli context. The top-down approach does not limit itself to the coercive nature of obligations made to the OECD, but also to the lesson drawing and diffusion of policies from member countries. The US and the EU present two different regimes with varying degree of involvement of the regulatees in the hybrid regulation.

It remains to be seen which model Israel will favor, and whether policy transfer will result in more pluralist agenda setting regime, transferring responsibilities to the industry for self monitoring.

As Majone (1989: 4) writes: "When science, technology, and public policy intersect, different attitudes, perspectives, and rules of argument come into sharp conflict." Such a conflict of interests between various policy actors is discussed in the section about state and non-state actors participating in establishment of the regulatory regime. The government plays an important role in taking upon itself the obligation to establish such a regime in Israel. At the same time, the economic forces and incentives for the industry to take an active role are strong, and it is expected that the industry will seek o actively participate in the formation of the regime and will eventually contribute to a shift of power balance between the regulators and regulatees.

This research further examined the role of non-state players in the agenda setting process of creating a regulatory regime. As demonstrated in chapter V, the role of non-state policy actors in policy learning and the governance of creating a regulatory regime is on the rise.

The main conclusion derived from the analysis in this paper is that the shift is power (chapter VI) is likely to result not only in higher standards of regulation but also in some form of hybrid forms regulation. The form of hybrid regulation may vary across a continuum: starting with mostly voluntary self regulation by a company or an industry, through third party regulation, moving towards a more hybrid form of co-regulation and ending with meta-regulation, which includes an enforcement element of regulation of self regulation.

The research examined two contradicting hypotheses: the top-down approach, which emphasized the role of the OECD and the government bureaucrats as policy transfer agents; and the pluralist bottom-up approach, which examined the role of non-state centred actors in shaping this process, thus establishing a certain impact on the outcome on the balance of power of the regulatory regime. A critical analysis of the answer in the chapter VI, touching upon a potential shift of power, suggests that a potential power shift is likely while a regulatory regime for chemicals is established. The less expected factor is that might result not only to the bottom-up approach which empowers the industry and civil society organizations, but simultaneously is also promoted by the top-down approach and stimulated by the OECD itself.

Given the characteristics of the policy formation process discussed in this paper, when used under the right circumstances, complementary regulatory instruments can offer significant

advantages over traditional command and control regulation in the area of risk regulation of chemicals in Israel. These advantages include, inter alia: flexibility and adaptability; potentially lower compliance and administrative costs for those involved; an ability to address industry-specific and consumer issues directly; ensuring industry or sectoral ownership of the regulatory arrangements; and providing for quick and low-cost complaints handling and dispute resolution mechanisms (Börzel and Risse, 2003).

However, while the limitations of traditional regulatory approaches are widely accepted and cited, it is far from evident, that "new modes of governance" have greater capacity to solve problems than the old ones. There is an argument, that "better regulation" might be synonymous to a withdrawal and weakening of the regulatory state and hence effectively abandonment of the aspirations and objectives of environmental policies (Hey et al, 2007). One can expect negative consequences from using these instruments if they are developed in an inappropriate way or are used in situations when other forms of regulation would have been a better choice, namely government enforcement. Therefore, when designing a chemical regulatory regime, several key elements of assessment should be taken into account.

In general, for a complementary regulatory regime (from self-regulation to meta-regulation) to be effective policy instruments it is necessary for the regime: to addresses clearly specified objectives; to be integrated and consistent with other forms of regulation; and to have effective monitoring and compliance mechanisms. In situations where the interests of the industry do not fully align with those of the community, self-regulation is unlikely to be an effective instrument, unless there are a number of safeguards built into the system, thus when economic motivations are not strong enough, co-regulation or meta-regulation would be a better model.

Will Israel wisely integrate those safeguards into its forthcoming regulatory regime for chemicals and choose a more hybrid complimentary structure of regulation? Only time will tell. However a certain degree of power shift and a greater involvement of the industry is already evident in the agenda setting process. That determines the process traced in this research as an interesting case study of regulation in an era of global governance.

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# תקציר


הארגון לשיתוף פעולה ופיתוח כלכלי (OECD) הינו פלטפורמה בינלאומית לדיוני מדיניות וקביעת סטנדרטים והמלצות למדיניות מיטבית (Best Practices). עד לאחרונה, היו חברות בארגון 30 מדינות דמוקרטיות, ליברליות, המאופיינות בכלכלת חופשית. ב- 16 ל-מאי 2007, הוזמנה מדינת ישראל, יחד עם צ'ילה, סלובניה, אסטוניה ורוסיה לפתוח במשא ומתן לקראת הצטרפותן לארגון. תהליך המשא ומתן של ישראל הגיע לשיאו ב-7 ל-ספטמבר 2010, עם הפיכתה לחברה ה-33 בארגון ה-OECD.

תהליך ההצטרפות בן 3 השנים, כלל בחינה מעמיקה של החקיקה והמדיניות של ישראל בתחומים רבים. אחד מפערי המדיניות הבולטים בין המדיניות הנהוגה בישראל לבין המסגרת המשפטית של ה-OECD נעוץ בתחום של רישוי וניהול כימיקלים. נכון להיום, אין לישראל משטר מובנה וקוהרנטי בתחום הכימיקלים- החל מיצור, דרך שיווק והובלה וכלה באישור של כימיקלים.

עבודת מחקר זו מבקשת להתחקות אחר תהליך ההצטרפות של ישראל ל-OECD בהקשר של חובת הקמתו של משטר רגולטורי לכימיקלים בישראל. הצפי הינו כי הלקונה הקיימת במדיניות בתחום זה, תעבור שינוי מהותי על מנת לעמוד בדרישות הסף של הכלים המשפטיים והנורמות הנהוגות ב-OECD.

המסגרת התיאורטית עליה נשען המחקר הינה שינוי מדיניות והעברת מידניות (Bennett & Howlett, 1992; Wolman, 1992; Dolowitz & Marsh, 2000). בקונטקסט של צמיחת ההשפעה של שחקנים בינלאומיים בעיצוב מדיניות לאומית. המחקר הכיר כבר בעבר בכוחם של סוכני שינוי שאינם נמנים עם הנציגות הרשמית של הממשל, כך שלתעשייה יכול להיות תפקיד חיוני בהעברת המדיניות.

ניתוח של השלבים ההתחלתיים בתהליך קביעת מתווה הפעולה של הקמת משטר ניהול כימיקלים מתמקד בכוחות המניעים יחד עם השיקולים והציפיות אשר מעצבים יחדיו את התהליך של שינוי רגולטורי. האינטרסים והאסטרטגיות של קבוצות המייצגות תעשיה הינם מקדם חשוב בקביעת תוצר המדיניות. יתרה מזו, היות והתעשייה בסופו של דבר תישא במרבית העלויות של חקיקה ומידניות סביבתית, חשוב להעריך נכונה את האינטרסים אשר יקבעו את רמת הציות והאפקטיביות של סטנדרטים לניהול כימיקלים, כמו גם יישור קו עם כלי מדיניות וולונטריים.

המחקר נוגע בשאלה עד כמה השינויים הללו משקפים לא רק הפקת לקחים והעברת מדיניות ( policy learning and policy transfer), אלא פוטנציאל להסטת יחסי הכוחות בין רגולציה של רשויות ממשלתיות לבין רגולציה אזרחית (civil regulation).

הדיון נסב סביב שתי היפותזות סותרות: הגישה הניו-ליברלית של מלמעלה-מטה, אשר מדגישה את תפקידו של ה-OECD וחשיבות הביורוקרטים הממשלתיים כסוכני שיוני מדיניות; והגישה הפלורליסטית של מלמטה-מעלה, אשר בוחנת את תפקיד השחקנים שאינם מדינה בעיצוב התהליך. התשובה המוצעת הינה שהשינוי ביחסי הכוחות הינו תוצר סביר לא רק בהסתכלות דרך גישת ה-bottom-up , אשר מעצימה את כוחם של התעשייה והארגונים הסביבתיים, אלא גם לפי גישת ה- top-down המחלחלת דרך ה-OECD עצמו.

תוצר המדיניות הצפוי מסיט את המיקוד מרגולציה מבוססת אכיפה על-ידי המדינה למבנה מורכב יותר של רגולציה חברתית-אזרחית. מודלים לרגולציה משלימה יכולים לנוע לאורכו של ציר: החל מרגולציה עצמית

וולונטרית של חברה או סקטור תעשייתי, דרך רגולציה ואקרדיטציה ע״י צד שלישי, אל עבר מודל כיליים של רגולציה בצוותא (קו-רגולציה) וכלה במטה-רגולציה. במבחן המציאות כאשר האינטרסים של התעשייה אינם תואמים במלואם את מחויבויות המדינה, רגולציה עצמית לא צפויה להיות כלי מדיניות יעיל.

במונחים של עבודת מחקר זו, בבואה של ישראל להקים משטר לניהול וריסוי כימיקלים, ראוי כי תתחשב בכך שכאשר המניעים הכלכליים אינם חזקים דיו, קו-רגולציה או מטה-רגולציה יהיו מודלים מועדפים למשטר ניהול הכימיקלים.

האוניברסיטה העברית בירושלים
הפקולטה למדעי החברה
בית הספר ע״ש פדרמן למדיניות ציבורית וממשל

# רגולציה בעידן של ממשלתיות גלובלית –

# משטר ניהול הכימיקלים הרגולטורי של ישראל בעקבות ההצטרפות לארגון ה-OECD

עבודת גמר לתאר מוסמך במדיניות ציבורית

בהדרכת פרופסור דוד לוי-פאור

מוגשת על-ידי: ריטה גולשטיין-גלפרין

מס' ת"ז: 306625088

מועד הגשה: 7 אוקטובר 2010