Int. Journal of Economics and Management 5(1): 53 - 97 (2011)

ISSN 1823 - 836X

# Biotechnology Policy Implementation from a Systems Perspective

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#### ABSTRACT

This study utilizes Viable System Model (VSM) in diagnosing one policy implementation call Malaysian Biotechnology policy. The policy implementation is viewed from the innovation theory, which regards research and development (R&D) as the core of innovation commercialization, which in turn become the nucleus for a firm's growth. Subsequently, the growth of firms as a group can lead to an industry's development. This study conducted interviews with the agencies involved in the policy implementation and took advantage of the extensive information relating to the agencies that are available in the public domain, by using content analysis as the study's methodology. This study enhances the understanding on the full use of VSM; it provides policy makers and implementers a guide in improving existing systems or designing new ones, while researchers are afforded an applicable theoretical conceptualization from a systems thinking perspective.

**Keywords**: Systems theories, systemic, Viable System Model, biotechnology, industry development, innovation theory.

#### **INTRODUCTION**

Systems view is a part of open systems theory, which suggests the existence of close relationships between a system and the elements within its environment. It is a powerful tool in explaining a system in a comprehensive manner, particularly in its ability to capture the elements of a system's environment into a model, thus the term systems or systemic perspective. Perspectives on systems view include 1) the living systems theory, 2) Bob Flood's Four-Windows Approach, 3) Emery's Open Systems Theory, and 4) the Viable System Model (VSM) (Barton, Emery,

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Any remaining errors or omissions rest solely with the author(s) of this paper.

Flood, Selsky and Wolstenholme, 2004). In regard to VSM, it was developed from the Cybernetic theories, which describe the relationship between a system and its environment as influencing each other, and the system being self-sufficient in its environment (Cybernetic, 2010; Espejo and Gill, 1997). Building upon a number of organization theories, as well as recursive teorems and law of cohesion, VSM interprets the concept of *self-sufficiency* into the constructs of: *complexity, variety, responsiveness, cohesion* dan *recursiveness* (Beer, 1989a; 1989b).

While there have been much interest in applying the systems models, most of them, including VSM, are complex and thus not easy to utilize. VSM that has been applied in academic research generally explains a particular organization or a policy setting as systems, but previous research generally lacks documentation of its full utilization (e.g., Harwood, 2009; Watts, 2009; Schwaninger, 2006). As such, understanding of its applications generally remains in the exclusive hands of systems scholars. Consequently, this might hinder the model from being selected as a diagnostic or design framework in myriads of systems implementations within businesses and societies. This might also deter it from being considered as an important theoretical conceptualization in mainstream academic research. In this study, we fulfill this research gap by utilizing VSM in diagnosing one policy implementation, which is the Malaysian Biotechnology Policy.

The Malaysian Biotechnology Policy was launched in 2005, and biotechnology has since been designated as a strategic industry within the country's economic development strategy, which ultimate aim is to achieve the developed country status by the year 2020. The policy has a three phased implementation plan: Phase 1 (2005-2010), focuses on developing the foundation that supports biotechnology industry's growth. Phase 2 (2011-2015), aims at building the industry's capabilities and competencies to achieve more rapid commercialization of biotechnology products, while Phase 3 (2016-2020) is expected to be the achievement phase in which the industry transforms into an important source of economics and wealth creation for the country (MOSTI, 2005). In support of this policy, the Malaysian government had allocated about RM2Billion (approximately USD600Million), with the industry was expected to contribute about 2.5% to the country's GDP by the end of 2010 (BiotechCorp, 2007).

The policy implementation is founded on nine core elements. The first three are the designated sectors targeted for development, which are agriculture, healthcare, and industrial, while the remaining six are their vital supporting measures. These include building capabilities in biotechnology research and development (R&D), human capital, and funding, as well as providing regulatory structure, and establishing strategic positioning in the biotechnology market. All these are to be achieved through a comprehensive government support system, including operating a dedicated biotechnology industry developmental agency, called Biotech Corporation (BiotechCorp) and various other supporting agencies. See Appendix A for the biotechnology policy thrusts.

In modeling the biotechnology policy implementation, this study draws from innovation theory, which provides the scope and establishes the focus of the study. Innovation theory regards R&D as core to innovation commercialization. These innovations become the nucleus for a firm's development and growth. In turn, the collective growth of firms in the industry can lead to an industry's development. Building on this perspective, R&D services, which directly contribute to biotechnology innovations, are presumed to lead to an increased number of firms created, and drive the rapid growth of existing firms, and consequently contribute to the overall development of the biotechnology industry (Jacobson, 1992; Martin, 1994; Schumpeter, 1934; 1942; Sundbo, 1998; Tornatzky & Fleischer, 1990). In this regard, R&D, Firm Creation/Development, and Industry Development, serve as the three core services in supporting the biotechnology policy implementation. Combining VSM with innovation theory and utilizing content analysis as its research methodology, this study demonstrates the full application of VSM, enabling enhanced understanding of its use, and contributing toward a more rapid diffusion of systems perspective in both research and practice.

#### VIABLE SYSTEM MODEL (VSM)

In VSM, complexity and variety are two important concepts. The complexity of a system (*system complexity*) is measured by "variety"; the greater the "variety" of a system, the higher its level of complexity. On the other hand, *requisite variety* is the ability of a system to absorb variety. A system is viable (*system viability*) if it has a requisite variety that is able to respond to different types of variety within its environment, including threats and opportunities, whether or not they are anticipated. The equilibrium between requisite variety and variety in the environment is determined by the objectives to be achieved by the system. The greater the variety in a system's environment, the higher is the need for requisite variety by the system to enable it to manage its environment. However, variety within the environment can be controlled by adjusting the order of its priority and focusing on variety that is considered most important. The level of variety can also be controlled by lowering the expected performance level of a system (Beer, 1989a; 1989b; Brocklesby and Cummings, 1996; Devine, 2005).

One of the key factors in VSM is its environment, which represents the elements outside of the system that have an influence on it. Elements in the environment include sources of input to the environmental scanning activities (intelligence function) and all groups of external users that utilize the system's outputs. Intelligence function collects information from its environment to provide requisite variety that helps the system to be viable in it; the function also disseminates information to them (Beer, 1989a; 1989b; Brocklesby and Cummings, 1996; Leonard, 2000). Figure 1 shows the standard VSM framework and its environmental elements.

From VSM's perspective, a system is composed of several subsystems, and each of these subsystems in turn has its own subsystems; this structural chain ends with a single person in the organization. Each subsystem has its own level of complexity which is measured by variety, and each needs requisite variety when providing appropriate responses to external stimuli. A viable system requires subsystems, which are also viable, and vice versa. This condition is described as *recursiveness*. Related to recursiveness is the concept of cohesion, which refers to the integrated relationship between a system and its subsystems, with the subsystems acting as a group to ensure they support the system's operation in accordance with the internal state of the system and its environment (Espejo and Gill, 1997; Espejo, Bowling, and Hoverstadt, 1999; Leonard, 2000). Table 1 provides the summary of descriptions of these concepts.

No.	Concepts in VSM	Definition
1	Variety	The elements (situations) within a system as well those surrounding it
2	Complexity	The number of variety in the system
3	Requisite variety	The level of <i>variety</i> within a system that allows it to manage the level of <i>complexity</i> in its environment
4	Responsiveness	The ability of the system to provide appropriate and timely feedback to its environment
5	Cohesiveness	The integrated relationship between the system and its subsystem in which each subsystem assists the system to properly respond to its changing environment
6	Recursiveness	The concept in which a viable system is supported by viable subsystems in which each subsystem is a miniature viable system itself

Table 1	Definition o	f concepts	in	VSM
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VSM defines that a system operates five basic functions to meet parts of system viability requirement: System 1 (implementation), System 2 (coordination), System 3 (control), System 4 (intelligence) and System 5 (policy making) (Espejo and Gill, 1997; Schwaninger, 2006). System 5 acts as a policy making function to the system, while System 4 scans internal and external activities. It then makes assessment, structures problems and opportunities originating from the environment and the internal system, and disseminates this information to System 5. As shown in Figure 1, System 4 in a viable system interacts with System 5 and its environment; it also helps communicate policy-related information to System 3, which then passes the information directly to management units of System 1 (implementation function). System 3 also controls the functional stability of System 1, which generates product and/or services based on the objectives of the system. System 3\* is the functional

entity that collects and distributes information from operating units directly to System 3. Moreover, it disseminates additional information from System 3 to the operating units without going through each of their functional management units. System 2, on the other hand, coordinates the functions of management units in System 1. In short, all five functions are connected to each other through mutual flows of information. Similarly, the flows of information between higher order system and its subsystems are also mutual. Systems 2, 3, 4, and 5 are generally referred to as meta systems (Brocklesby and Cummings, 1996; Devine, 2005; Leonard, 2000; Espejo & Gill, 1997).

System 1 has two components, namely the management units, which oversee the activities of the operating units, which are illustrated as square boxes, and the operating units, which directly produce the products and services of the system, shown in the form of the oval shapes in Figure 1. Each management unit (square box) in Subsystem 1 reports directly to System 3, as well as provides and receives information from System 2. To ensure that the system is viable, the operating units gather information relevant to their consumers and external stakeholders, and in turn provide information about itself to interested groups in the environment (indicated by a line of relationship between an operating unit and the environment). This intelligence activity provides input (key information) relevant to their respective management unit. The full description of the lines and forms in VSM is tabulated in Table 2.

Applications of VSM in the literature have mainly focused on explaining the specific functions of a system, its meta systems, or the external environment of a firm, with few documentations of its full usage. For example, Watts (2009) mainly analyzes the control and communication function of a policy-networks system, while Harwood (2009) examines the industry structure. Others generally emphasize on the meta systems, with only minimal treatment on either the implementation subsystems or their relationships with the environmental elements (Schwaninger, 2006). The general absence of VSM's full application from the systems thinking literature reduces the potential of its usage in highlighting problems and generating potential solutions systemically, which are the main elements of its philosophy. This is the research gap that the study intends to fulfill.

As VSM is a general model for diagnosing and designing a viable system, its application requires the use of relevant theoretical perspectives in support of data explanation and interpretation. In this study, we view the biotechnology policy implementation from the innovation theory perspective, which strengthens the VSM conceptualization of the policy implementation system. Innovation theory generally views R&D as the core source of innovation commercialization. Particularly the Schumpeterian perspective, the innovation theory emphasizes the need for firms to be innovative. In fact, innovating is equated to strategizing, and it is achieved through the firms' entrepreneurial act, which is the ability of firms to identify and develop opportunities to produce new products/services or to integrate them in

their processes or systems that not only benefit the customers but also bringing in profits to the firms. This capability to innovate could lead to high growth of firms (firm development) and rapid development of industries (industry development). In turn, high growth of firms and industries, which promote economic development in a society, benefit both the consumers and businesses (Jacobson, 1992; Khairul Akmaliah & Mohd Fuaad, 2008; Martin, 1994; Shane & Venkataraman, 2000; Schumpeter, 1934; 1942). Thus, building on this Schumpeterian-innovation perspective, the biotechnology policy implementation subsystem is categorized



*Note*: Subsystem 1, 2, 3 = Subsystems to SYSTEM 1; Operating Units = Operating Units for each Subsystem.

Source: Beer (1981); Espejo and Gill (1997)



into services of R&D, Firm Creation/Development, and Industry Development. The categorization of these activities is also in line with the approach taken by the Malaysian government in allocating resources to the relevant agencies for programs or projects related to the biotechnology policy implementation.

No.	Concepts in VSM	Definition
1	Reciprocal lines among System 5, 4, 3, 2 and 1	Authority-based information flow.
2	Reciprocal lines between System 4 and the environment	The flows relate to the gathering and dissemination of information from the system to its environment and vice-versa.
3	Triangle	Coordination or Audit function
4	Lines with arrows that connect management units with System 3	The flow of authority between System 3 and the management units in System 1. Authority flows describe the flows of financial allocation and application from subsystems to top management.
5	Lines that connect the operating units with System 3*	The flow of information is non-authority based - a two-way flow of information between operational units and audit functions without going through each management unit
6	Square box	Management units in the high-level system and subsystems
7	Oval shape	Operating unit for each subsystem
8	Curve lines between operating units	Flow of information, which is not related to authority that happened among the operating units, and is needed to ensure overall cohesiveness of system viability.
9	Reciprocal lines between square and oval boxes	Authority-based information flow, which indicates reports by operating units to the management unit and instructions they received from the management unit.
10	Reciprocal lines between operating units and environment	Flows relate to the gathering and dissemination of information from /to the environment to/from operating units.

Table 2 Definition of forms and lines in VSM

# **RESEARCH METHODOLOGY**

The nature of the data on the biotechnology policy implementation, which were collected from the published sources in the public domain, as well as through direct interviewing of the agencies, are mainly available in textual forms. This warranted a research methodology that can address the need to analyze volumes of text-based data. Therefore, content analysis methodology, which is one of the empirical

techniques in gaining in-depth understanding of a phenomena through analyzing textual data, was utilized as our research approach (Krippendorff, 2004; Duriau, Reger, and Pfarrer, 2007; Stemler, 2001; Mohd Fuaad and Khairul Akmaliah, 2010). In using content analysis as a methodological procedure, we adapted the six important questions outlined by Stemler (2001), which are developed based on Krippendorff (1980), to ensure the study's reliability and validity. They are: a) which data are collected and analyzed? b) how are they defined? c) what is the population from which the data are drawn? d) what are the contexts that are relevant to the data being analyzed? e) what are the boundaries of the analysis? and f) what is the target of the inferences?

Data that were collected are those on the functions of all agencies and institutions involved in the implementation of biotechnology policy as well as their environment. They, as a whole, formed the study's context and boundary. The data were gathered through direct interviewing with the agencies involved in the biotechnology policy implementation and via extensive research on their information in the public domain, mainly from the Internet. The latter are those classified as official data, including published policy papers, texts of ministers' speeches, agencies and institutions' technical reports, communication papers and brochures, and websites. This was done to ensure their authenticity and accuracy, which is an important step in ensuring data reliability and internal validity of the findings. The gathering of data began in March 2010, and it was completed on the 31<sup>st</sup> of August, 2010.

Since all data gathered are factual, rather than perceptual, problems of data ambiguity and improper coding were significantly reduced. Moreover, taking only the factual data addresses the challenges of data instability, which relate to biases in making data interpretations. This procedure, which also allows the reproducibility of the study's findings (Stemler, 2001) contributes toward ensuring internal validity of the study. These steps within the data collection and analysis addressed the first five of the Stemler-Krippendorff's (2001) procedures outlined above.

The sixth and final Stemler-Krippendorff's (2001)'s procedure involved mapping the gathered data onto the structure of VSM. The construction of the data onto VSM allowed us to draw accurate conclusions regarding the functions of the agencies and institutions and their existing relationships and interactions. VSM structure also indicates the relationships between the biotechnology policy and the actors in its related environment. Such application of VSM framework demonstrates one approach toward VSM application, which provides important implications to the policy's stakeholders and researchers.

#### FINDINGS

The first part of the findings section discusses the meta systems of the biotechnology policy implementation, which are Systems 5, 4, 3, and 2. The functions and list

of agencies and institutions in the meta systems are presented in Figure 2 and elaborated in Columns C and D in Table 3. The grouping of the agencies in Column D corresponds to their functions outlined in Column E. The grouping further emphasizes the important functions performed by these agencies.

The second part of the findings section presents the study's outcome on System 1, which is the implementation function. The implementation of the biotechnology policy is divided into three subsystems. For each subsystem, information regarding the agencies involved are discussed in Table 4 (Column C) and they are grouped into those that directly contribute to the operations of the subsystem and those that provide supporting services to the operating agencies.

The third part of the findings section presents the environmental elements of the biotechnology policy implementation. These include elements in the environment of System 4, and Subsystems 1, 2, and 3. The environmental elements of the Subsystems 1, 2, and 3 are summarized in Column D of Table 4. In the final part of the findings section, the study discusses the monitoring function and the relationships that exist among the operating units.

# THE META-SYSTEMS OF BIOTECHNOLOGY POLICY IMPLEMENTATION (POLICY MAKING, INTELLIGENCE, CONTROL AND COORDINATION)

## System 5: Policy Making

The meta-systems of biotechnology policy implementation (as shown in Figure 2) include the functions of Systems 5, 4, 3, and 2. VSM considers the agencies and institutions within this systemic level as major players of the policy implementation. System 5 includes 1) the Biotechnology Implementation Council (BIC), a ministerial level policy making committee chaired by the Prime Minister; 2) the National Innovation Council (NIC); and 3) Ministry of Science, Technology and Innovation (MOSTI) and the Ministry of Finance (MOF). MOF and MOSTI are the lead ministries in the policy making function mainly because the former is the centralized treasury for government projects, while the latter is the key operation agency for biotechnology development in the country. In addition to MOSTI and MOF, seven other ministries are also involved in the policy making activity, with their ministers participating as members in BIC. These ministries are: 1) Ministry of International Trade and Industry (MITI); 2) Ministry of Agriculture & Agro-Based Industries (MOA); 3) Ministry of Plantation Industries and Commodities (MPIC); 4) Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC); 5) Ministry of Natural Resources and Environment (MNRE); 6) Ministry of Health (MOH); and 7) Ministry of Higher Education (MOHE). The Prime Minister and Deputy Prime Minister are also members of BIC. This means that the Prime Minister's Department is member of BIC (BiotechCorp, 2010).



*Note:* See Tables 3 and 4 for the full description of the functions of institutions, working groups, and Operations Units that make up the subsystems; List of abbreviations in this figure and throughout the paper are given in Appendix B. The symbol "?" indicates absence of the monitoring function, while symbol ?\* indicates absence of intelligence in one of the operating units, which is R&D subsystems; Subsystems 1 and 2 have intelligence function. \*\* Agencies in boldface indicate their coordination role. *Source*: See sources of Table 3.

Figure 2 Meta systems of biotechnology policy implementation program from VSM perspective

			rogy roucy implementation	
A Types of systems	B System Functions*	C Functions of Agencies and institutions within biotechnology policy implementation	D ***List of agencies and institutions or working groups, within biotechnology policy implementation	E Groups/categories
System 5	<b>Policy</b> 1) Performs policy making function; 2) Provides explanation on purpose and values of the system.	Performs policy function for Biotechnology Policy implementation	1) BIC; 2) NIC; 3) MOSTI, MOF	<ol> <li>Dedicated Biotechnology Industry Development Policy Makers (BIC)</li> <li>Overall Country-Level Innovation Policy Maker (NIC)</li> <li>Key/Leading Operations (MOSTI) and Control (MOF) ministries in Biotechnology Policy Implementation</li> </ol>
System 4	<ul> <li>Intelligence</li> <li>1) Performs the function of identifying opportunities and challenges from the system's internal and external environment;</li> <li>2) Communicates the identify and purpose of the system to outsiders.</li> </ul>	Performs intelligence functions for Biotechnology Policy implementation	BIOTEK 1) NIC; 2) IAP, MIGHT, BIOTEK; 3) MIDA, MITI, MOSTI, MASTIC; 4) BiotechCop; 5) EPU	<ol> <li>Overall Innovation Policy Intelligence (NIC)</li> <li>Biotechnology Policy Intelligence (BIOTEK, IAP, MIGHT)</li> <li>Biotechnology Policy Promotion (MIDA, MITI, MASTIC, MOSTI, e.g., BioMalaysia)</li> <li>Intelligence for BioNexus Partner Program (BiotechCorp)</li> <li>Intelligence for overall country development plans (EPU)</li> <li>BIOTEK performs coordinating function for intelligence, shown in bold in Column D and Figure 2.</li> </ol>
System 3	<ul> <li>Control</li> <li>1) Designs and implements control mechanism for the implementation function (System One) and to enable status of important activities within the system to be communicated across the system 1;</li> <li>2) Communicates important policy information to System 1;</li> <li>3) Allocates resources to System 1.</li> </ul>	Performs control function for Biotechnology Policy implementation	1) MOSTI, BIC; 2) AG, MOF; 3) EPU	<ol> <li>Biotechnology Policy Implementation Control (BIC, MOSTI)</li> <li>Centralized treasury-coordinating government unit (AG, MOF)</li> <li>Centralized controllling unit for overall country development plans (EPU)</li> </ol>

 Table 3
 Summary of the types and functions of system in VSM and functions of institutions and agencies in the meta

Biotechnology Policy Implementation from a Systems Perspective

System 3*	Monitoring/auditing Monitors/audits operating units directly (Subsystem 1), to be reported to System 3	Performs monitoring or auditing function for Biotechnology Policy implementation	Absent	Absent
System 2	<b>Coordination</b> Performs coordination function amongst the implementer units within the system (System 1)	Coordinates operations functions of Biotechnology Policy implementation	BIC 1) BIC; 2) EPU, ICU	<ol> <li>Inter-ministerial coordinating function (BIC).</li> <li>Centralized treasury and coordinating government agencies (EPU and ICU).</li> <li>BIC performs overall coordination function for Biotechnology Policy implementation, shown in bold in Column D and Figure 2.</li> </ol>
System 1	Implementation Performs the implementation function, i.e. produces the products or services of the system, as defined by the system's objectives	Performs implementation function for the Biotechnology Policy implementation	See details in Table 4.	See details in Table 4.
*Description a Source: AG (2) (2010); MOST	ddapted from Espejo and Gill (1997) and Leonard (7 010); Bernama (2010); BiotechCorp (2005; 2009; 2 1 (2010a; 2010b; 2010c); MyMDANA (2010); NIG	2000); see literature review section. 010); BIOTEK (2009; 2010); EPU C (2010). Agencies in boldface ind	(2006; 2010); ICU ( 2010); MASTIC ( icate their coordination role.	2010); MIDA (2006; 2010); MIGHT (2007; 2010); MITI (2010); MOF

The appointment of these ministers in this committee suggests the important roles of their ministries in the biotechnology policy implementation. In fact, the function of each ministry corresponds with the nine thrusts specified in the Biotechnology Policy. MPIC, MOA, MOH and MNRE are the anchor ministries in the biotechnology policy implementation as they are directly involved in the three biotechnology thrust sectors, while the other five ministries are their direct supporters. Appendix A shows the connections amongst the biotechnology policy thrusts and the involvement of the respective ministries.

The NIC is chaired by the Prime Minister and the Deputy Prime Minister serves as the deputy chairman, thus, both are the council's core members. Another important member is the Minister in MOSTI, while other members include the heads of various ministries and representatives from industries, non-governmental organizations (NGOs), professional bodies, as well as institutions of higher educations. NIC is responsible for developing the framework and coordinating innovation development efforts in Malaysia. This involves planning, coordinating, and monitoring the implementation of the National Innovation Policy, which includes the Biotechnology Policy (NIC, 2010). In this respect, NIC functions as the policy maker in the biotechnology policy implementation system. Tables 3 and 4 provide the summary of VSM functions in the implementation of biotechnology policy and agencies involved in each function.

#### System 4: Intelligence

The intelligence function is carried out by System 4, which among others, comprises NIC and International Advisory Panel (IAP). NIC is responsible for formulating overall innovation framework of the country, and thus it gathers information on all aspects of innovation in Malaysia which are to be utilized in formulating relevant innovation policies, including the Biotechnology Policy. IAP acts as an advisory council to the biotechnology policy implementation, specifically BIC, which serves as the policy maker, and also advises BiotechCorp on similar relevant issues (BiotechCorp, 2010). Another unit under System 4 is a division of MOSTI's, the National Biotechnology Division or BIOTEK. It was formed in 2005 and evolved from one of MOSTI's department, the National Directorate of Biotechnology which was established in 1995 (Technology Business Review, 2009). The creation of this directorate is a part of the incremental biotechnology industry development initiatives which began in 1984. Since then, the biotechnology industry was given more focus and the amount of monetary allocation for the industry continued to increase. This finally led to the launching of the Biotechnology Policy in 2005 (Saridan, 2007).

BIOTEK serves as a secretariat to the BIC and maintains information on the discourses of the ministries involved in BIC, which indicates that it performs the coordinating role in the intelligence function. BIOTEK is responsible for coordinating, monitoring and updating the documents for Biotechnology Policy Paper and Biotechnology Implementation Blueprint, which means that it functions in the coordinating and controlling roles for System 4, shown in boldface in Figure 2. This information perhaps serves as input for the formulation of Biotechnology Policy which is carried out by BIC. BIOTEK is also responsible for promoting public awareness and creating understanding of biotechnology, and thus plays the role of the public relations office to the overall implementation of the biotechnology policy (BIOTEK, 2010). All these underscore BIOTEK's involvement in the intelligence function.

The Malaysian Science and Technology Information Centre (MASTIC), a division of MOSTI, is also involved in the intelligence efforts. This unit is responsible for performing the intelligence function of MOSTI, specifically the one that relates to Science and Technology (S&T) policy, which includes the Biotechnology Policy. It collects, disseminates, and links the relevant information to its major stakeholders who are policy makers, research fund providers, researchers, as well as users and developers of research results (MASTIC, 2010). MASTIC operates an integrated portal called Knowledge Resource for Science and Technology Excellence, Malaysia or KRSTE.my. This portal comprises MASTICLink, which is a meta-database for important information on S&T policy, and MyMDANA, which is a portal that gathers and provides information regarding funds managed by MOSTI (MyMDANA, 2010).

The Malaysian Industrial Development Authority (MIDA), an agency under the Ministry of International Trade and Industry (MITI), on the other hand, is tasked to directly promote the Biotechnology Policy initiatives as well as incentives offered under the policy's BioNexus Program at the international level. This promotion is carried out in collaboration with BiotechCorp with the intention of persuading foreign companies to set up their biotechnology businesses in the country (MIDA, 2010; 2006). BiotechCorp and MOSTI also play a major role in promoting the Biotechnology Policy initiative by organizing BioMalaysia, an annual international biotechnology conference and exhibition. This conference hosts IAP meeting, and consists of BioInno Awarding ceremony, multiple conference tracks, workshops, meetings, and networking events (BioMalaysia 2010, 2010). BiotechCorp and MOSTI also collaborates in promoting the Malaysian biotechnology industry, albeit reciprocally, by attending and organizing conferences and dialogues with potential international partners to promote Malaysian biotechnologies abroad for undertaking to interested parties, and attracting foreign companies to establish businesses in the country (Iskandar Mizal, 2009). Therefore, MIDA, MITI, MOSTI and BiotechCorp are part of the intelligence function.

Another agency that plays a role in the intelligence function (System 4) is the Malaysian Industry-Government Group for High Technology (MIGHT), a think-tank that is responsible for conducting studies, which findings are utilized in formulating the Biotechnology Policy. MIGHT was formed in 1993 and its

members are representatives from the public and private sectors (MIGHT, 2010). It gains visibility mainly through its involvement in the Multimedia Super Corridor (MSC) program, which is an IT industry development policy that began in 1996, 10 years before the commencement of the Biotechnology Policy. MIGHT supports MOSTI in promoting Biotechnology Policy to business communities, thus, it provides the policy with a link back to its environment, and highlights its role in the intelligence function. The Economic Planning Unit (EPU), a unit under the Prime Minister's Department (PMD), is responsible for conducting government research relating to industry development as well as monitoring and evaluating government development programs to the general public through its reports. Thus, it is directly involved in the intelligence functions of the policy (EPU, 2010).

#### System 3: Control

This stage involves the participation of MOSTI's BIOTEK, MOF, BIC, EPU and Accountant General's Department (AG). BIOTEK is responsible for reviewing and evaluating the progress and development of the biotechnology industry with regards to Biotechnology Policy and Biotechnology Implementation Plan (BIOTEK, 2010). Therefore, BIOTEK plays an important role in monitoring the functions of System 1 of the biotechnology policy. The operation of BiotechCorp, even though it is a subsidiary of MOF, is under the purview of MOSTI. BiotechCorp's sister company, InnoBiologics (InnoBio), has a similar ownership and reporting structures as BiotechCorp. This indicates that both MOSTI and MOF act as controlling entities (System 3) in all implementation activities involving BiotechCorp and InnoBio. BIC also governs BiotechCorp's which has direct involvement of BiotechCorp.

Resource allocation for government project and programs, including for biotechnology policy implementation, requires approval from EPU. Justification for the project proposal approval by the EPU is based on relevant programs and policies. EPU, which is responsible for evaluating all government development programs, also performs the control functions for the biotechnology policy implementation (EPU, 2010). Once approved by the EPU, the proposal is send to the treasury (MOF) for further consent. MOF, particularly through its AG, is the controlling authority for all treasury-related projects undertaken by all government agencies within the biotechnology policy implementation program. The AG generally advises the decision makers in the government agencies in relation to accounting and finance. AG controls the biotechnology policy implementation through its function in designing, developing, and implementing government accounting system. Account statements for all implementers of the biotechnology policy are revised at the end of each accounting year as a part of audit procedure being implemented in the country's accounting system (AG, 2010).

#### System 2: Coordination

The function of System 2, which is the coordinating function of System 1, has two categories. The first category involves the efforts by BIC, which acts as a platform for inter-ministerial forum. This coordinating function is critical because the functions of the subsystems in System 1 are performed by many ministries. As all of the agencies and working groups are under the ministries that are represented in the BIC, BIC plays the overall coordinating function for the policy implementation (BiotechCorp, 2010). This also makes BIC as the lead committee in the system coordination, as shown in boldface in Figure 2. The second category includes EPU and Coordination Unit (ICU) of the Prime Minister's Department. EPU is involved in coordinating the implementation of the biotechnology policy, as it is responsible for managing all government development programs through its involvement in the country's five-year development planning and the preparation of necessary documentation (EPU, 2010). Coordination of the biotechnology policy implementation also involves ICU, whose responsibilities includes coordinating, monitoring and evaluating government policies and development projects, of which biotechnology policy implementation is one of them (ICU, 2010).

# Relationships of Meta-Systems (Policy Making, Intelligence, Control and Coordination) within the Biotechnology Policy Implementation

As shown in Figure 2, there is a direct flow of information from one system in the meta-system to the other, shown by the arrows going in and out between them. For example, in the case of MOSTI, its function in intelligence is either directly performed through BIOTEK or BiotechCorp, to serve as input into its policy making function. The information collected via the intelligence function are then directly disseminated to its controlling function. MOSTI is also directly involved in the implementation function, by its participation as an entity in all implementation activities involving BiotechCorp and InnoBio. Another example of relationships that exist within the meta-systems is that of MOF, which gathers intelligence through its subsidiary, BiotechCorp, and serves as the controlling agency through its Accountant General's Department (AG). MOF also indirectly controls the implementation activities via its two subsidiaries, BiotechCorp and InnoBio, and directly linked to the coordination function through the ICU.

#### SYSTEM 1: BIOTECHNOLOGY POLICY IMPLEMENTATION

To achieve the objectives of the biotechnology policy implementation, the activities and programs implemented are divided into three major activities: 1) research and development (R&D), R&D commercialization/technology development/ acquisition/transfer services; 2) firm creation/firm development services; and 3) industry development services. VSM modeling of System 1 is shown in detail in Figure 3.





Figure 3 System 1 (Implementation) of Biotechnology Policy from VSM perspective

	Ξ	Intelligence function	by operating units	R&D units do not perform intelligence directly, intelligence is performed by the management and supporting units.
tal elements	D	Environmental	elements	<ol> <li>Customers: Entrepreneurs and biotechnology companies.</li> <li>Supporting private opmanies: Private R&amp;D institutes, private operated R&amp;D facilities, private fund and financing providers, and R&amp;D of private institutes of higher learning.</li> </ol>
ith respective environmen	С	ating Units	*Agencies Involved	Group 1.1 R&D Services: IPharm, GENOMalaysia, ABI, TPM Biotech, Public Universities, Research Institutes (IMR, MPOB,MCB, MRB, MARDI, FRIM) Group 1.2 Supporting Services Agencies: MTDC, MLSCF, BiotechCorp, and Cradle Fund; b) Research facilities: ImoBio, TPM Biotech, and GENOMalaysia, and ImoBio, TPM Biotech, and GENOMalaysia, and Imobio (Facilitation for talent fey BiotechCorp]): d) those that create conducive environment for R&D conduct, and M/PO.
according to management and operating units, with resl	C	Operi	Description	<ol> <li>Performs the function of discovery and scientific research on biotechnology and R&amp;D commercialization, technology development, acquisition, and transition, and transition, and transition, and transition, and transition, and transition, and transition, and</li> </ol>
nagement an		ent Units	*Agencies involved	MOSTI, BIOTEK, MOHE MOHE
ording to ma	B	Managem	Description	Management agencies of the operating units
according to manage	V	ems to System 1		R&D/R&D Commercialization/ Technology development/ Acquisition/Transfer
		Subsyst		Subsystem 1

Table 4 Summary of functions of institutions and agencies in System 1 of Biotechnology Policy implementation,

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ble 4 (Co ibsystem 2	<i>int 'd)</i> Firm Creation/	Management	BIOTEK,	1) Performs the	Group 2.1 Firm Creation/	1) Customers:	Information gathered
7 112	Development	agencies of the operating	MOSTI, BiotechCorp,	function of creating and developing	Development Services: BiotechCorp, MTDC,	Entrepreneurs and biotechnology	from environment: a) BioNexus
		units	MOF	biotechnology firms.	MLSCF, TPM	companies.	companies, overall
				2) FLOVIDES UNCOL	Group 2.2 Supporting	2) Supporting	International and local hiotechnology
				for biotechnology	Services Agencies:	private .	industry, and
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				development.	Cladic Fund, MLSCF,		ministries by
					SME Bank, and MUV;	and nnancing	BiotechCorp;
					b) Kesearch and	providers,	b) International and
					manufacturing facilities:	private-operated	local hiotechnology
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					and GENOMalaysia;	institutes of higher	VATING ALL OF
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					and nublic universities	property protection	entrepreneurs and
					(talent development	and development	companies by
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					[bv BiotechCorn]. and		Information
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							General public
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							MTDC; c) Client
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#### Subsystem 1: R&D Services

Subsystem 1 involves services of a) R&D, and b) R&D commercialization, technology development, acquisition, and transfer within the biotechnology field. The latter activity is defined as a set of activities that will lead to the commercialization of biotechnology products or services. Many agencies and institutions are involved in this subsystem in various ways, and they are categorized into two groups 1) R&D services (Group 1.1); 2) their supporting agencies (Group 2.1).

In Group 1.1, biotechnology R&D activity is carried out by the three designated biotechnology institutes—Malaysian Institute of Pharmaceuticals and Nutraceuticals (IPharm), Malaysia Genome Institute (GENOMalaysia), and Agro-Biotechnology Institute (ABI), which are under the purview of MOSTI, with BIOTEK serving as the monitoring unit. IPharm is an R&D institute for pharmaceuticals and nutraceuticals focusing on drug discovery and development (IPharm, 2010). ABI, on the other hand, is a pure R&D and commercialization institute for agro-biotechnology. It also manages R&D commercialization in collaboration with universities, research institutes, and industry players (ABI, 2010). GENOMalaysia's focus is to discover marketable and useful tropical bioresources via research. As GENOMalaysia also operates an R&D facility, which can be utilized by researchers, it also plays a role in biotechnology R&D commercialization (GENOMalaysia, 2010).

Group 1.1 also comprises public-funded universities and government research institutes. Research in biotechnology was conducted by 15 public-funded universities whose research spanned from simple agriculture-biotechnology to the more complex ones, like DNA recombinant exploitation (BiotechCorp, 2010). These universities receive funding from MOSTI with six of them operating a dedicated unit or institute for biotechnology research. The operations of these universities are under the jurisdiction of the Ministry of Higher Education (MOHE), which means it is responsible for devising policies concerning research activities and output commercialization for the universities.

Besides these public universities, 13 government research institutes conduct research in biotechnology (BiotechCorp, 2010). All of them perform R&D as their own operations, not on the behalf of other parties. In contrast to the public universities, which focus on science-based research, these research institutes mostly conduct applied-based research. These research institutes include the Malaysian Agriculture Research and Development Institute (MARDI), Malaysian Palm Oil Board (MPOB), Institute of Medical Research (IMR), Forest Research Institute of Malaysia (FRIM), Malaysian Rubber Board (MRB), and Malaysian Cocoa Board (MCB). They were well established research institutes prior to the launching of the Biotechnology Policy in 2005. However, with the launching of the policy, the institutes intensify their research efforts and include biotechnology as one of their focus area (EPU, 2006).

Group 1.2 of the R&D services comprises fund providers and other supporting agencies. MOSTI is one of the major fund providers through its administration of the Science Fund and the ER-Biotek Fund, which are offered to researchers in the public universities and research institutes. The Science Fund is specifically designed to support value analysis, conceptualization of ideas as well as basic and applied research conduct, while the ER-Biotek Fund is an R&D and R&D commercialization grant. MOSTI also manages two other grants, the Techno Fund and the Inno Fund, which are aimed at providing financial assistance to entrepreneurs/firms in their pre-commercialization activities, such as prototype development/commercialization, technology/IP acquisition, and pilot plant construction. Techno Fund is offered to researchers in government research institutes and public universities, small and medium sized enterprises (SMEs) and large companies. However, those in government research institutes and public universities are encouraged to include an industry partner in their teams, and vice versa. Inno Fund, on the other hand, is offered to individuals, owners of small enterprises, and community groups to support commercialization of their products and services (MASTIC, 2010). MOSTI is also responsible for organizing the annual National Biotechnology Seminar, which is a platform for biotechnology researchers, from private and public higher learning institutions, as well as research institutes in the country, to meet and exchange research ideas. The seminar, which mainly involved research funded by MOSTI grants, enable a more synergistic relationship between the private sector and public research institutes, and aims at reducing redundancy and direct competition among them.

MOF also participates directly in the Group 2.2 of R&D subsystem through its MOF Inc.'s two subsidiaries, the InnoBio and Malaysia Venture Capital Management Bhd (MAVCAP). InnoBio is a government entity that provides direct consultancy and contract research (mainly in process and manufacturing) in the field of biopharmaceuticals to client organizations, which may include research institutes and biotechnology businesses, particularly pharmaceutical companies (InnoBio, 2010). These services, which are available to firms with or without the BioNexus status, contribute directly to the functions of technology commercialization and development. InnoBio also contributes to technology development by conducting training for researchers in universities and research institutes to help them keep abreast with leading-edge technologies. MOF Inc.'s MAVCAP subsidiary, Cradle Fund, which distributes pre-seeding and firm development funds is also one of the service agencies operating in Group 2.2 of Subsystem 1 (BIOTEK, 2009; Cradle Fund, 2010).

BIOTEK also plays an important function in this subsystem. Its role is to facilitate and coordinate the disbursements of R&D funds and technology transfer involving projects under its responsibilities as well as all R&D projects undertaken by MOSTI's agencies. Part of BIOTEK's responsibility is to facilitate the application for patent funding, particularly for those research funded by MOSTI.

Technology Park Malaysia Corporation Sdn Bhd (TPM), a science park operator and manager, which operates an incubating facility that support R&D conduct, is also a supporting agency in the R&D services function. TPM was formed in 1996 in conjunction with the launching of the Multimedia Super Corridor (MSC) Program, in which TPM is created and designated as one the anchor agencies in the development of IT business cluster and its areas being specified as part of the MSC area. TPM's roles has since been expanded to also directly support biotechnology policy when it was launched in 2005. The biotechnology ventures and companies in TPM Park have access to services and facilities provided by TPM's subsidiaries in various areas of expertise, including biotechnology, ICT, and engineering. Specifically, a TPM's subsidiary, called TPM Biotech, performs biotechnology R&D in developing and commercializing its own biotechnologyrelated products. It also offers contract R&D and manufacturing, and marketing services to client companies that are located within and outside of the park (TPM, 2010; TPM Biotech, 2010).

BiotechCorp is also involved in this subsystem as it is responsible for administering the Seed Fund, which is granted to companies with BioNexus status in support of their business startup process. The fund pays for entrepreneurs' operational costs, as well as support the development and commercialization of their biotechnology projects and R&D findings. Moreover, BiotechCorp supports R&D Commercialization through its acquisition of a French platform technology, which enables biotechnology firms to generate applications related to diagnostic and drug delivery systems.

The handling of the R&D commercialization process from universities to industries is a major function of Malaysian Technology Development Corporation (MTDC). MTDC was formed in 1992 and its function was strengthened in 1996 in support of the earlier-launched MSC Program. Its roles has since been expanded and refocused for the biotechnology policy when the policy was launched in 2005. In support of this policy implementation, the agency performs three major activities. First, it administers three university-based incubators, and second, it manages and organizes the Symbiosis Program. Third, it handles the Commercialization of R&D Funds (CRDF), the Technology Acquisition Funds (TAF), and the Malaysian Life Sciences Capital Funds (MLSCF) (BIOTEK, 2009).

The three incubators managed by MTDC act as mediums for commercializing inventions and technologies from local universities. They also play hosts to firms that need incubating facilities to support their growth. One of the incubators, the UKM-MTDC, is a dedicated site for promoting commercialization of biotechnology and pharmaceuticals research findings. All MTDC's incubator programs are linked to its grant programs, thus, its incubators' tenants have preferential access to information on its CRDF and TAF and this improves their odds of achieving rapid technology development and commercialization. The UPM-MTDC incubator, which began as an ICT incubator, has gradually moved into hosting

more biotechnology ventures. This is perhaps in line with its MTDC corporate unit's more focused efforts to support biotechnology-life sciences businesses. The function of MTDC Symbiosis Program is to assist in the commercialization of innovative technologies resulting from research activities at local universities and research institutes. So far, the program involves collaborations with the Forest Research Institute of Malaysia (FRIM) to commercialize bio-forest technologies, and with UKM to bring to market biotechnology-related inventions that originated from the university (MTDC, 2010; RAIDAH, 2010).

In regard to funding, MTDC's CRDF is a grant offered to qualified researchers and technopreneurs to help them commercialize research findings from local universities and research institutes. MTDC also supports technology development through its MLSCF's biotechnology venture capital fund that it co-managed with Burill & Co., a San Francisco-based life-sciences merchant bank. MLSCF's investments focus on both early stage and later-stage companies that meet its criteria, including producing highly innovative products or services in either one of the three focused sectors of the Biotechnology Policy, which are agriculture, healthcare, and industrial (MLSCF, 2010).

Intellectual Property Corporation of Malaysia (MyIPO), an agency under MDTCC, provides registration services of patents, trademarks and other types of intellectual property (IP) indications in Malaysia, including those related to biotechnology products, services and processes. It also offers advisory and consultancy services on IP to companies, disseminates IP information and statistical data, as well as conducts training programs on IP-related issues and patent agent examination (MyIPO, 2010; 2007; Rohazar Wati, 2007). Therefore, in this respect, MyIPO provides direct support to the function of technology development, commercialization, transfer and acquisition.

In regard to the management function in Subsystem 1, MOSTI and MOF play the key function, as the former is the lead agency that manages most government research funds in biotechnology, while the latter oversees all monetary allocation and disbursements to all the related research units. There are also some coordinating activities occurring. BIOTEK is in charge of coordinating fund applications under its perusal, which are the Science Fund, Techno Fund, Inno Fund and ER-Biotek Fund. This suggests that BIOTEK's activities transcend across two subsystems within System 1, and these include R&D, R&D commercialization, firm creation, and firm development. The coordination of these funds are supported by an online portal called MyMDANA (MyMDANA, 2010). BIOTEK also manages the research projects at three MOSTI research institutes, which are ABI, GENOMalaysia, and IPharm. Moreover, it coordinates the activities of all technology transfer projects involving MOSTI funds undertaken under the 9th Malaysia Plan, which is a fiveyear government development plan, which begins in 2006 and ends in 2010. As the lead biotechnology development unit, BIOTEK also coordinates the Biotechnology Agency Cluster, thus directly oversees the joint activities of IPharm, ABI, and GENOMalaysia with other agencies in the cluster, including InnoBio, BiotechCorp, MTDC, TPM and MIGHT (MOSTI, 2010b). MOSTI is also making the effort to link the various R&D entities through virtual connections. For example, MOSTI's MASTIC operates KRSTE.my, which comprises MASTICLink and MyMDANA, thus making KRSTE.my the coordinating function for all R&D entities in Subsystem 1 which receives funding from MOSTI. MOHE also plays the management function for research conducted by public universities.

To summarize, there are two categories of agencies and institutions in this Subsystem: a) the management units; and b) the operating units, which can be divided into R&D institutions and their related services agencies. The operating units include universities and research institutes conducting science-based and applied R&D. The services agencies are those that support R&D functions, such as: a) fund providers, such as MOSTI, MTDC, MLSCF, BiotechCorp, and Cradle Fund; b) those that provide research facilities, such as InnoBio, TPM Biotech, and GENOMalaysia; c) those involved in developing R&D talents, such as, GENOMalaysia and InnoBio, with BioTalent assuming the role of facilitator; and d) those that create conducive environment for R&D conduct, such as MTDC, TPM, and MyIPO. All these functions are managed by BIOTEK, MOSTI and MOF, while MOHE serves as the management function for all R&D activities in the public universities. Availability of these functions which covers funding, research facilities, talent development, as well as IP protection and development in Subsystem 1, suggests that there exist comprehensive supports for biotechnology R&D function within the biotechnology policy implementation. The operations of these units are also well facilitated.

## Subsystem 2: Firm Creation/Development Services

Subsystem 2 involves services for firm creation/development, which is categorized into two groups of agencies: Firm Creation/Development Services (Group 2.1) and their supporting services agencies (Group 2.2). In Group 2.1, BiotechCorp, which is created specifically as a one-stop developmental agency for the biotechnology industry development, is the key agency in this subsystem. It performs the functions of *advisor, processor and facilitator* in assisting technology and firm development. Its services are offered through the BioNexus Program, which is a comprehensive support program for developing biotechnology companies. BioNexus status is granted to firms that are involved in the high-end biotechnology businesses in the three focused areas of the Biotechnology Policy. BioNexus companies receive many incentives including tax exemptions, direct funding, financing and immigration facilitation, human capital development and product registration/testing assistance, and location advisory, as well as access to expertise in the BiotechCorp network (BiotechCorp, 2007). All these are to promote rapid growth of the companies and to encourage foreign direct investment in the biotechnology industry. The number

of BioNexus status companies had grown rapidly from about 50 in early 2008 to more than 150 companies in early 2010. By June 2009, most BioNexus companies are involved in healthcare and agro-biotechnology, while the rest is in the industrial and bioinformatics sector (Iskandar Mizal, 2009). These companies are members of a group which is expected to contribute to the 2.5% in the biotechnology industry contribution to Malaysian GDP by the end of year 2010.

Besides serving the existing BioNexus status firms, some BiotechCorp programs are offered to companies that have high potential to qualify for the status in the future. This is in line with the expectation of the Malaysian government to increase the number of BioNexus companies to 185 in 2011 (Bernama, 2009). BiotechCorp has also acquired a French platform technology that enables biotechnology firms to generate applications for diagnostic and drug delivery systems. It also manages the R&D Matching Fund and the International Business Development Matching Fund, which are offered to firms with BioNexus status (BiotechCorp, 2010). All these indicate BiotechCorp's direct contribution to firm development.

BiotechCorp also organizes the BioNexus Partner Program, a plan that provides a network of partners that offer services, equipment and facilities to companies with BioNexus status and other biotechnology commercial entities. These partners include laboratories and units within public universities, research institutes, government-linked companies, technology/science parks and incubators. Through its Triple-Helix portal, BiotechCorp maintains a database of life-sciences/ biotechnology commercialization or collaboration partners, projects/products for investment, patented products by Malaysian researchers, research facilities/ equipment/services, and expertise. It also provides updated information on latest R&Ds and patents on biotechnology-related products by Malaysian researchers within the healthcare, agricultural, industrial and environmental sectors. These services are specifically designed to enhance cooperation among the three key biotechnology players—researchers, industry, and government, and to enable BioNexus companies to have access to various facilities in support of their development (BiotechCorp, 2010).

To enhance its BioNexus Partner Program, BiotechCorp also manages the BioTalent portal, which is an online site for jobseekers, students/interns, academicians, consultants, researchers and employers, in its support to build human capital capabilities in biotechnology (BiotechCorp, 2010). It is a source for human resource and skills development in biotechnology industry which can be utilized by entities in Subsystems 1 and 2 to provide and access information. It can be considered to directly supporting human resource development, thus contributing toward firm development.

MTDC also plays a direct part in promoting firm development as it is responsible for administering the MLSCF, a dedicated biotechnology venture capital fund (MLSCF, 2010), and TAF, which is a grant to facilitate acquisition of technology by companies that intend to improve their operations. Its three business incubators also function in support of firm development. Its Symbiosis Program, which is a comprehensive program of technology commercialization, involves bringing to the market new technologies from universities and research institutes, and investing in human capital development, directly supports the functions of entrepreneurial development and firm creation. All these indicate MTDC's function in Subsystem 2.

The TPM Science Park, which includes an incubator and an enterprise complex, which host technology-based companies, including those involved in biotechnology businesses, directly supports the development of biotechnology products and companies. Its subsidiary, TPM Biotech, which provides research and production facilities as well as marketing services for biotechnology companies, also contributes directly to firm creation and development.

In Group 2.2, SME Bank offers Biotechnology Entrepreneur Program's loan to biotechnology firms, to be used in support of their firms' development (SME Bank, 2010). MOSTI is also involved in supporting firm creation and development through the provision of its Inno Fund and Techno Fund, which are offered to researchers in government research institutes and public universities, small and medium sized enterprises (SMEs) and large companies, in various stages of technology development. Malaysia Debt Ventures Bhd. (MDV), a subsidiary of MOF, also has an important role in the development of biotechnology companies, as it offers financing to companies that have received and are in the process of fulfilling their customers' product orders (MDV, 2010). Another financing agency is MAVCAP, a government-owned venture capital company which began its operation in 2001 and is the parent company of Cradle Fund. Cradle Fund manages the preseeding grant that supports commercialization of innovative ideas including those in biotechnology. Its grants include U-CIP, which is targeted toward academic community (lecturers, students or researchers) interested in commercializing their technology ideas and R&D, and CIP500 Grant, which helps entrepreneurs to move from seed phase to technology commercialization phase. In combination with its grants, Cradle Fund provides assistance such as mentoring, advising, coaching and financial training. In this regard, it directly contributes to firm creation as well as firm development (Cradle Fund, 2010).

One important supporting entity in this subsystem is InnoBio, an agency, which provides processing and current Good Manufacturing Practice (cGMP) manufacturing facility for biopharmaceuticals to Malaysian biotechnology firms and research institutes. This is to help its clients produce high-quality healthcare products at affordable prices, while enabling them to achieve compliance of their products with global regulatory guidelines and standards. Therefore, InnoBio's operations directly contribute to firm development. Besides, InnoBio's training for those from the industries to help them keep abreast with the latest technology development (InnoBio, 2010), help to develop human resource in the biotechnology companies, thus contributing directly to their firm development.

In addition to its main activity in conducting research, GENOMalaysia is also involved in training and providing research labs and development facilities to other researchers and industry players (GENOMalaysia, 2010). As the training contributes to the development of human resource in biotechnology firms, and the research being conducted at its platform can lead to technology being commercialized or adopted by existing biotechnology firms, GENOMalaysia contributes directly to firm creation and development.

In regard to human resource development, MOHE is given the responsibility of ensuring that an adequate and qualified number of workers are available for firms in the biotechnology industry and that its related areas are properly developed (EPU, 2006). In this respect, public universities are making important contribution toward firm development as they provide the graduates needed for the development of biotechnology firms. MyIPO is another agency that supports firm development as it provides registration services of patents, trademarks and other types of IP indications including those related to biotechnology products, services and processes (MyIPO, 2010; Rohazar Wati, 2007).

BIOTEK plays a major role in facilitating and coordinating biotechnology R&D technology transfer, involving many agencies operating within Subsystem 2, as well as facilitating patent applications of technologies and innovations that are developed using MOSTI and other government funds into the industry. As the technology or the IP that is created and transferred are undertaken by entrepreneurs and existing firms contributes to the firm creation and/or development, it is a direct management function of Subsystem 2.

Another management unit within Subsystem 2 is the BiotechCorp which is the coordinating function of important agencies operating within the subsystem. BiotechCorp's BioNexus Partner Program requires that it manages the communication links among the agencies, institutions and industry players in the subsystem who are members of this Program. This is done with the help of its Triple-Helix online portal, which assists the coordination function that transcends across agencies, institutions and firms within the subsystem (BiotechCorp, 2010). This portal also connects Subsystem 2 to industry players (especially the BioNexus companies), thus providing a direct link between the subsystem and its environment.

To summarize, there are two categories of agencies and institutions in this Subsystem: 1) the management units; and 2) the firm developer units and their related services agencies. Firm developer units are full-service houses such as BiotechCorp, MTDC, MLSCF, and TPM. Services agencies include a) fund providers such as MOSTI, Cradle Fund, MLSCF, SME Bank, and MDV, b) specialized services providers which include InnoBio (talent development, research and manufacturing facilities), GENOMalaysia (talent development and research facilities), TPM Biotech (research and production facilities), public universities (support for human resource development), and MyIPO (support for IP protection and development). Talent development is facilitated and supported by

BiotechCorp's BioTalent and Triple-Helix System. The services agencies operating within Subsystem 2 are led and facilitated by BiotechCorp through its BioNexus Partner Program, as well as BIOTEK as the leading agency for the Biotechnology Agency Cluster, while MOF functions as the controller of all the agencies. These information on the operating and management units of Subsystem 2 indicate that there are comprehensive support for biotechnology firm creation and development within the biotechnology policy implementation. This support covers funding, research and manufacturing facilities, talent development, as well as IP protection and development, and their operations are also well facilitated.

#### Subsystem 3: Industry Development Services

Initially, Biotechnology Policy stated that agriculture, healthcare, and industrial sectors would be its major thrusts for industry development. However, bioinformatics was later added into the Policy's list of focused industry. This is because the sector could capitalize on the country's existing strengths and infrastructures of an earlier-launched MSC Program, in which IT-multimedia industry is the major focus areas of development. This shows the importance of resources sharing among existing institutions in supporting biotechnology industry development (EPU, 2006).

The agri-biotechnology sector development focuses on technologies, such as genetic engineering, genomics, proteomics and biopharming, as well as transgenic plants and livestocks. The development of the healthcare-biotechnology sector, on the contrary, aims at leveraging the country's biodiversity and local knowledge in traditional/complementary medicine, to develop leads for the pharmaceutical/nutraceutical products and industry development. Therefore, contract R&D of biogenerics, diagnostics and vaccines become major focus development areas. Lastly, the industrial biotechnology development focuses on biocatalysts, bioprocessing (including biofuel) and biomanufacturing (EPU, 2006).

The services provided for industry development comprises of Group 3.1, which provides direct support, and Group 3.2, which plays the supporting roles. BiotechCorp's acquisition of the French platform technology, which helps BioNexus healthcare-biotechnology companies to generate a number of applications for diagnostic and drug delivery systems, has the ultimate aim of rapidly developing the biotechnology industry. BiotechCorp's planned acquisition of platform technologies for agriculture and industrial sectors in 2011 also reflects its aim of supporting the industry development (Iskandar Mizal, 2009).

The MTDC's Symbiosis program directly supports the development of new firms, and it being a host to the cluster of firms, which either operates within the MTDC incubators and/or those receiving grants or venture capital (MLSCF) that it managed, generally promotes the development of biotechnology industry. The companies in this MTDC family have access to important information and are

linked to each other via the RAIDAH online portal (MTDC, 2010; MLSCF, 2010; RAIDAH, 2010).

The TPM Science Park is another cluster program in which technology-based companies, including those in biotechnology, along with their supporting entities mainly in the form of TPM own subsidiaries, are grouped together geographically within the park. The TPM Park includes an incubator and an enterprise complex, which together hosts both small and medium-sized companies. TPM also has land for lease for the setting up of larger business operations which directly support the function of biotechnology industry development. The tenants within the park have access to important services and facilities provided by TPM's subsidiaries in various areas of expertise, including biotechnology, ICT, and engineering. They also benefit from being closely located to other similar firms. This grouping allows a more efficient exchange amongst the firms operating within the park (TPM, 2010; TPM Biotech, 2010). All these contribute directly to the development of the biotechnology industry.

Industry development for biotechnology requires each of the focused biotechnology sectors, which are agro-biotechnology, healthcare, and industrial biotechnology, are developed. One effort toward achieving this is through development of a biotechnology geographical-cluster in healthcare, called Bio Xcell. The objective is to create a cluster of biotechnology firms in one geographical location by building supportive physical infrastructure and attracting established anchor companies to set their operations there. This effort involves a joint land development project in Nusajaya, Johor, involving BiotechCorp, UEM Land (who is the land owner), and the Johor state government. Bio Xcell operates a pilot plant facility, incubating space, shared laboratories as well as other amenities with a focus on the R&D and manufacturing of the healthcare biotechnology that companies and its employees within the park can utilize in support of their business operations (Bio Xcell, 2010). Meanwhile, another geographical-based cluster is in development, through InnoBio's planned biotechnology healthcare ecosystem, which involves construction of a Bio Innovation Centre within the vicinity of its existing bio-manufacturing facilities in Nilai (Bio Innovation Centre, 2010).

Within the supporting Group 3.2, InnoBio provides contract research and manufacturing as well as consultancy for process and manufacturing research. As more firms use InnoBio's consultancy and manufacturing facilities, its services help them to grow; thus InnoBio plays an important role in supporting industry development. As InnoBio also conducts training for industries, universities and research institutes, it also contributes to developing human capital for the industry, and hence contributes toward biotechnology industry development. GENOMalaysia, which is also involved in industry development as it provides training for skilled workforce in cutting-edge biotechnologies, also contributes to industry development. As MOHE is responsible for ensuring an adequate and qualified supply of human resource in biotechnology and developing its

related areas (EPU, 2006), it directly functions in support of the biotechnology industry development. MyIPO is also one of the agencies that directly support the development of biotechnology industry as it promotes the protection and development of IP within the industry (MyIPO, 2010; Rohazar Wati, 2007). MIDA, BiotechCorp and MOSTI, which are involved in promoting the biotechnology industry to the business communities, also play important role in supporting the industry development.

BiotechCorp is the facilitation function of Subsystem 3 through its BioNexus Partner Program, which members include three key biotechnology players researchers, government, and industry, including companies with the BioNexus status. The operation of the BioNexus Partner Program is enabled by BiotechCorp Triple-Helix portal, which is specifically designed to enhance cooperation among its members. This portal system assists biotechnology firms and relevant players to achieve the aim of forming and strengthening a business cluster on the selected focused biotechnology fields (BiotechCorp, 2010). In this regard, BiotechCorp promotes the biotechnology industry development. Moreover, BiotechCorp's BioTalent portal, which is a source for human resource and skills development in biotechnology industry and directly contributes to the development of human capital, is also contributing directly toward industry development.

BIOTEK is the coordinator of all the agencies within the Biotechnology Agency Cluster, a virtual cluster connecting eight important agencies in the Biotechnology Policy implementation, which are IPharm, ABI, GENOMalaysia, TPM, InnoBio, MTDC, MIGHT, and BiotechCorp. The objective of these agencies' grouping is to collectively facilitate services provision amongst the agencies; and thus promoting a more efficient communication between the agencies, allowing them to serve their customers more efficiently (MOSTI, 2010b). In this regard, BIOTEK is performing the function of facilitation amongst the key agencies in the industry development subsystem.

To summarize, there are two categories of agencies and institutions in this Subsystem: a) the management units; and b) the agencies that are directly involved in developing biotechnology industry and their related services agencies. Agencies that are directly involved in developing the industry include those that are drawn into the various biotechnology-related cluster programs, which are: a) BiotechCorp virtual cluster; b) MTDC cluster; c) TPM Science Park; d) Bio Xcell cluster; e) InnoBio cluster, and f) Biotechnology Agency Cluster and the agencies include BIOTEK, BiotechCorp, UEM Land, MTDC, InnoBio and TPM. The services agencies include a) human capital developers, which are public universities, InnoBio, GENOMalaysia; b) specialized service providers, which include MyIPO (support for IP protection and development), and c) international relations and networks and promotion, which include MIDA, BiotechCorp, and MOSTI. The provision of these agencies' services are facilitated by BiotechCorp, through its BioNexus Partner Program, as well as BIOTEK as the leading agency for the Biotechnology Agency Cluster, while the development of human capital by the public universities are facilitated by MOHE. The agencies within this Subsystem 3 are under the purview of MOF.

## Environmental Elements of the Biotechnology Policy Implementation

The biotechnology policy system's environment is handled at various systemic levels by relevant agencies. In this paper, we discuss the environments at the corporate level and systemic lower level for each subsystem. These are environments of System 4, as well as Subsystems 1, 2 and 3. These environmental elements are summarized in Columns D and E in Table 3 and Column E in Table 4.

## **SYSTEM 4: INTELLIGENCE FUNCTION**

Table 3 shows the groupings of agencies within the intelligence function, and it shows information exchange between System 4 and its environment. Information for the biotechnology policy implementation is gathered from the following groups: 1) Industry players and all government ministries (by NIC) (NIC, 2010); 2) International biotechnology communities, industry players and all government ministries (by BIOTEK, IAP and MIGHT); 3) International business communities, MOSTI units and researcher community (by MIDA, MITI, MIGHT, MASTIC and MOSTI); 4) Researcher and business communities (by BiotechCorp); 5) BIOTEK and government research (by EPU). In turn, several agencies help promote biotechnology policy to its environment. Group 1 is not directly involved in promotion; Group 2, except IAP, promotes biotechnology policy to the general Malaysian public; Groups 3 and 4, promotes the biotechnology policy to foreign biotechnology investors; Groups 4 and 5 promotes the program to the general Malaysian public, and local biotechnology and general business communities. All these indicate that the biotechnology policy already possesses a comprehensive intelligence function for its purpose, covering domestic as well as international arena. These efforts are also well facilitated with BIOTEK functioning as the coordinator to the function.

# Subsystem 1: R&D, R&D Commercialization, Technology Development/Acquisition/ Transfer Services Subsystem

The clients of Subsystem 1 operating units are the entrepreneurs involved in biotechnology ventures or companies. The environment also comprises supporting companies for the entrepreneurs, such as 1) private R&D institutes; 2) private-operated R&D facilities that entrepreneurs can utilize to develop and commercialize their technologies; 3) private fund and financing providers, including venture capitalists and angel investors that support technology development and/ or acquisition and/or commercialization by entrepreneurs and biotechnology companies; and 4) R&D units of private institutes of higher learning.

It appears that the R&D operating units focused only on gathering scientific or R&D information that is directly related to their R&D activities. Intelligence for other environmental elements, most importantly on their customers, is absent (indicated by the question mark symbol, on the line connecting Subsystem 1 to its environment). These operating units rely on the information gathered by their management units. For example, within Subsystem 1, many of the operating units are directly under MOSTI or under its purview, therefore, information regarding them are gathered mainly by BIOTEK on behalf of MOSTI. Thus, their intelligence is mainly carried out through formal control hierarchical channel. Some of their intelligence function is also taken up by the supporting functions in the R&D activities, such as MOSTI, BIOTEK, BiotechCorp and MTDC.

## Subsystem 2: Firm Creation/Development Services Subsystem

The clients of Subsystem 2 operating units are the BioNexus companies and other biotechnology companies, while their supporting companies include 1) private fund and financing providers, including banks, venture capitalists that provide financing/ funding to or make equity investments in biotechnology firms, and angel investors that support firm creation and development by entrepreneurs and biotechnology companies. By 2010, there are about 30 venture capitalists in Malaysia and they provide funding to biotechnology firms at various development stages (MVCA, 2010); 2)private-operated facilities; 3)private institutes of higher learning; and 4) private firms that support IP protection and development. These operating units conduct intelligence on their environment (indicated by the lines connecting the operating units to their environment).

## Subsystem 3: Industry Development Services Subsystem

The clients of Subsystem 3 are the customers of biotechnology products and services and the general public. Their supporting companies are 1) private-operated production/manufacturing facilities that entrepreneurs can utilize to develop and commercialize their technologies; 2) private fund and financing providers, which include banks, venture capitalists that provide financing/funding to or make equity investments in biotechnology firms, and angel investors that support firm creation and firm development by entrepreneurs and biotechnology companies; 3) private institutes of higher learning; and 4) private firms that support IP property protection and development. These operating units conduct intelligence on their environment, (indicated by the lines connecting the operating units to their environment).

## **Relationships Between the Control Function and Operating Units and Between the Operating Units of One Subsystem to Another**

Direct relationship between the control function and the operating units is absent as indicated by the missing function of overall monitoring or direct "auditing" of operating units within Subsystem 1 (shown by the question mark symbol, on the line connecting Subsystems 1, 2 and 3 to System 3\*). Although there exist some intelligence gathering within the operating units at Subsystems 2 and 3, for example, BiotechCorp gathering information regarding BioNexus companies, and MTDC and MLSCF collecting information from the entrepreneurs and companies under their care via the RAIDAH platform, these information are perhaps not efficiently fed back into the control function due to the absence of monitoring function. Moreover, while there is some evidence of TPM conducting intelligence, most of the information are static and in the form of tenant directory. Unlike BiotechCorp and MTDC, TPM does not have an interactive system, except for its tenant online application system.

The in and out arrows from one operating unit to another, as shown in Figure 3, indicate that the operating units are directly related to one another. Subsystem 2 (firm creation/development) requires the output of Subsystem 1 (R&D), therefore, it is important that the operating units within Subsystem 1 are directly related to those in Subsystem 2. Similarly, Subsystem 3 (industry development) depends on collective development of the biotechnology firms within Subsystem 2, therefore, requiring collaborations among the operating units of these two subsystems. There is some evidence of direct relationships between an operating unit in Subsystem 1 to an operating unit in Subsystem 2. For example, UKM and MTDC in Subsystem 1 progress together into Subsystem 2 through the MTDC Symbiosis Program. In this case, UKM's collaboration through the MTDC Symbiosis Program enables the technologies developed in UKM labs to be commercialized in the market place, through university spin-off companies. This group of spin-off companies perhaps will progress to contributing to industry development in Subsystem 3. Such a winwin collaboration indicates synergistic relationships between the operating units.

The operating units of the Subsystems are also connected through two important programs. For example in the Agro subsystem, the Ministry of Agriculture and Agro-Industry (MOA) and the Federal Agricultural Marketing Authority (FAMA) co-organize the annual Malaysian Agriculture, Horticulture and Agrotourism Show (MAHA). This event is organized not only to promote the agriculture and biotechnology-related sectors (intelligence function at the agro subsystem), but also to serve as the meeting place for those involved in the upstream (researchers and technology inventors community) and downstream activities (entrepreneurs and industry players) of the agro-biotechnology value chain (MOA, 2010). Similar to MAHA, the BioMalaysia conference and exhibition also serves the same purpose, although the scope of this event covers nearly all types of biotechnology products

and services, rather than just agriculture (BioMalaysia 2010, 2010). In this regard, BiotechCorp and MOSTI, which organize BioMalaysia, play an important role in connecting the operating units within System 1.

#### DISCUSSION

This study, which demonstrates the application of VSM model in a thorough manner, enhances understanding on the use of the model, particularly in describing and explaining a policy implementation. The comprehensive diagnosis of the policy implementation using VSM is supported by content analysis as the methodology and innovation theory as the main theoretical perspective. The utilization of innovation theory provides the basis for the analysis, and supports the interpretation of study's findings. The use of the content analysis helps to provide structure to the process of defining and analyzing the data. This helps achieve the objectives of the study as well as overcomes existing limitations within VSM studies, which generally do not lean on specific methodologies in their applications. The demonstration of the full application of this model, which includes detailed explanation of all forms and lines within VSM, enhances the understanding of a systems model application. This approach in using VSM provides a practical guide to managers and policy makers in applying the model.

The resulting mapping of the agencies' and institutions' functions onto VSM gives a clear picture about the Biotechnology Policy implementation. First, the emergent model identifies the agencies and institutions that are directly involved in the implementation of the policy, as well as their functions and the relationships that exist among them. This not only enables identification of the number of agencies involved, but also verification of whether the policy implementation system functions are congruence and incongruence with the VSM framework. This also helps in identifying any missing functions or roles. Second, the emergent model indicates which agencies are in the leading roles in the system. For example, the emergent model shows that MOSTI and MOF act as the lead agencies in the metasystems (Systems 2 through 5), as well as in the policy implementation process (System 1). MOSTI is directly involved in all subsystems of System 1, while MOF supports the entire operations through its role in the provision, distribution, and control of budgets. Third, within the specific functions, the emergent model enables categorization of agencies according to the types of their roles (either in leading versus supporting, or as major versus minor roles), thus, further elaborates on their roles, functions, and inter-relationships. Finally, the emergent model identifies horizontal relationships of the biotechnology policy implementation with its sister policy implementation (MSC Program).

The above provides important implications for policy implementations. Information on the agencies' functions and their relationships provided by VSM modeling allow each agency to identify its function *vis-a-vis* the policy and those

of others. Without this modeling, it is difficult for the units involved to get a clear picture of their functions and the relationships of their functions to others, and vice versa. The identification of missing functions and the absence of the overall system monitoring and certain intelligence function provide important information to the system's management in elaborating on their possible problems and developing appropriate solutions. In fact, all the forms and lines in VSM underscores the workings of the policy implementation, and provide opportunities for clarification of functions and if needed, to proceed with rectification. The emergent model, which also identifies relationships of the biotechnology policy implementation with its sister policy implementation, provides important venues for system improvement or design by policy decision makers. As the study's focus is only to demonstrate VSM application, the comprehensive interpretation of the emergent model is beyond the scope of the study. These are reported in the second part of the study (Khairul Akmaliah, Hasmiah, Mohd Fuaad & Igel, 2010).

As the utility and efficacy of VSM are shaped by the theoretical perspectives taken, identification of functions and problems is both facilitated and limited by the innovation theory, which is the perspective adopted in the study. The innovation theory not only provides scope to the study, but also supports explanation and facilitates interpretation concerning the policy implementation system, which involves a technology-based industry. These enable a more focused modeling and conceptualization to be achieved. They also highlight to future researchers the importance of selecting appropriate theoretical perspectives that will serve the needs of the diagnosis and analysis of the system. Application of VSM, however, demands good understanding on the philosophies and application of the model, as well as intimate knowledge on research phenomena. It also requires interpretation by the researchers, which necessitates high analytical thinking and conceptualization.

#### CONCLUSIONS

The application of VSM in this study provides to policy makers and implementers, the framework for diagnosis of future systems and important insights in the model application; both can help in improving their current systems or designing new ones. However, successful improvement and design of a new system also requires information on its purpose. For the researchers, on the other hand, they have an applicable theoretical conceptualization in describing and explaining research phenomena from a systems thinking perspective. The study highlights that usage of VSM requires a) an in-depth understanding of the model's concepts and philosophies, b) abilities to conceptualize the theoretical perspectives to provide scope and focus, as well as to assist in VSM modeling interpretation, and c) high analytical skills in model application and interpretation. Thus, the use of VSM involves considerable time and efforts, and any future application requires substantial allocation of resources.

#### ACKNOWLEDGEMENT

The authors acknowledge the research assistance of Saida Farhanah and the financial support of two research grants, a) GSB grant, Code No. GSB-012-2010 and b) UKM Operational Grant Code No. UKM-OUP-JKKBG-03-12/2009, led by Associate Professor Dr Madeline Berma of Faculty of Economics and Management at UKM.

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#### **APPENDIX A**

#### **Thrusts of Biotechnology Policy and Key Ministries In-Charged**



*Source:* Refer to the sources in Tables 3 and 4.Additional sources are BioMalaysia (2010); FRIM (2010); MARDI (2010); MDTCC (2010); MNRE (2005, 2010); MOA (2010); MOH (2009; 2010); MOSTI (2005; 2010a); MPIC (2005; 2010); MPOB (2010); PMO (2005). See Appendix B for the full names of the ministries.

# **APPENDIX B**

# List of Abbreviations (in alphabetical order)

No.	Abbreviations	Full Name
1	ABI	Agro-Biotechnology Institute, Malaysia
2	AG	Accountant General's Department
3	BIC	Biotechnology Implementation Council
4	BiotechCorp	Malaysian Biotechnology Corporation Sdn Bhd
5	Cradle Fund	Cradle Fund Sdn Bhd
6	CRDF	Commercialization of R&D Funds
7	EPU	Economic Planning Unit
8	FRIM	Forest Research Institute of Malaysia
9	GENOMalaysia	Malaysia Genome Institute
10	IAP	International Advisory Panel
11	ICU	Implementation Coordination Unit, Malaysia
12	IMR	Institute of Medical Research
13	InnoBio	InnoBiologics Sdn. Bhd.
14	IPharm	Malaysian Institute of Pharmaceuticals and Nutraceuticals
15	MAHA	Malaysian Agriculture, Horticulture and Agrotourism Show
16	MARDI	Malaysian Agriculture Research and Development Institute
17	MASTIC	Malaysian Science and Technology Information Centre
18	MAVCAP	Malaysia Venture Capital Management Bhd
19	MCB	Malaysian Cocoa Board
20	MDTCC	Ministry of Domestic Trade, Co-operatives and
		Consumerism
21	MDV	Malaysia Debt Ventures Bhd.
22	MIDA	Malaysian Industrial Development Authority
23	MIGHT	Malaysian Industry-Government Group for High Technology
24	MITI	Ministry of International Trade and Industry
25	MLSCF	Malaysia Life Sciences Capital Fund
26	MNRE	Ministry of Natural Resources and Environment
27	MOA	Ministry of Agriculture & Agro-Based Industries
28	MOF	Ministry of Finance
29	MOH	Ministry of Health
30	MOHE	Ministry of Higher Education
31	MOSTI	Ministry of Science, Technology and Innovation
32	MPIC	Ministry of Plantation Industries and Commodities
33	MPOB	Malaysian Palm Oil Board
34	MRB	Malaysian Rubber Board
35	MTDC	Malaysian Technology Development Corporation
36	MSC	Multimedia Super Corridor

37	MVCA	Malaysian Venture Capital and Private Equity
		Associations
38	MyIPO	Intellectual Property Corporation of Malaysia
39	MyMDANA	Integrated Fund Management System
40	NIC	National Innovation Council
41	PMO	Prime Minister's Office
42	RAIDAH	Research and Innovation Database Homepage
43	TAF	Technology Acquisition Fund
44	TPM	Technology Park Malaysia Corporation Sdn Bhd
45	TPM Biotech	TPM Biotech Sdn Bhd
46	UEM Land	UEM Land Holdings Berhad
47	VSM	Viable System Model