

# Government, Governance and the Development of the Innovation Systems: The example of the Taiwanese biotechnology and related sectoral policies

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Chao-chen Chung  
Manchester Business School

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# Abstract

## Government, Governance and the Development of the Innovation System: The example of the Taiwanese biotechnology and related sectoral policies

Chao-chen Chung

The University of Manchester for the degree of Doctor of  
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This thesis focuses on the research of RTDI policies (research, technology, development and innovation), and the main theme of this thesis is to link the three variables together: RTDI policy-making process---the contents of RTDI policies---the appropriateness of RTDI policies on configuration of the national, the sectoral and the technological innovation systems. We assume the policy-making process of RTDI policies would shape the contents of the RTDI policies. Once the contents of RTDI policies are implemented, the RTDI policies would influence, whether appropriate or inappropriate, on configuration of the three innovation systems. We define the configuration of the three innovation systems as *national, sectoral and technological innovation system* (NSTIS).

We use the Taiwanese biotechnology and related sectoral policies as the empirical examples. Biotechnology in Taiwan configures with three sectors, i.e. pharmaceuticals, agriculture and medical device. Between 2000 and 2008, the Taiwanese government intensively promoted many policies in order to support the development of biotechnology and related sectors. Among the various policies, we choose the National Science and Technology Programs and the regulation policies (in terms of Law of Pharmaceutical Affairs and the Agro-pesticides Management Act) as our two empirical cases and set up the in-depth discussion for the policy-making process of the two policies.

On the basis of the empirical cases of Taiwan, we explore the influence of the RTDI policy-making process on the contents of RTDI policies which further shapes the development of the NSTIS.

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# **Chapter 1 Introduction**

## **1.1 Research background and research rationale**

Why some policies appropriately support the national technological and industrial development but others fail? It is one of the frequently asked questions of the date but lacking unified answers. While the scholars of innovation systems focus on the influence of national institutions and RTDI (research, technology, development and innovation) policies, as a special part of national institutions, on the different levels of innovation systems, political scientists analyze RTDI policies through the approaches of political science.

From the perspective of the scholars of innovation systems, different approaches not only use different criteria to draw the boundaries of innovation systems but also discuss the roles of national institutions and RTDI policies from different perspectives. From the perspective of national innovation system, Freeman (1987) has compared the empirical cases of Japan and Britain in order to explain how national policies shaped the national innovation systems of the two countries, and Nelson (1993) has compared the empirical cases of 15 countries to discuss the roles of governments played in the development of each nation's industrial innovations. While Malerba (2004) use the framework of sectoral innovation systems to describe that national institutions should 'match' the development of the sectoral innovation system within the national border, Jacobsson and Bergek (1998) have used the framework of the system of technological innovation to compare the energy systems in Germany, Sweden and Netherlands and explained that national institutions do effect the development of technological innovation systems within each national border. Yet, even though Makard and Truffer (2008) already show the

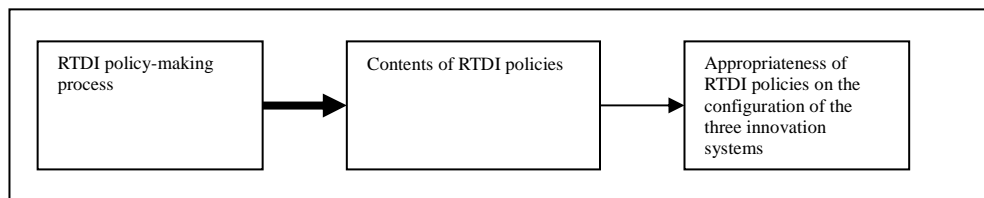


configuration of the national, the sectoral and the technological innovation systems, until now, the influence of the national institutions and RTDI policies on the configuration of the three innovation systems remain unclear.

From the perspective of the political scientists, RTDI policies are 'man-made' and shaped by a series of policy-making process rather than 'born to have'. Through the network governance approach, Jensen (1991) and Biegelbauer (2003) point out that RTDI policies are made through the interactions between actors involving in the network of governance. Through analyzing the roles of business interest groups and scientists in the RTDI policies, Inzelt (2008) and Tournon (1993) show how business interest groups and scientists shape the RTDI policies. From the perspectives of public management, Braun (2008) describes how the relationships between the actors inside the government shape the coordination of RTDI policies. On the basis of the political science, RTDI policies are made through a series of policy-making process, and the interactions between actors in the process indeed shape these RTDI policies. Nevertheless, until now, since different political scientists analyze the policy-making process of RTDI policies from different perspectives and show the particular aspect of the policy-making process only, we have very limited understanding towards the whole policy-making process of the RTDI policies and the influence of the whole policy process on the RTDI policies.

In this thesis, we search for the integrated perspective for the analysis of RTDI policies. On one hand, we tend to understand the policy-making process of RTDI policies which shapes the RTDI policies. On the other hand, we tend to understand the influence of RTDI policies, whether appropriate or inappropriate, on the development of the configuration of the three innovation systems. In fact, the main theme of the thesis is to link the three variables together: RTDI policy-making process---the contents of RTDI

policies---the appropriateness of RTDI policies on configuration of the three innovation systems. We assume the policy-making process of RTDI policies would shape the contents of the RTDI policies, in terms of policy objectives and policy instruments. Once the contents of RTDI policies are implemented, the RTDI policies would influence, whether appropriately or inappropriately, on development of the configuration of the three innovation systems. The main theme of the thesis is highlighted again in the dialog box below. As shown in the box, since we pay more attention to the linkage between RTDI policy-making process and the contents of RTDI policies, we use the thicker arrow for the linkage between the two variables.



We choose the empirical examples according to the theme of the thesis. The policies of the Taiwanese biotechnology and related sectors are chosen because of two reasons. Each of the two reasons is discussed below.

First, the development of biotechnology, from our point of view, is not fully explored. Biotechnology, as described by Brink et al (2004), intersects with plural sectors. Geseisk (2000) and Reiss et al (2004) also show that biotechnology in fact intersects with the national innovation systems of plural countries and is deeply shaped by the RTDI policies of different nations. Biotechnology, therefore, provides an interesting empirical example to show the configuration of the three innovation systems, as well as the appropriateness of the RTDI policies on the configuration of the three innovation systems.

Second, the country of Taiwan offers a fascinating example to discuss the

development of biotechnology, the policy-making process and the appropriateness of policies. Biotechnology in Taiwan was developed in the very unique modes. There were three sectors adopted biotechnology as their knowledge base, i.e. pharmaceuticals, agriculture and medical device. Each of the sectors offered contrasting opportunities for the development of biotechnology. In the pharmaceutical sector, local small and medium enterprises (SMEs) were the main forces of the sector. The original knowledge base of the pharmaceutical sector was chemical engineering. Only after the late 1990s, the pharmaceutical companies gradually adopted biotechnology as one of their knowledge bases. In the agriculture sector, the main actors for innovation were the public research institutions and large public company. The private local SMEs only played minor roles in the agricultural innovation and production. The sector adopted biotechnology as its main knowledge base from the beginning of its development. In the medical device sector, local SMEs were the pillars in innovation and manufacturing. The major knowledge base of the sector was machinery and information and communication technologies (ICT). Only in the late 1990s, with the development of biochips, the sector started to adopt biotechnology as one of its minor knowledge bases. We also refer the three sectors to the 'biotechnology related sectors'. Through analyzing the history of the development of the Taiwanese biotechnology and related sectors from 1945 to 2000, we tend to clearly discuss the configuration between biotechnology and the three sectors within the country's national border and further recognize the configuration of the three innovation systems. Furthermore, the Taiwanese government, especially during 2000 to 2008, promoted lots of policies to support the development of biotechnology and all of the policies were made under the context that the Taiwanese government was the divided-government under the presidential polity, the ministers of the cabinet and administrators within the government faced serious problems for coordination, and interest groups and academics were not fully involved

in the policy-making process. Through analyzing the unique policy-making process of the Taiwanese biotechnology and related sectoral policies, we will discuss how such policy-making process shaped the contents of biotechnology and related sectoral policies in Taiwan and further shape the appropriateness on the configuration of the three innovation systems.

## **1.2 Research questions**

The thesis focuses on the four research questions which contribute to our understanding to the theme of the thesis. Each of the four research questions is established upon a variable which we assume to influence the RTDI policy-making process, as well as the contents and appropriateness of RTDI policies. The four variables we assume to influence the RTDI policies are polity, the horizontal coordination, the vertical coordination and the involvement of external stakeholders. Moreover, from our perspective, the four variables will not only influence the appropriateness but also the consistencies of RTDI policies which refer to the condition that a set of RTDI policies are not contradictory and ideally complementary to each other. The consistencies and appropriateness of RTDI policies will be further discussed and defined in Chapter 3. Here, we only shortly introduce the four research questions of the thesis as below.

Research question 1: How does a divided government under the presidential polity influence the consistencies and appropriateness of RTDI policies?

Research question 2: How does the horizontal coordination between actors influence the consistencies and appropriateness of RTDI policies? The actors refer to both elected politicians and administrators.

Research question3: How does vertical coordination between elected

politicians and administrators influence the consistencies and appropriateness of RTDI policies?

Research question 4: How does the involvement of external stakeholders influence the consistencies and appropriateness of RTDI policies? The external stakeholders refer to both interest groups and scientists.

### **1.3 Methodology**

Our empirical research is based on the qualitative methodology of case study and adopts the ‘two case design’; moreover, we choose the ‘policy’ as the analytical unit, and each of our cases refers to be a policy. As we have slightly mentioned in section 1.1, the Taiwanese government has promoted many biotechnology and related sectoral policies between 2000 and 2008. Instead of discussing the policy-making process of all these policies, we only emphasize the detailed policy-making process of two cases, the National Science and Technology Programs (typically shortened to be the National Programs) and the regulation policies, in terms of the Law of Pharmaceutical Affairs (typically shortened to be the Law) and the Agro-pesticides Management Act (typically shortened to be the Management Act). The two cases are chosen because they are considered to be the most suitable cases to observe the influence of the four variables on the RTDI policy-making process. We will further discuss the rationale to choose the two cases in Chapter 4.

Interview is our main method to collect the first-hand empirical data. We have interviewed 36 interviewees in Taiwan, including the elected politicians, the congressmen of the opposition party, the administrators, the companies and academics who involved in the policy-making process of the two cases. The majority of the interviewees are the high level management

of public and private organizations. From our point of view, since it is usually the heads, the directors or the chief executives to involve in the core of the policy-making process, we consider that the interviews to the high level management of each organization will maximize our understanding towards the policy-making process of the two policies and minimize our bias to the standpoints of each actors in the policy-making process. The detailed name list and the positions of the interviewees are presented in Chapter 4.

#### **1.4 Structure of the thesis**

The whole thesis is structured according to the theme of the thesis. The first part of the thesis, from Chapter 2 to Chapter 4, we focus on the establishment of the concepts of the thesis which provide the framework to link the three variables of the theme of the thesis together. The concept established in the first part include the concept of the intersections of the three innovation systems and the conceptual framework of the RTDI policy-making process which not only analyze the RTDI policy-making process but also analyze the influence of the policy-making process on the contents and the appropriateness of RTDI policies. In addition, in the second part of the thesis, in Chapter 5 and Chapter 6, we will apply the concepts established in the first part for the analysis of the empirical examples of Taiwan and further explore the linkage of the three variables of the theme of the thesis empirically. In the third part of the thesis, Chapter 7 and Chapter 8, we will reflect the concepts established in the first part by the empirical discussion described in the second part of the thesis. The main contents of each of the Chapters are summarized below.

Chapter One outlines the background and the theme of the thesis.

Chapter Two reviews the existing literature related to this thesis. The contributions and the conceptual and empirical gaps of the existing literature which motivates the research of this thesis will be discussed in the Chapter. Moreover, in the Chapter, we will establish our concept of the configuration of the three innovation systems.

Chapter Three discusses the four research questions in details and establishes the conceptual framework of the RTDI policy-making process which not only uncovers the black-box of the policy-making process of the RTDI policies but also analyzes the influence of the four variables. We assume the four variables would impact on the policy-making process, the contents and the appropriateness of RTDI policies which affect the development of the configuration of the three innovation systems. The conceptual framework will be applied for the empirical analysis of the two cases in Chapter 6.

Chapter Four introduces the detailed methodology of the thesis. The rationale to adopt the methodology of the case study, the method to collect the empirical data and the name lists of the interviewees will be described in the Chapter.

Chapter Five is the introduction for the history of the three Taiwanese biotechnology related innovation systems from 1945 to 2000. In the Chapter, we will apply the concept of the configuration of the three innovation systems for the analysis of the development of biotechnology and related sectors in Taiwan. The dynamics of the intersections between biotechnology and the three biotechnology sectors in Taiwan are the core of the Chapter. The national institutions of Taiwan which shape the configuration of the biotechnology and the three sectors will also be discussed in the Chapter.

Chapter Six emphasizes the policy-making process of the Taiwanese biotechnology and related sectoral policies from 2000 to 2008. We will apply the conceptual framework established in Chapter 3 for the analysis of the policy-making process of the two cases, the National Programs and regulation policies. We will especially focus on the influence of the four variables on the different stages of the policy-making process of the two policies.

Chapter Seven discusses the key findings of the thesis and the answers for our research questions. On the basis of the two empirical cases in Taiwan, we will identify the influence of each of the four variables on the RTDI policy-making process, on the contents and on the appropriateness of RTDI policies. Moreover, we will further explore the conceptual framework by the empirical cases in the Chapter.

Chapter Eight is the conclusion of the thesis. We will summarize the key findings of the thesis, discuss the main contributions of the thesis to the literature, and the suggestions to the research in the future.



## **Chapter 2 Literature Review**

### **2.1 Introduction**

This chapter has two aims. The first aim is to identify existing literature which strengthens our analysis of RTDI policy - making process and the impact of RTDI policies on the development of innovation systems. The second aim is to define the conceptual and empirical gaps of contemporary literature and thus justify the contribution of this thesis.

In this chapter we reviewed the literature which can be classified in three categories, all of which relate closely to our research, i.e. literature on innovation systems, political science literature on political structures and policy - making processes, and literature of empirical research of biotechnology and Taiwan. Each category of literature is discussed in terms of its contents, its contributions and its shortcomings.

The whole chapter is structured as follows: Section 2.2 is the review of the literature of innovation systems. Section 2.3 discusses the contributions and the conceptual gaps of political science. Section 2.4 is the discussion of the empirical research of biotechnology and Taiwan. Section 2.5 is the conclusion of the chapter.

### **2.2 The literature on innovation systems**

The approaches of innovation systems that relate to this thesis are national innovation system approaches, sectoral innovation system approach and technological innovation system approach. In the following sections, we will review each of the system approaches, as well as the critical reflections

towards the approaches of innovation systems.

### 2.2.1 National innovation system approaches

The literature on national innovation systems adopts the nation as the unit of analysis. The development of the nation is the central concern of the literature and according to the approaches the boundary of the innovation system is drawn by the spatial border of a nation.

In *Technology policy and economic performance* (Freeman, 1987), Freeman has done one of the earliest research for the national system of innovation. In his book Freeman focuses mainly on the national innovation system of Japan. Besides the strategies of the Japanese companies which opened the technology gap by importing technologies and ‘reverse - engineering’, the Japanese government, especially the Ministry of International Trade and Industry (MITI), also played a critical role in promoting the most advanced technologies of the day. The most important roles of MITI, from Freeman’s perspective, were to forecast technological change and to develop a long - term vision to guide the directions for the Japanese national innovation system. Since the post – war period MITI has fully integrated the technology policies with the industrial policies. Furthermore, with the sophisticated vision, MITI effectively gave the Japanese companies sufficient confidence to make their own long - term investments in R&D, software and personnel training. However, as described by Freeman, Britain had a national innovation system which was quite different from the Japanese one. Compared to the Japanese government, which has possessed strong guidance, provided overall supportive technology policies and tended to shape the Japanese national innovations in the long - term, the British government has only started to promote relatively long - term technology

policies since the late 1980s. Despite the fact that British companies failed to take advantage of early work in the design and the development of equipments to occupy a leading position in manufacturing and export, the British government offered limited support to the British companies. Even though the British government also seemed to learn lessons from the Japanese model of technological development and to integrate technology policies with industrial policies, the majority of these policies only promoted fundamental research within the universities and neglected the need for the results of this research to be effectively commercialized by industry. According to Freeman, the policies of the British government were neither sufficient to guide the long - term development of Britain, nor sufficient to 'fix' the weaknesses of the British national innovation system.

Moreover, in the famous book, *National innovation systems* (Nelson, 1993), Nelson and the co - authors of the book collected the experiences from 15 countries in developing high - technology or R&D intensive industries. These 15 countries were sorted into 3 groups: the group with large high - income countries included the United States, Japan, Germany, Britain, France and Italy; the group with smaller high - income countries contained Denmark, Sweden, Canada and Australia; the group with lower income countries included South Korea, Taiwan, Brazil, Argentina and Israel. All countries were compared with each other according to the evolution of their high - tech industries, R&D expenditures, different types of networks within the high - tech sectors, as well as the actors (particularly firms and universities) involved in the activities of national innovations. Statistical data were used for showing each country's macro economic performance and provide persuasive supplementary empirical evidences for the key points of the book. In fact, for Nelson, the comparisons of national innovation systems are equivalent to the comparisons of high - tech industrial developments in each nation. Nelson and other authors put

national industry as the centre of their analysis. They directed most of their efforts discussing firms' strategies for innovation, companies' relationships with their private and public partners and the performance of the industries. Under such context, governments are mainly analyzed by their economic and technological functions such as funding basic research, providing national education systems, building the infrastructures of research (especially universities' technology transfer), supporting industrial technology development and so on.

A book with a similar title as Nelson's book is Lundvall's '*National systems of innovation*' (Lundvall, 1992). Despite the similarity of the titles the two books adopt different approaches for analyzing national innovation systems. Instead of case - by -case studies, Lundvall and the co - authors of the book emphasize the innovation process of the nations and tend to outline the general points of view of national innovations. From Lundvall's point of view, national innovation systems are open systems which are embedded in the international society. Lundvall pays attention to the international economic interactions between nations, such as international trade and foreign direct investment (FDI). Besides, Lundvall also puts emphasis on the active roles of public sectors in the process of national innovation.

Indeed, different approaches of national innovation systems do provide great theoretical and empirical research to analyze the dynamics of national innovations; in addition, the approaches also clearly recognize the influence of the national institutions on the national innovation. While Freeman (1987) points out how the policies of the government shape and support the development of the national innovation system, Nelson (1993) focuses on the uniqueness of each nation and Lundvall (1992) tends to uncover the general principles which underlie the dynamics of national innovation systems shaped by national institutions. From our point of view the

approaches of the national innovation systems give us a very important entry point for the analysis of RTDI policies and the context of the policy - making processes which produce these policies.

Nevertheless, there are three common insufficiencies of the approaches of national innovation systems. First, these approaches use the national boundary as the single boundary of innovation systems, and the sectoral and technological differences within the national border are ignored. Even though Freeman (1987) notices that Japan has been especially successful in semiconductor and computer industries, he does not fully discuss the reasons why Japan succeeded to become a leading power in these two industries. Nelson (1993) and Lundvall (1992) also do not take into account the uniqueness of each sectoral and technological innovation system within the national border. Second, the openness of a national innovation system is not fully discussed by the authors. Although Lundvall already discovers that national innovation systems are open systems, he and his co - authors limit their research on international economic factors (such as exporting) only . Even though international political factors (such as colonization and international organizations) also influence developments of the national innovation systems, Lundvall does not consider these factors in his book. Third, these approaches recognize the important roles of the government in the development of national innovation system, yet they do not analyze the factors which make the government promote particular policies. The policy - making process of the government is not discussed. The same insufficiency, as we are going to describe in the following sections, also appears in the approaches of sectoral innovation systems and technological innovation systems.

### 2.2.2 Critical reflections towards national innovation system approaches

The approaches of national innovation systems, as an important entry point for our analysis of RTDI policies, however, are not without their critics. Compared with the scholars of national innovation systems (see above) who provide the theoretical and empirical analysis to strengthen the approaches of national systems of innovation, some other scholars possess critical perspectives and emphasize the historical process through which different approaches of national innovation systems were gradually formulated and used as political rhetoric in the policy-making process.

The system approaches for national innovation, as analyzed by Godin (2009), was initially set up by OECD and further established by the scholars of national innovation systems. In the 1960s and the 1970s, OECD used the term ‘Research System’ in its early works to describe the national systems of knowledge production and diffusion. From the perspective of OECD, the research system’s ultimate goal was innovation, and the system was part of a larger system consisted of components, such as government, university, industry and environment. OECD’s concept of research system considerably influenced the authors of national innovation systems, i.e. Freeman, Nelson and Lundvall, in the late 1980s. Indeed since the 1980s, there were two groups of authors in the literature of national innovation systems: the ones centering on the analysis of national institutions (such as Nelson) and the ones focusing on the knowledge distribution and learning process (such as Lundvall). From the latter group of literature, the concept of Knowledge-Based Economy which firstly emerged in the late 1960s re-emerged in the 1990s. During the 1990s, Knowledge-Based Economy not only co-existed with national innovation systems in OECD but competed with the approaches of national innovation systems for the attendance of policy makers. Only after the mid 1990s, it was the approaches of national

systems of innovation which caught more attentions of policy makers than Knowledge-Based Economy became the mainstream approach to analyze national technological and industrial developments. In fact, Sharif (2006) shares the similar perspective with Godin. Through the perspective of social constructivist, he traces the origins of the concept of national innovation systems since the 1980s and analyzes how the different approaches of national innovation were socially constructed by different scholars. By interviewing the founders of the national innovation system approaches, Sharif speculates that the approaches of national innovation systems arose simultaneously in academic community and OECD policy-making and played the role as a refutation of the neoclassical economics. The epistemic community of innovation system approaches was gradually developed since the 1980s. Yet until recently several disagreements still embeds among the different approaches of national innovation systems, i.e. the flexible interpretation of the concept, the over-theorization of the concept, and the presence of national innovation systems in all countries<sup>1</sup>. Moreover, while Miettinen (2002) criticizes that the approaches of national innovation systems were used as a political rhetoric rather than a scientific concept in the policy-making process of the Finish government in the 1990s, Balzat and Hanusch (2004) review the three trends for the development of the approaches of national innovation systems and recognize that the national innovation system approaches themselves do evolve over time.

The critical discussions for the national innovation systems provide a fundamental reflection towards these approaches. According to the critical reflections, we understand that the system approach for national innovation is socially constructed, and these approaches which according to Sharif (2006) and Balzat and Hanusch (2004) have their own underlying

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<sup>1</sup> According to Sharif (2008), Jakobsson, Freeman and Malerba agree that every country has a system of diffusing technology, while Smith states that only under a certain social and economic condition, a country could claim to have an innovation system. Therefore there is in fact no unified consensus for the presence of national innovation systems in all countries.

disagreements and their own path of evolution are only one of the possible frameworks to explain national technological and industrial development in the real world. Furthermore, as described by Godin (2009) and Miettinen (2002), the development of national innovation system approaches is entangled with particular political background. The approaches become the mainstream because they are adopted by OECD and attract more attentions of policy makers than others. In other words, a national innovation system, as a socially constructed concept, does not actually exist in the objective world, and there are other alternative concepts, such as the knowledge-base economy, which may also be used to explain the reality. Moreover, the approaches of national systems of innovation are not yet perfectly established and continuously evolve over time.

However, we still adopt the system approaches of national innovation because they provide a relatively comprehensive framework for the analysis of RTDI policies and the context of RTDI policy-making process. A system, according to the description of Godin (2009), is composed of a group of components which serve a common purpose, and the ultimate goal of an innovation system is innovation. The system approach for innovation which tends to map the overall blueprint for all the components and their relationships in the process of innovation in fact help us to map the broad context in which RTDI policies are made. In another words, while RTDI policy-making is a complex process which involves plural actors and dynamic interactions, the system approach which emphasizes the overall components and the evolution of their relationships effectively supports us to detect the actors and their relationships which may influence the RTDI policy-making process, as well as RTDI policies. However, as we already noticed in section 2.2.1, the national innovation system approaches ignore the technological and sectoral differences within the national border. Therefore the approaches of national systems of innovation are only able to



catch the general national context in which RTDI policies are made, yet these approaches are limited in precisely analyzing the RTDI policies which are directed towards a particular technology and a particular sector within the national border. To balance the limitations of national innovation system approaches, we tend to link the national innovation systems with the technological and the sectoral innovation system approaches which are reviewed in the following sections.

### 2.2.3 The approach of technological innovation systems

The approach of technological innovation system uses technology as the boundary of an innovation system. The dynamics of technological innovation and the economic competence of a system are the cores of analysis.

Carlsson et al (2002) establishes the theoretical descriptions of technological innovation systems. From their perspective, technology, in the sense of a knowledge field, is the most important variable to draw the boundary of a technological innovation system. Within the particular knowledge field, the actors, including the buyers and sellers, of a dynamic network interact in a specific economic or industrial arena which is under specific institutional infrastructures. The interactions of actors in the network are both market and non - market ones. Knowledge flows within the network. Indeed, the technological system involves the technological generation, diffusion and utilization. In the context of technological innovation system, as described by Carlsson and Stankiewicz (1991), national boundaries are not necessary the boundaries of the technological innovation system. Furthermore, Carlsson et al (2002) discuss the methods to determine actors and components of a technological innovation system, as well as the methods to measure the performance of the system. In addition, offering practical

guidelines to policy makers, Bergek et al (2008) describe a step-by-step manipulative process to analyze a technological innovation system.

Besides the theoretical contribution, the scholars of technological innovation systems also apply the concepts of technological innovation systems for analyzing empirical cases. Carlsson (1995) applies the concepts of the technological innovation for analyzing the factory automation. Jacobsson and Bergek (1998) further use the concepts of technological innovation to compare the energy innovation systems of Germany, Sweden and Netherlands. The impacts of national institutions on the technological innovation system within each nation's national border are discussed. For example, the German energy innovation system has better performance than the Swedish and the Dutch ones due to Germany's relatively supportive national institutions. Moreover, Jacobsson and Launber (2004) also discuss the historical context of German energy policies in more detail. The policy - making process of the German government and the influence of the German government on the energy innovation system are mentioned briefly. For instance, the coordination problem between the Ministry of Economics and the Ministry of Research has been noted.

The scholars of the approach of technological innovation system set up a persuasive framework to analyze an innovation system. This approach provides great insights into the dynamics of technological changes, as well as the process of technological generation, diffusion and utilization. The approach observes that the boundary of an innovation system does not coincide with the national border. The observation that the technological innovation system develops on a global base complements the disadvantages of the approaches of national innovation system which do not deal with transnational factors.

Yet, there are still two insufficiencies which are worth mentioning for the approach. First, the approach uses technology (or a particular knowledge field) as a single boundary of an innovation system. Although Jacobsson and Bergek (1998) introduce empirical cases to explain how a particular technological innovation system is influenced by different national institutions, they do not explicitly establish the concept of national technological innovation systems. Moreover, Bergek et al (2008) describe that a technological system may be a sub - system of a sectoral innovation system or may cut across several sectoral innovation systems, but they do not analyze the dynamics of the configuration of the technological innovation system and sectoral innovation systems. Second, the influence of politics on the development of the technological innovation system is not deeply discussed. Even though Jacobsson and Launber (2004) attempt to discuss the politics of technological policies through discussing the problem of coordination within the German government, they do not discuss how the problem of coordination influences the development of the technological innovation system within the national border. We will further discuss the issue in the following chapters of the thesis.

#### 2.2.4 The approach of sectoral innovation systems

The approach of sectoral innovation systems adopts a sector as the boundary of an innovation system. An industry is the unit of analysis.

Malerba (2002) establishes a theoretical approach for the study of sectoral innovation systems. From his point of view a sectoral innovation system is defined as a set of products, as well as a group of actors carrying out market and non - market actions for the creation, production and sale of the products. In other words, a set of products draws the boundary of the sectoral innovation system. The sectoral innovation system should have a

set of specific knowledge basis, inputs and demands. The actors of the system interact through communication, competition, cooperation and commands. These actors' networks are shaped by institutions such as national institutions. Indeed, the knowledge and the technology, actors and networks, and the institutions are the three blocks of a sectoral innovation system.

In his book '*Sectoral innovation systems*' Malerba and his co - authors (2004) apply the theories of sectoral innovation systems for empirical case studies. Six European sectors chosen in the book and are pharmaceuticals, chemicals, fixed internet and mobile communication, software, machine tools and services. The six sectors were chosen because technological changes in these sectors are rapid and innovation plays a major role in the growth of these sectors. In the book, Montobbio (2004) applies the concepts of sectoral innovation for transnational comparisons. Large sets of statistic data are used to compare the sectoral innovation systems in the United States with equivalent ones in European Union countries and Japan. Moreover, Coriat and Weinstein (2004) discuss the roles of national institutions in the development of a sectoral innovation system. From their points of view, national institutions should play complementary roles to support the sectoral innovation system. The most important national institutions related to the sectoral innovation system are intellectual property laws, banks and financial regulations, education systems and labour regulations.

The scholars of the sectoral innovation system provide a different perspective to analyze an innovation system. The approach discovers that an innovation system is neither fixed to a particular national border, nor fixed to a particular technology. The particular set of products, which are composed of several technologies and innovated under a global context,

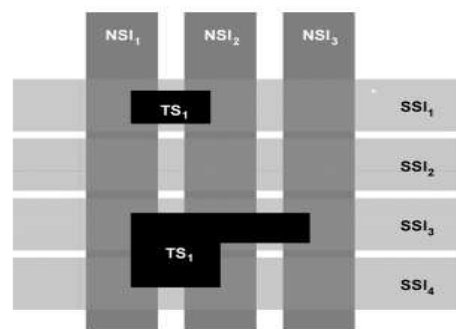
should be considered as the boundary of an innovation system.

However, there are two weaknesses of the existing approach. First, the approach uses a set of products as the single boundary of an innovation system. Malerba and the other authors of '*Sectoral innovation systems*' (2004) try to link the relationship between a sectoral innovation system to a country's international performance. They also try to link the sector to the technological opportunities which can be mobilized to develop new products and processes of the sector. Yet, the intersections between a sector, a nation and a technology are not fully explored. Second, the authors of the approach, such as Coriat and Weinstein (2004), analyze the roles of national institutions from purely economic and technological perspective. The political factors which shape the national institutions are ignored.

### 2.2.5 The configuration of the three innovation systems

Even though the intersections of the three innovation systems have been more or less discussed by the scholars of innovation systems, it is Markard and Truffer (2008) who made one of the first attempts to concretely show the configuration of the three

Figure 2.1 Potential relationships between national (NSI) and sectoral (SSI) systems of innovation and a technological innovation systems (TS)



\* Source: Markard and Truffer (2008)

innovation systems within one picture. As shown in Figure 2.1, a national system is delineated on a spatial basis, while a sectoral system usually crosses a geographical boundary and a technological innovation system typically crosses geographical and sectoral boundaries. Even though the two authors focus on the theoretical comparisons between the technological

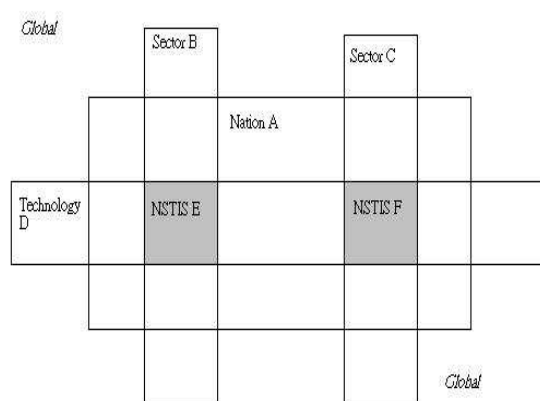
innovation system and the multi - level perspective, the picture shown is indeed impressive and contributes extensively to our understanding of the intersections of the three innovation systems. Since the two authors provide only a limited discussion about the configuration of these three innovation systems, we will further define their configuration and add the empirical analysis which demonstrates their intersections.

## 2.2.6 Brief conclusion of the section

The literature on innovation systems contributes to our understanding towards the dynamics of innovation systems. Furthermore, some authors, such as Freeman (1987), extensively increased our understanding towards the roles of the government in shaping the development of an innovation system. Yet, we found two common shortcomings observed in all of the literature reviewed.

First of all, there is not yet an explicit explanation for the configuration of national, sectoral and technological innovation systems. While a nation is fixed to the geographical border, a sector and a technology are developed on a global base. Even if Makard and Truffer (2008) have produced a nice picture to describe the relationships between the national, sectoral and technological innovation systems, the two authors have not provided an in - depth discussion about the configuration of these three innovation systems. In order to fulfil the academic

Figure 2.2 Relationship of national, technological and sectoral innovation systems and NSTIS



gap, we concretely define the intersection of the three innovation systems as *'national sectoral and technological innovation systems'* (briefly written as *NSTIS*). The system is shown in Figure 2.2. We assume that the system exists within a particular national border and is influenced by international, political and economic factors. The political factors include colonization and international organizations and the economic factors include exporting, international technology transfer, international economic competition and so on. Indeed, every factor which influences the sectoral and technological innovation systems on a global level is able to influence the development of NSTIS. The actors within the system use the knowledge of a particular technological field to produce a set of particular products. The actors within the system carry out market and non - market interactions in order to generate, diffuse and utilize the knowledge of a particular technological field to create, produce and sell a particular set of products. The interactions and networks between the actors are shaped by national institutions. The national government plays the central role in the establishment of the national institutions.

Second, until now the political nature of the government and the policy - making process of RTDI policies are seldom mentioned by the literature of innovation systems. All of the three innovation system approaches have considered the importance of national institutions. Yet, the government, as the most important actor to shape the national institutions, is considered as a unified entity, and government's policies, in the majority of articles, are analyzed through pure economic or technological perspectives. The complex political nature of the government and the policy process behind the national policies are ignored. Solely analyzing the policies from economic and technological perspectives is indeed limited. What is the political nature of the government? How does the government's policy - making process influence the development of NSTIS? The literature has not

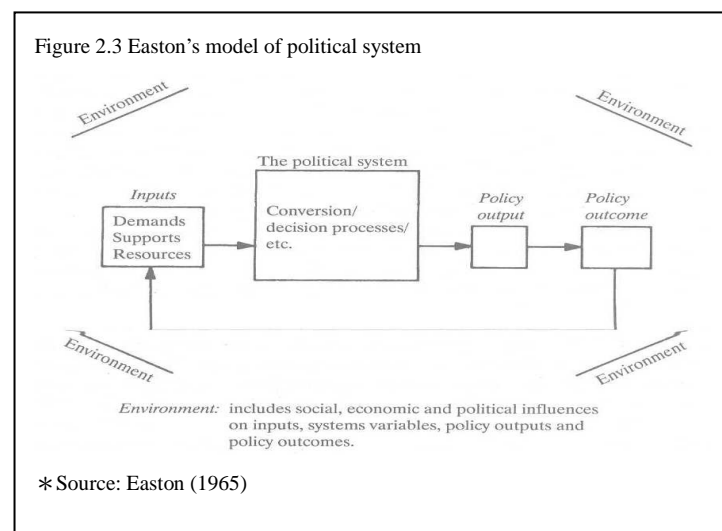
provided sufficient answers for these questions yet. To gain deeper understanding towards the inner world of the government the contributions of political science are discussed in the next section.

## 2.3 The literature of political science

The government is the core of political science research. Among the multiple sub - disciplines of political science, comparative politics and public administration are the two sub - disciplines closely related to our research. Both of the sub -- disciplines are deeply influenced by two underlying theoretical foundations: the theory of political system, which considers the government as the core of a political system and institutionalism in which in its various forms focuses on political institutions. Before we discuss comparative politics and public administration we first introduce the theory of political system in the following section.

### 2.3.1 The theory of political system

In his book '*A Framework of Political Analysis*' (1965) David Easton applies the concept of political system for analyzing the policy process. According to his model, which is shown in Figure 2.3, the government is the integral part of the political system which is embedded in the environment surrounding it. The environment contains both the intra - societal environment





(almost equal to the domestic environment) and the extra - societal environment (almost equal to the international environment). The intra - societal environment is composed of several sub - systems including ecological systems, biological systems and personal systems. The extra-societal environment is composed of international political systems, international ecological systems and international social systems. The environment surrounding the political system gives the political system demands and supports as *inputs* to the political system. The political system converts the inputs of the environment into *outputs*, and these outputs of the political system have an impact on the environment. The environment then responds to the outputs of the political system and through the feedback loop, the response of the environment becomes inputs of the political system again.

Easton offers a very original framework to analyze a government. Unlike the traditional institutional research, which focuses on the constitution and the history of the government, Easton initiates that the government should be analyzed from a *systematic* perspective. He also notices that the political system is embedded in the surrounding environment, rather than exists alone. Furthermore, not only the intra - societal (domestic) environment, but also the extra - societal (international) environment has an impact on the operation of the political system. From Easton's perspective, the political system is a semi - closed system. The environment only interacts with the political system through the inputs and outputs of the political system, and during the policy - making process the environment does not interact with the political system at all.

Jenkins (1997) amends Easton's model with the following two points. First of all, the environment surrounding the political system is structured, rather than without structure. The environment is made up of individuals, interest

groups and organizations with values and interests, operating alone or together over time. Second, from Jenkins' point of view, the political system is an open system. Both the interactions across and within the system must be recognized. Therefore, he claims that policy analysts need to explore the nature of the political system and the relationship between decisions and outcomes in more detail.

Since Easton has published his framework, the theory of political system has deeply influenced the development of political sciences. The concept that the government needs to be conceptualized as being an integral part of a political system is widely accepted by political scientists and is frequently combined with institutionalism to analyze comparative politics and public administration. For example, Almond et al (1996) consider the government as the core of the political system, and combine the theory of political system with institutionalism for the analysis of comparative politics. Such an approach, as we are going to discuss in section 2.3.2, has become one of the most influential streams of comparative politics. Moreover, the scholars of public administration are also influenced by the theory of political systems and parts of the scholars also combine the theory of the political system with institutionalism for the analysis of public administration. For example, Sabatier and Mazmanian (1979) combine the theory of political system and institutionalism for analyzing policy implementation. In order to manage the political system, in the process of implementation the policy makers need to identify a number of legal and political mechanisms to affect and constrain the behaviours of street - level administrators and target groups. In addition, Thurber (1991) and Rocci (1993) recognize the interest groups and scientists as actors 'outside the political system'. This literature will be discussed further in section 2.3.3.

The theory of the political system fundamentally contributes to our analysis

of the policy - making process. We fully adopt the key points of the theory of the political system that the policies are produced through the process inside the political system, which is embedded in the surrounding environment. We also agree that the government is an integral part of the political system.

Nevertheless, we also discover that the theory of the political system has two significant weaknesses which need further discussion. First of all, the original theory of political system has a somewhat limited understanding of the interior of the political system. Neither Easton's nor Jenkins's model discussed the political mechanisms inside the political system which shape the policy - making process. Second, the concept of the political system has not been linked up to the approaches of innovation systems. When Easton's book was published in 1965 the concepts of innovation systems had not been defined. Yet, even when Jenkins amended the Easton's model in 1997, he has not bridged the linkage between the two approaches.

### 2.3.2 Comparative politics

Political institutions represent the main research topic of comparative politics. Political institutionalism assumes that political institutions decisively shape the behaviours of political actors. However, with the development of the theory of political system, some strands of the literature of comparative politics are influenced by both institutionalism and the theory of political system and tend to integrate the two theoretical foundations. Almond et al (1996) and Hague and Harrop (2008) are two representative examples in the literature.

Almond et al (1996) and Hague and Harrop (2008) adopt very similar approaches to analyze the comparative politics. In the book '*Comparative*

*politics*' (1996), Almond et al combine the theory of the political system with institutionalism for the analysis of comparative politics. From the authors' perspective, a government is the core of a political system which has its own legitimacy and is structured by the components which have different functions. The constitution 'contains a set of decision rules which govern the policy - making process within the political system' (1996: 129). The three major kinds of constitutional design all over the world are: presidential polity, parliamentary polity and semi - presidential polity. The government, as the core of the political system, is composed of institutions and actors. The institutions, according to Almond et al, are referred to be political organizations such as the cabinet, the legislature and the bureaucracy. The functions of political institutions in the policy - making process are determined by the constitution. Moreover, the actors are referred to be the individuals who serve in the political institutions, such as the prime minister in the cabinet. From the perspective of Almond et al the interactions between actors inside the government are deeply shaped by the institutions. Furthermore, outside the government there are interest articulations. The interests outside the government are presented by interest groups and carried into the government via political parties. Government's policies, which are decided inside the government, are influenced by and should response to the interests articulated outside the government. In addition, Hague and Harrop (2008) also consider that the government is composed of institutions and actors. The political institutions are referred to be the political organizations, and the actors are the individuals in the institutions. The constitution defines the structure of the government and the policy - making process. The two authors especially compare the different policy processes of presidential polity and parliamentary polity and explain how the two polities shape the policy process to be different.

In addition, in the book '*The new institutional politics*' (2000) Lane and

Ersson assume that the operation of the political system is shaped by political institutions. As described by the two authors, different political institutionalists have different definitions of political institutions, and the political institution, as defined by the neo - institutionalism is represented by the political organizations, political rules and political practice (2000:4-7). Indeed, on the basis of the literature (Almond et al, 1996; Hague and Harrop, 2008; Lane and Ersson, 2000), we adopt the synthetic definitions for the terms constitution and political institutions. From our perspective, the constitution is the legal framework which shapes the structure of the government and the policy - making process of the political system, and the political institutions contain the political organizations, political rules and political practice.

Besides the general conceptual discussions of comparative politics, some literature provides the perceptions for the constitution of presidential polity or the parliamentary polity. Since our empirical case, Taiwan, embedded in the presidential polity, we only review the literature which discusses the presidential polity. Burke (1992) describes that presidential polity is established upon the principle of the separation of powers. The president, who is the head of the executive branch, and the congress, which is the head of the legislative branch, are separately elected and independent from one another. Under the presidential polity, the divided government is especially discussed by some scholars. Elgie (2001:6) defines the divided government as the situation in which no single party simultaneously controls both the executive and legislative branches. Samuels (2007) also describes that once the president and the congress in the divided government cannot achieve consensus for particular policies, the 'dead-lock' relationship between the two branches happens and the presidential polity provides no institutional solution for the dead - lock between the two branches. While Cox and McCubbins (2000) express that the situation of the divided government

make the government as a whole unable to decide (indecisive) and unable to stick to a decision once made (irresolute), Weatherford (1994) and Pfiffner (1994) discuss the solutions to manage the dead - lock of the divided government. From the perspective of the two authors, the president should use his / her leadership to persuade and bargain with the congress in order to achieve his / her legislative goals.

Moreover, some scholars pay special attention to the roles of the executive branch or the legislative branch under the presidential polity. For the executive branch, Bennett (1996), Moe (2005) and Pfiffner (2005) focus on the discussion about the relationships between the president and the cabinet under the presidential polity. From their perspective, under the presidential polity even if the president is the head of the government, it is the cabinet which decides and implements the majority of policies. For the legislative branch, many scholars such as Blodel (1973), Aberbach (1990), Monsma (1969), Smith et al (2006), Weingast and Marshall (1988) and Cox and McCubbins (2005), analyze the operations of the congress in the presidential polity, such as the voting behaviours of the congressmen. From their perspective, the congress under the presidential polity has high autonomy to make or to influence the decisions of the policies.

The literature of comparative politics does provide rich analysis of the political institutions. Based on the discussions of comparative politics we comprehensively understand that the government, as the core of the political system, is composed of institutions and actors. The constitution shapes the structure of the government, the policy process of the political system and the function of political institutions in the policy process. Furthermore, the actors' relationships inside the government are shaped by the political institutions. We will review and exploit the literature of comparative politics, particularly the literature of presidential polity, in more detail when we

establish our research questions and conceptual framework in Chapter 3.

In addition, we have considered three weak points of the literature. First, the scholars of comparative politics seldom link their work to the approaches of innovation systems. Second, the literature of comparative politics mainly focuses on the analysis of constitution and the institutions and the actors within the government, but there are only few discussions to describe ‘how’ the constitution, institutions and actors influence the policy - making process and the policy contents. Hague and Harrop (2008) offer the initial discussions to speculate how presidential and parliamentary polities influence the policy process. Yet, more comprehensive analysis are needed. Third, although some political scientists of comparative politics like Almond et al (1996) have noticed that there are interest accumulations outside the government, they have very limited discussions about the dynamic interactions between the government and interest groups. How do the interactions between the government and interest groups influence the policy - making process and policy contents? The literature of comparative politics has not focused on this question.

### 2.3.3 Public administration: network governance and public policies

Public administration, as described by Peters and Pierre (2003), concerns about governing and managing the public sector where public administrators play essential roles. As a sub - discipline of the political science, public administration is also deeply influenced by both the theory of political system and institutionalism. On one hand, many scholars accept the concept that a government is an integral part of a political system. On the other hand, unlike the sub - discipline of comparative politics which emphasizes the analysis of the ‘government’, public administration extensively focuses on the analysis of ‘governance’, which is defined by Rhodes (1997) as the ‘self

- organizing, inter - organizational networks'. The literature of this sub - discipline includes the approach of network governance, public management, the research of interest groups and scientists and the stagist approach for public policy analysis.

#### 2.3.3.1 The network governance approach

In Marin and Mayntz' book, '*Policy networks*' (1991), the authors use the concept of policy networks to describe the interactions between the government and the society. From Marin and Mayntz's point of view the policy network refers to the network which is consisted of autonomous but independent actors. Both the government and the social groups are the actors of the policy network. These actors of the policy network possess divergent and mutually contingent interests and they take collectively organized actions in the public policy - making process. In fact, the concept of policy network emphasizes the horizontal, informal and decentralized relationships between the government and the social groups. The two authors also note that the policy networks are distinct from sector to sector, from country to country, and from time to time. Within the book Jansen (1991) compares the policy network of the German superconductor technology in different periods of times. Laumann et al (1991) compare the policy network of interest groups in the United States in agricultural policies with the networks of interest groups in the United States' energy, labour and health policies.

Moreover, in his book '*Modern governance*' (1993a) Kooiman and his co - authors use the concept of 'interactive governance' to explain the interactions between the government and other societal stakeholders. From Kooiman's point of view, the traditional mode of governing which refers to the condition that the government is the only governor to govern the society



is no longer sufficient to manage the modern society. In order to fully govern the dynamic, complex and diverse problems of the modern society, the government interacts and forms new collaborative partnerships with social groups. The new mode of governing is called 'modern governance'. In the book, the co-authors apply the concept of modern interactive governance for analyzing several social policies in different countries. For instance, Royall (1993) discusses the governance of labour policies in Ireland, and Stenvall (1993) analyzes the governance of educational policies in Finland. Duclaud and Williams (1993) make transnational comparisons for the educational governance in Britain and France.

Besides Kooiman, Rhodes (1997) comprehensively enriches the concept of governance in her book, '*Understanding governance*'. By analyzing the theoretical background of the governance, Rhodes clearly points out how neo-institutionalism is applied for the analysis of governance. In addition, by describing the historical evolution of the British public administration from 1979 to 1997, Rhodes advocates how the British public administration is transformed from government to governance.

In the field of RTDI policies, some scholars discuss the governance of RTDI policies. In the book, '*New modes of governance*' (2005a) Lyall, Tait and their co-authors express the new modes of governance for science and technology. As perceived by Lyall and Tait (Lyall and Tait, 2005b; Tait and Lyall, 2005), to deal with the uncertainty and complexity of science and technology, the new modes of governance are needed. Indeed, the new modes of governance search for the integrated policy approaches to '*remove contradictions, inconsistencies and inefficiencies caused when policies or regulations emerging from different government departments or different levels of government.*' The governance not only considers the role of government but also emphasize the increasing role of the non-governmental

actors and stakeholders in the policy-making process to mitigate public controversies over new technology development. Furthermore, Biegelbauer (2003) points out that RTDI policies are made through the interactions between the variety of actors, including multiple ministries, interest groups, and political parties. Through comparing the three European countries (Austria, Sweden and Netherlands), he concludes that the three countries searched for the different positions in the EU FP5 because of their different policy-making process.

Even if different scholars use different phrases to describe the approach of policy networks and the approach of governance, these two approaches are in fact highly complementary to each other. While Kenis and Schneider (1991) state in the book of Marin and Mayntz (1991) that ‘policy networks should be seen as the integrated hybrid structures of political governance’, Rhodes (1997) also defines governance as ‘self - organizing, inter - organizational networks’. Therefore, we combine the two approaches and refer to the combination of the two approaches as ‘the network governance approach’.

However, besides the literature on the network of governance we have mentioned above, many scholars also use the term governance to describe different levels of management in the public sector. For example, Six et al (2002) use the term governance to refer to inter - organizational management within the government. Robert and Nell (2008) use the term governance to refer to the intra - organizational management, while in their book ‘*Changing governance of research and technology policy*’ (2003) Edler, Kuhlman and Behrens use the term governance to discuss the transnational research and the technology policies on the European Union level and analyze the multi - level governance under the framework of European Union. According to the existing literature, we agree that

governance is indeed multi - level and operated on transnational, national, sub - governmental and intra - organizational levels. Yet, in order to clarify the utility of the term '*governance*', we only use governance for describing the interactions between a national government and policy stakeholders on the national level. We refer to inter - organizational management within the government to be 'public management', while the governing mechanisms on the international level are described as the 'international factors'. Since we do not discuss the intra - organizational management, we don't provide further definition to the intra - organizational management.

The network governance approach intensively contributes to our understanding towards the interactions between the government and policy stakeholders and how different actors are involved in the policy - making process. The assumption of the approach that the government is embedded in the network and interacts frequently with stakeholders is one of the most important theoretical assumptions underlying our own conceptual framework established in Chapter 3.

However, we have noticed two insufficiencies of this approach. First of all, the approach does not systematically bridge the linkage between the policy - making process and policy contents. Even though some scholars of the approach, such as the authors of '*Modern governance*' (1993a), discuss the actors' interactions during the policy - making process of particular policies, the influence of the dynamic interactions between actors on the policy contents is still worth further discussion. Second, even if some authors, such as Jansen (1991), use empirical cases to analyze the governance of RTDI policies, the theoretical linkage between the governance approach and the approaches of innovation systems is still blurred. How does the RTDI policy - making process in the context of governance influence the development of NSTIS? Until now, there is no sufficient insight into the question.

#### 2.3.3.2 Public management: coordination, implementation and evaluation of policies

Public management, as defined by Lynn (2003), concerns about the effective management of the public sector. The literature is both influenced by the theory of political system and neo - institutionalism. The scholars of public management concentrate their efforts on searching for the most proper institutions which effectively increase the efficiency and the performance of the government with minimum public expenditures. Since different scholars frequently use different terms to refer to the same actors within the government, in order to keep our analysis clear, before we open the discussion of the public management, we think it would be useful to provide the definitions to each of the terms here. '*Government officials*' are the ones who serve in the government. We use the term '*elected politicians*' to refer to government officials who are elected by voters or by the higher level management of the government, while we use the term '*administrators*' to refer to government officials who take the responsibilities to administrate the policies. Although some scholars use the term '*bureaucrats*' to refer to the administrators, we tend to use the term '*administrators*' because compared with bureaucrats, the term administrators is able to more accurately refer to the ones who administrate and implement policies. Moreover, the '*policy makers*' refer to government officials who make the major decisions of policies. The policy makers are usually the elected politicians or the high level administrators who are asked to decide policies according to the commands of the elected politicians.

The main topics of public management include the coordination of policies, policy implementation and evaluation. Each of the topics is discussed below.

The coordination of policies is recognized as one of most important issue related to increase the efficiency and the performance of the government. Six et al (2002) state that the ideal condition for a government is the '*holistic government*' in which not only the policy objectives, but also the policy means of a set of policies are mutually reinforcing each other. The authors of the book have revealed several principles to improve the institutions within the government in order to make the government holistic, including managing inter - organizational relationships within the government, as well as improving the information system, the accountability and the finance of the government.

However, many scholars point out the difficulties for policy coordination. Peters (1998) discusses the political nature of policy coordination and claims that policy coordination may fail when two organizations perform the same tasks (redundancy), when no organization performs a necessary task (lacunae) and when policies with the same clients have different goals and requirements (incoherence). Peters (1995: 211-252) also notices that the competition between agencies limits the internal consistencies or coherence of governments. From the perspectives of the Laurence and O'Toole (2003), ministries or agencies are incentivised to concert action only under three conditions: authority, common interests and the exchanges of interests. The inter-organizational cooperation may be derived through building common interests and facilitating exchanges of interests. In addition, OECD (1998) applies the concept of policy coordination for analyzing RTDI policies. From OECD's perspective, the governments should play the roles of integrating and coordinating the formulation and the implementation of innovation and technology policies in order to best '*manage*' the national innovation systems. Yet, OECD also points out that many science and technology policies of OECD countries remain piecemeal rather than coordinated. Moreover, Braun (2008) expresses that the knowledge space

which is the '*centre*' of the innovation system can be distinguished into four sectors, higher education, vocational training, technology innovation and basic research. Each of the four sectors of the knowledge space needs different resources to support its development and policies should be coordinated in order to integrate the resources to support each of the sectors. Braun further articulates five institutional options for policy coordination: external coordination, internal coordination, coordination at agency level, leadership at the cabinet level and the strategy intelligence. However, from his perspective each institutional option is only able to be practiced if the interests of actors are enlarged or secured.

Policy implementation is another important issue related to the efficiency and the performance of the government. Sabatier and Jenkins - Smith (1993a) introduce the '*advocacy coalition approach*' to discuss the policy change and learning and substantially contribute to the analysis of the implementation of policies. With the acknowledgement that the government is an integral part of a political system, they assume that various governmental and private organizations, which share a set of normative and causal beliefs, form an advocacy coalition and act together. Each advocacy coalition adopts a strategy to envisage institutional innovations to further its members' policy objectives. The government programs are the end results of the competition and mediation of different advocacy coalitions. Once implemented, the government program produces policy outputs at operational level and has an impact on the problem which the program aims to resolve.

However, scholars of public management debate whether implementation is a '*top - down*' or a '*bottom - up*' process. From the perspective of top - down, Sabatier and Mazmanian (1979) start their analysis of implementation with a policy decision made by government officials and

concern the extent for the implementation to achieve the policy objectives. They assume government officials are the main actors to decide and implement policies. The implementation is the process from the top level policy makers to the down level implementing officials. To make sure that implementation of the policy is able to accomplish policy objectives the authors advocate five necessary conditions for '*effective implementation*'. These necessary conditions refer to clear and consistent objectives, the adequacy of jurisdiction given to implementation bodies, the compliance of implementation bodies and interest groups, committed and skilful implementation officials, support of interest groups and changes in social and economic conditions. Nevertheless, from the perspective of bottom - up, Hjern and Hull (1982) and Hjern and Porter (1997) are aware of the weakness of the top - down approach. Unlike the top - down approach which starts with the analysis of policy decisions, the bottom - up approach starts its analysis with the network of actors involved in the service delivery and concerns the actors' goals rather than policy objectives. According to scholars of bottom - up, implementation is the process from the street - level administrators to the top level policy makers. Based on the key points of both top - down and bottom - up approaches, Sabatier (1997) provides a synthetic approach. While he still recognizes the '*comparative advantage*' of top - down approach, because the approach is '*more useful in making a preliminary assessment of government programs*' (1997:285), he also acknowledges that the network analysis used by the bottom - up approach contribute to the deeper understanding of advocacy coalitions. Indeed, according to the synthetic approaches provided by Sabatier, we agree that implementation is both a top - down and a bottom - up process. As the top - down approach we recognize that the implementation of a policy decision is mainly decided and implemented by administrators. Yet, as bottom - up approach, we also recognize that the actors involved in the network of service delivery, including both government officials and private actors,

play important roles in implementation. Moreover, during implementation, the implementation bodies not only implement the policies decided by the top level government officials, but also influence the policies from the bottom to the top. We will apply the synthetic concept of implementation in Chapter 3 when we analyze our own conceptual framework.

Besides the discussions of top - down and bottom - up approaches, some scholars attempt to analyze implementation from other divergent perspectives. For example, Elmore (1997) introduces four models for analyzing implementation: the model of systems management, the model of bureaucratic process, the model of organizational development and the model of conflict of the bargaining. Lane (1997) also introduces different perspectives in analyzing implementation, such as policy management, evolution, learning and so on. The literature broadens our understanding of the policy implementation. We will further discuss the details of the two articles when we establish our research questions in Chapter 3.

Furthermore, administrators, who are considered to be among the most important actors involved in implementation, are also discussed by some scholars. Lindblom and Woodhouse (1993) describe that administrators are active participants in the policy - making process through modifying and implementing policies. They are also infrequently instructed by the policy makers to make policies. Nevertheless, according to the two authors, during implementation, administrators tend to self - protectively cover up errors, instead of correcting them. Moreover, because policy makers are only able to devote very limited time and energy to supervise implementation, it is very difficult for the policy makers to monitor the implementation. The two authors then conclude that in practice it is very difficult to make administrators to loyally implement policies. Hogwood and Gunn (1997) are also pessimistic regarding the extent that administrators are able to



‘perfectly’ implement policies. As described by the two authors, the ‘*perfect implementation*’ which refers to the conditions that administrators’ implementation is able to fully achieve the policy objectives is unattainable, because the preconditions of the ‘*perfect implementation*’ are too difficult to be fulfilled. The preconditions include perfect communication and coordination between administrators, combination of resources across different bureaucratic department, and so on.

The evaluation of public policies, as one of the stages of the policy - making process which is discussed in the next section, is also an important issue related to the efficiency and the performance of the government. Rossi et al (2004) introduce the general guidelines for the evaluation of public policies, while Fenwick (1995) and Flynn (2002) reveal the ‘3E’ model as the principles to evaluate a public policy. The ‘3E’ refers to economy, efficiency and effectiveness of a public policy or multiple public policies. Among the ‘3E’ the policy effectiveness, which is judged by the percentage of the targeting groups positively affected by the policy, is the most important index. However, in the book ‘*Politics of program evaluation*’, Palumbo (1987a) is aware of the politics of evaluation. In this book, Palumbo (1987b: 21-23) describes that the appropriate evaluation for academics is quite different from the appropriate evaluation for administrators. While academics tend to help administrators understand and improve their implementation, as well as uncover the negative aspects of the implementation, administrators usually tend to turn up the negative aspects of implementation. Therefore, administrators do not always welcome the academics to evaluate their implementation. Chelimsky (1987:76-80) also points out that evaluative information serves not only elected politicians and administrators in the executive branch, but also congressmen in the legislative branch.

Many scholars apply the concept of evaluation for analyzing RTDI policies. Some scholars such as Meyer-Krahmer (1988), Gibbons (1988), Hill and Hansen (1988), deLeon (1988) and Eveland and Hetzer (1988) suggest the methods, the principles and the tools for evaluating single RTDI policies on the program level. For example, Meyer-Krahmer (1988) recognizes five methods of evaluation: comparing the ‘before / after’ type, controlling group concept, econometric models, case study approach and monitoring. Nevertheless, Arnold (2004) advocates that the methods of traditional evaluation, which only focus on the performance of a single policy, are obsolete. The new methods of policy evaluation should evaluate the performance of RTDI policies by judging the extent for the RTDI policies to support the development of a national innovation system, especially when the national innovation system suffers ‘system failure’. Miles and Cunningham (2006) share a similar view with Arnold and describe that the evaluation of RTDI policies should identify the ‘innovation bottleneck’ of the system and evaluate the systematic effects of the RTDI policies through four standards: policy mismatch and policy synergies, level of aggregation, risk and dynamic effects. According to the literature presented above we agree with the perspective of Arnold (2004) and Miles and Cunningham (2006) and recognize that the evaluations of RTDI policies should consider the effects of policies on the development of the innovation system. This concept of evaluating RTDI policies on the system level is especially important for us to define the appropriateness of RTDI policies. We will further discuss this concept in Chapter 3. Furthermore, some scholars have carried out empirical research about the evaluation of specific RTDI policies. For example, Becher and Kuhlmann (1995) evaluate the German technology policy and programs, while Shapira, Kuhlmann and other authors (2003) evaluate the science and technology policies in the United States and Europe.

The scholars of public management provide rich analysis for us to understand the concept and practice of policy coordination, implementation and evaluation. They especially contribute to the establishment of our research questions and our conceptual framework in Chapter 3. However, we also recognize that the literature about public management has no systematic linkage to the approaches of innovation systems. OECD (1999), Braun (2008), Arnold (2004) and Miles and Cunningham (2006) only initiate the discussions that RTDI policies should be coordinated and evaluated to support national innovation systems. Yet, the scholars have not answered the question: ‘how’ the coordination, implementation and evaluation of policies influence the development of innovation systems. Furthermore, as we have described in section 2.2.5, a nation should not be the only dimension to draw the boundary of an innovation system. The configuration of the three innovation systems, NSTIS, is the most suitable boundary for an innovation system, because many RTDI policies in fact impact on the three dimensions of an innovation system. How RTDI policies need to be coordinated, implemented and evaluated in the context of NSTIS? Until now public management has not yet provided sufficient answers to the question.

#### 2.3.3.3 The research of interest groups and scientists

The political institutionalism and the theory of the political system also influence the research of interest groups and scientists. While some scholars, such as Steinmo and Watts (1995) and May et al (2005), describe the influence of the organizations of the political systems on the capabilities of interest groups, some scholars, such as Thurber (1991) and Rocci (1993), consider interest groups and scientists as actors outside the political system. In the following paragraphs we will first introduce the literature of interest groups and later review the research of scientists.

For the research of interest groups some literature emphasizes the capability and tactics used by interest groups, while other literature focuses on the interest groups of specific industries and regions. Different literature is introduced in the following paragraphs.

Many scholars emphasize the capabilities of interest groups and the tactics used by interest groups to influence the decisions of the actors inside the government. Goldstein (1999), Greenwald (1977), Rotherberg (1991) and Scott (1997) analyze the factors which influence the capabilities of interest groups in the policy - making process. From their point of view the capabilities of interest groups are influenced by the size and characters of memberships of the groups, the financial resources, the capabilities of the groups to make coalitions with others, the length of the groups' history and the access of the groups to the government. Furthermore, many scholars describe the tactics used by interest groups to access the actors inside the government. The congressmen of the government of the presidential polity may be one of the most important targets for lobbying. As described by Bennedsen and Feldmann (2002: 922), Steinmo and Watts (1995) and May et al (2005), the presidential polity in which high autonomy and powers are situated within the congress in fact encourages interest groups to link their interests to the policies through lobbying congressmen. Evans (1991:264), Zeigler and Baer (1969), Hayes (1981) and Scott and Cornelius (2004) describe the interactions between congressmen and interest groups, as well as the tactics used by the interest groups to access the congressmen, including writing letters, financing congressional elections, testifying in hearings and negotiating with congressmen. Besides the congressmen, Pika (1991) describes the possible access of interest groups to the president. Chubb (1983: 213) uses the empirical examples of the United States' R&D agencies to explain the interactions between interest groups and bureaucracy.

From his perspective the individual companies which successfully get R&D subsidies from the government are likely to motivate other members of the interest groups to take further collective lobbying actions. In addition, Hrebienar and Scott (1982:164-165) also indicate that interest groups intend to aggressively lobby the administrators of the regulatory agencies to influence their decisions. The tactics for interest groups to contact administrators include giving advice to the implementation of policies, helping administrators to gather information, participating in administrative hearings and so on.

Some literature focuses on the interest groups in particular industries or regions. For particular industries, the groups of pharmaceutical companies are one of the most influential business interest groups involved in the lobbying activities. For instance, Landers and Sehgal (2004), Harvey et al (2004) and Abraham (2002) portray the political impact of pharmaceutical business groups in the United States' health care and trade policies. Furthermore, Inzelt (2008) has explained the involvement of private sectors in the RTDI policy - making process in Hungary. As for particular regions, the majority of empirical research focuses on the interest groups in the United States (Schier, 2000; Baumgartner and Leech, 1998; Goldstein, 1999; Rozell and Wilcox, 1999; Wilcox et al, 1998; Heinz, 1993), European Union (Greenwood and Aspinwall, 1998; Coen, 2007; Pedler, 2002; Greenwood, 2007) or individual European countries (Stewart, 1958; Marks and Steenberge, 2004).

The roles of scientists in the policy - making process are also discussed by scholars. In Barker and Peters's book, *'The politics of expert advice'* (1993), the authors, such as Tournon (1993) and Barker and Peters (1993), discuss how scientific advisors involve in the policy - making process of nuclear and radiation policies. From their point of view, while the interests of

scientists are influenced by policies, they are in fact self - interested political actors who possess their own interests through influencing the policy - making process. A similar point of view is shared by Hove (2007), Guston (2000) and Gerrie (2006). The authors speculate that even though traditionally scientific activities are viewed as the activities which are neutral and above all social and political frays, in reality, science and politics are mutually intersected and co - evolve. Moreover, Schooler (1971), Rocci (1993) and Pollitt (2006) have described the interactions between academics and actors inside the government. For example, Schooler (1971:69,259) describes that scientists are able to influence the congressmen through the involvement of public hearings or the congressional investigations. Scientists are also able to influence the decisions of elected politicians and vest their interests through serving the particular positions in the cabinet. We will discuss the literature in more detail when we establish our research questions and conceptual framework in Chapter 3.

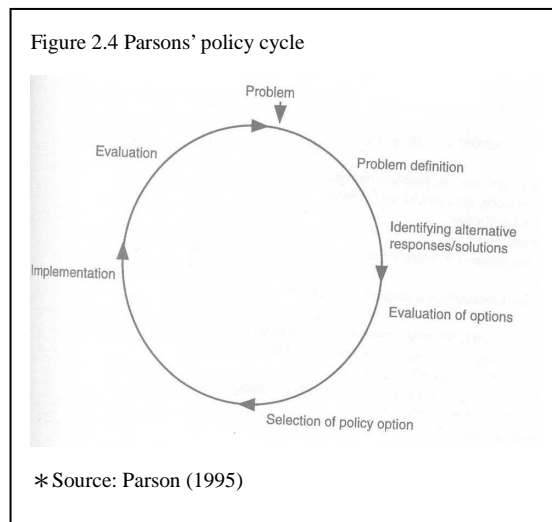
The literature about interest groups and scientists describes the political participation of interest groups and scientists who are policy stakeholders outside the government. While the network governance approach analyzes the overall policy network from a relatively macro perspective, the literature about interest groups and scientists emphasizes the micro observations for the characters of the two policy stakeholders and their interactions with the government. The literature contributes a lot to our establishment of research questions of policy stakeholders, as well as our analysis for the interactions between the policy stakeholders and the government in Chapter 3.

However, there are at least two weak points of the literature. First of all, the linkage between the stakeholders' involvements in the policy - making process and policy contents remains unclear. Even though some scholars, such as Inzelt (2008) and Politt (2006), try to link the involvement of

stakeholders with the policy - making process, the relationship between the stakeholders' participation and policy contents is not yet uncovered. Furthermore, the literature of interest groups' and scientists' political participations in the RTDI policy - making process is seldom linked to the approaches of innovation systems. Would the involvement of policy stakeholders in the policy - making process make the RTDI policies better support the development of NSTIS? The question has not been answered yet.

#### 2.3.3.4 The stagist approach for public policy analysis

The stagist approach, as described by Jenkins-Smith and Sabatier (1993a), is deeply influenced by the Easton's model of political system. From the stagists' point of view, the policy - making process within the political system could be divided into several stages. Since the RTDI policy - making process is the core of the thesis, we review the literature of the stage model below.



Different stagists have divided the policy - making process into different stages. In *Public Policy*, Parsons (1995) divides the policy - making process into seven stages which form the policy cycle, as shown in Figure 2.4. According to Figure 2.4 the policy cycle starts from the stage of problem definition — identifying alternative responses / solution — evaluation of options — selection of policy option — implementation — evaluation — problem — problem definition.

From Parsons' perspective, in different stages of the policy - making process there are different obligations to be fulfilled. Moreover, different stages of the policy - making process could be analyzed from different perspectives and could be influenced by different factors. For instance, the stage of problem - definition and the stage of agenda - setting are both influenced by the internal triggers (such as natural catastrophes and technological and ecological change) and external triggers (such as act of war and international conflict). In addition, the policy - making process of the two stages could be analyzed from the perspectives of pluralism and / or neo - Marxism (Parsons, 1995:85-153). Nevertheless, in '*Policy cycle*', May and Wildasky (1978) only divide the stages of policy - making process into five stages. The policy cycle starts from the stage of agenda - setting — issue analysis — service delivery — implementation utilization of policy evaluation — termination. From the authors' point of view different stages have different missions and empirical examples are given in order to describe the missions of each stage.

Besides the discussions of the overall policy cycle some scholars focus on one of the particular stages of the policy - making process only. We will introduce the literature of the stages of agenda - setting, the stages of implementation and the stages of evaluation in the following paragraphs.

For the stage of agenda - setting, in '*Agendas, alternatives and public policies*', Kingdon (2003) defines the stage as the process where government officials select a series of subjects to which they pay more serious attention than others (2003: 196). For Kingdon, the administration, including the president, the staff and the political appointees who are responsible for the president substantially influence the policy agendas. However, actors outside the government, including interest groups, academics, the media, the election - related participants and the public



opinion also interact with the administration in order to link their interests to the particular policy agendas. In the field of RTDI policies, Flanagan et al (2010) recognize that the stage of agenda - setting is the stage for policy makers to decide the policy rationale of RTDI policies and design the mixed policy instruments according to the policy rationale. However, the authors also describe that the mixed policy instruments are selected through the interactions of multiple actors on multiple levels. The selections of mixed policy instruments in reality is the results of trade - offs between different actors.

Besides Kingdon (2003) and Flanagan et al (2010), some other authors consider different terms and meanings for 'agenda - setting'. While Parsons (1995:245) uses the term 'decision - making' to refer to the stage in which the administration in the executive branch decides the agendas of policy proposals and bills, Cox and McCubbins (2005) use the term 'setting the agenda' to refer to the stage in which the congressmen formally authorize the agendas of policy proposals and bills. In order to clarify the terms we use, we consider the stage of agenda - setting as the stage for the elected politician to decide policy proposals, and we refer the stage of deciding as the stage in which congressmen authorize policy proposals and bills.

The stage of the implementation, as described by Lane (1997:297-298), is the stage to execute policies and to accomplish the policy objectives; the stage of evaluation, as defined by Meyer-Krahmer (1988:121), is the stage that examines and assesses the mode of action and the effectiveness of government policies. However, since the literature of the two stages is highly overlapping with the literature of public management, in this section we will not review this part of the literature again.

The stagist approach introduces a model for the analysis of the policy -

making process. Although the approach does not perfectly reflect the complexity of the policy - making process as criticized by some scholars<sup>2</sup>, the stagist approach offers a clear and useful tool for the empirical analysis of the policy - making process. Adopting the contributions of the stagists, in Chapter 3, our conceptual framework also divides the policy - making process into several stages. Since there is no consistent method to divide the stages, we only divide the policy - making process into four stages which are discussed by more scholars. The four stages are the stage of agenda - setting, the stage of deciding, the stage of implementation and the stage of evaluation.

Yet, we are also aware of the two limitations of the stage approach. First, the stagist approach only focuses on the stages of the policy - making process. There is no linkage between stages of the policy - making process and policy contents. In addition, the stagist approach has seldom been linked to the approaches of innovation systems. The influence of each stage of the policy - making process on the development of the innovation systems is indeed worth of further analysis.

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<sup>2</sup> For example, Cohen et al (1972) have suggested the 'garbage can model' and Lindblom (1959) has established the 'muddling through' approach. Both of the two approaches don't consider policy process as the linear process which could be clearly cut into several stages. Instead, the two approaches consider policy process as a 'garbage can' or 'mud' in which the problems, solutions, participants and opportunities all pool together immediately. Nevertheless, as John (1998:22) declaims, just 'because the policy process is complex and apparently chaotic, there is a need to impose some conceptual order on the policy process in order to comprehend it.' The stage approach, according to John (1998), thus serves as the attempt to simplify decision-making by cutting policy process into distinct stages and by distinguishing policy goals from policy outputs in order to enable policy researchers to analyze how powerful are certain groups, parties and institutions able to get their policies on the agenda. According to the articles above, we are aware that there are alternatives to analyze policy process, and in the reality, the policy process may not be able to be neatly cut into different stages. However, we agree with John (1998:36) that even though there are no clear divisions of policy process, the stage approach still shows the evolution of changing interests, ideas and problems through policy process. Since we are interested in the changes of actors and their interactions in the policy process, and the stagist provides a simplified but clear framework to explain the changes of governance structure in the policy process, we still adopt stage approach in our conceptual framework.

#### 2.3.4 Brief conclusion of the section

Political scientists have done extensive research which tends to understand the policy process from different perspectives. According to the contributions of political scientists, internal mechanisms of the government, interactions between the government and policy stakeholders and the different stages of the policy - making process are understood. The policy - making process is no longer the 'black - box', but the mechanisms which are able to be analyzed from divergent perspectives.

Although the political scientists have formed many different complex approaches to analyze the policy – making process, one of the common shortcomings of the political science research is that political scientists have not yet provided a relatively integrated approach for the analysis of RTDI policies. Indeed, the RTDI policy, according to the description of Biegelbauer (2003), is a special kind of policy which is not only complex, but also needs the interactions between the government and stakeholders to make this complexity manageable. In the real world, through the stages of RTDI policy - making process, all internal institutions and actors of the government, as well as actors outside the government would shape the decisions of the government. The context of the government's policy - making process is complex. How do the institutions and actors together shape the RTDI policies? There is no clear answer found within the political science literature yet.

Another common shortcoming of the political science research is that political scientists seldom link their research to innovation system approaches. Although there has been a small group of political scientists starting to link political science to the RTDI policy research and to the approaches of innovation systems, political scientists should be able to

contribute much more to the innovation research than the current status.

According to the common shortcomings of the political science research we recognize that a new integrated conceptual framework of RTDI policy - making process is needed. The conceptual framework should not only integrate different perspectives of the political science for the analysis of RTDI policies, but should also fully link the research of RTDI policies to the approaches of innovation systems.

Based on the existing literature we get our initial understanding towards the RTDI policy - making process. A government is the integral part of the political system, which is the sub - system of a NSTIS. The governance of NSTIS can be best described as network governance. The government is embedded in the network of governance which governs the NSTIS. The government is composed of institutions and actors. The actors within the boundary of the government would interact with actors who are outside the government but involved in the network of governance. The policy - making process of RTDI policies is divided into several stages, and in each stage of the policy - making process different modes of interactions between actors inside and outside the government would shape the RTDI policies. Furthermore, different RTDI policies have different impacts on the development of NSTIS, including the knowledge accumulation in a particular technological field, the network of actors and the particular set of products carried out by the actors of the NSTIS. However, we will formally introduce the new conceptual framework of the RTDI policy - making process in Chapter 3.

## **2.4 The empirical literature of biotechnology and Taiwan**

### **2.4.1 The empirical literature of biotechnology**

What is referred to as biotechnology in this thesis is distinguished from modern biotechnology and traditional biotechnology. Modern biotechnology, as defined by Laage-Hellman et al (2004), refers to the biotechnology which is developed in the post - genetic engineering era. Modern biotechnology is comprised of a broad range of knowledge fields, including DNA (the coding), proteins and molecules, cell and tissue culture and engineering, process biotechnology, and sub - cellular organisms. We fully agree with Laage-Hellman et al and adopt their definition of modern biotechnology as our definition in the thesis. Moreover, we further define the traditional biotechnology as the biotechnology which is developed before the post - genetic engineering era. The definition of modern and traditional biotechnology is especially important when we discuss the development of biotechnology in Taiwan, in Chapter 5.

Modern biotechnology, as described by many scholars, is developed through the networks of actors. McKelvey et al (2004) have described that the development of modern biotechnology is closely related to the fundamental science research. Not only scientists, but also companies are involved in the scientific research. The formulation of cluster is important for the development of modern biotechnology. The network between scientists and companies and the network between different companies are both important for the knowledge distributions of modern biotechnology. The perspective of McKelvey et al is widely shared by many other scholars, such as Stuart et al (2008), Zucker et al (1998), Powell et al (2005) and Colyvas (2007). Not only the technology transfers from universities to companies, but also the alliances between companies are essential to the innovation of modern biotechnology.

The development of modern biotechnology in fact intersects with several

sectors and with many countries. For the intersections of modern biotechnology and sectors, as described by Brink et al (2004) and Senker et al (2004), modern biotechnology is adopted by several sectors such as pharmaceuticals, agriculture, equipments and instruments and so on. The entanglement between the development of modern biotechnology and pharmaceuticals is frequently discussed by many scholars. Indeed, through discussing the origins of modern biotechnology, McKelvey (1996) analyzes the tightly inter - linked evolution between modern biotechnology and pharmaceutical sector. From her perspective, the origin of modern biotechnology was the development of recombinant DNA and genetic engineering techniques in the early 1970s in universities in the United States, such as the University of California. The American pharmaceutical multinational company (MNC), Eli Lilly, the new American bio - pharmaceutical company, Genetech, and the European pharmaceutical MNC, Kabi (Swedish), were the companies which commercialized the techniques of genetic engineering and applied the techniques for manufacturing pharmaceuticals. Since the appearance of modern biotechnology its development was tightly entangled with the development of the pharmaceutical sector. McKelvey et al (2004) further analyze the evolution of the pharmaceutical sector through the approach of sectoral innovation system. From their perspective, before the 1970s, the main knowledge base of the pharmaceutical sector was chemistry; only after the 1970s, modern biotechnology gradually became one of the knowledge bases of the pharmaceutical sector. In addition, Chataway et al (2004) also identify the intersection between biotechnology and agriculture and describe how agricultural MNCs re-orient their R&D strategies to incorporate the new biotechnology in their products. For the intersections between biotechnology and national innovation systems, Kaiser and Prange (2004) discussed the reconfiguration of the German national innovation system and the bio - pharmaceutical innovation within the national border of Germany.

Indeed, many scholars notice that the development of biotechnology is deeply influenced by the governments' policies. Geseisk (2000) compares the contrasting roles of the government of the United States and the government of Germany in the development of biotechnology. From her perspective, the triple helix between academia, state and industry is embedded in the innovation of biotechnology. Since biotechnology is a science - based technology and especially dependent on the cooperation and interactions among actors to transfer knowledge, national institutions and government policies play a critical role to provide the mechanisms of knowledge transfers. She further points out that start - ups are the motor of the innovation of biotechnology, and the role of the government in the development of biotechnology is to overcome the blockages of the national innovation system which are inappropriate to the development of biotechnology, and to establish the favourable 'economic ecology' which makes the start-ups develop and grow. The favourable 'economic ecology' includes the entrepreneurship of academics mobilizing knowledge flows, the mechanisms facilitating technology transfers (such as the patent system) and the financial market supporting the development of start - ups (such as the venture capital companies willing to invest in the new technologies). As she describes, the government of the United States has more positive support to the development of biotechnology than the German government, because the government of the United States establishes the favourable 'economic ecology' for the development of biotechnology. Geseisk also notices that polity and politics of the biotechnology policies in the United States and Germany are very different. While the United States doesn't have any central agency for coordinating biotechnology policies, the German government promotes all the biotechnology policies through the Ministry of Science and Technology. From her point of view, even though there is no central agency, the American approach is more effective because it supports

the institutional arrangement which is favourable to specific needs of biotechnology. On the contrary, even though the German government promotes all biotechnology through only one ministry, the policy process of the government is 'locked' by the actors of the 'inner - circle', such as a small group of scientists and experts. The German government then is not able to pursue a science and technology policy which effectively establishes the favourable 'economic ecology' and furthers technology transfers. Moreover, Reiss et al (2004) and Senker et al (2000) compare the development of biotechnology in different European countries. As concluded by Senker et al there are three lessons derived from the biotechnology policies of European countries: (1) the countries need to coordinate science and technology policies and seek for the view of industry while promoting public research; (2) different start - ups demand tailored mechanism for technology transfers; (3) academic entrepreneurship can be stimulated.

The literature of biotechnology indeed provides us a very important understanding towards the dynamics of the innovation of biotechnology and the proper policies which are able to support the development of biotechnology. On the basis of the existing literature we understand that biotechnology is a technology which is adopted by plural sectors and intersects with the national innovation systems of many countries. The modern biotechnology is developed through the interactions of actors in the network which is composed by companies, scientists and government. Knowledge flow between actors is essential for the development of modern biotechnology, and the most important role of the government in the development of biotechnology is to facilitate the flows of knowledge between actors and remove the barriers which hamper the interactions between actors. The analysis of the existing literature is indeed very important for us to assess the appropriateness of the Taiwanese



biotechnology and related sectoral policies in Chapter 6.

However, taking into account the discussions above, we find two insufficiencies of the empirical existing literature of biotechnology. First of all, the intersections of biotechnology, the different sectoral innovation systems and national innovation systems are not yet fully explored. McKelvey et al (2004) have analyzed the intersection between biotechnology and the pharmaceutical sector, and Chataway et al (2004) have discussed the intersection between biotechnology and agricultural sector. The authors, such as Geseisk (2000), Kaiser and Prange (2004), Reiss et al (2004) and Senker et al (2000), have discussed the intersections between biotechnology and different national innovation systems. However, how biotechnology intersects with different sectors within one country? There are no existing answers for this question yet. Second, the policy and politics of the biotechnology policies are not fully explored. Geseisk (2000) provides a very interesting initial discussion for the policy process of biotechnology policies in the United States and Germany. The 'lock - in' policy process of the German government didn't enable the government to promote the policies which actually support the development of biotechnology in Germany. From the discussion we get the initial understanding that the policy process of biotechnology policies should not be locked - in and include the new incentives from outside the 'inner - circle'. However, Geseisk does not fully discuss the importance of policy coordination in the biotechnology policies. While Geseisk shows that the government of United States, which has no central agency to coordinate policies, promotes more effectively the RTDI policies and the German government, which has only one ministry to promote biotechnology policies promotes policies ineffectively, she in fact doesn't link the relationships between policy coordination with the effectiveness of biotechnology policies. It is Senker et al (2000) who mention the importance of policy

coordination in the biotechnology policies, as well as the importance of the consideration of the view of the industry. Yet, ‘how’ could government coordinate biotechnology policies with the consideration of the view of the industry? A clear answer for this question cannot be found in the existing literature.

#### 2.4.2 The empirical literature of Taiwan

The Taiwanese experience in industrialization and innovation has attracted the attention of some scholars and has been analyzed by three strands of literature, i.e. literature on national innovation systems, literature on East Asian regional studies and some political science literature. Each sort of literature is introduced in the following sections.

##### 2.4.2.1 Taiwan and the literature of national innovation systems

###### 2.4.2.1.1 Taiwan and the approaches of national innovation systems

In Nelson’s book, *‘National innovation systems’*, Taiwan has been chosen as one of the empirical examples among 15 countries. According to Nelson, Hou and Gee (1993) have written a book chapter to analyze the Taiwanese national innovation system. The book chapter has focused on the Taiwanese history of industrial evolution from 1945 to 1993. The Taiwanese companies, including public enterprises, private SMEs and MNCs, played important roles in the acquisition and development of technologies. Furthermore, the Taiwanese government also played an essential role in the national innovation. Not only the public policies, such as education policies, fiscal / financial policies, but also the public sponsored research institutions have positively supported the development of the Taiwanese manufacturing and ICT related technologies and sectors. Besides, the Taiwanese universities

extensively contributed to the national technological innovation through the collaboration with public sponsored research institutions.

Moreover, in the Edquist and Hommen's book, '*Small country innovation systems*' (2008), Taiwan is also selected to be one of the empirical examples among 10 small countries. Edquist and Hommen adopt a system approach within their volume which is similar to that of Nelson's. In Edquist and Hommen's book, Balaquer et al (2008) analyze the Taiwanese national innovation system. The history of the Taiwanese industrial development (from 1945 to 2008), the knowledge inputs to national innovation, the industrial structure constituted by SMEs and the evolution of the innovation policies promoted by the Taiwanese government are all described. Furthermore, the same chapter compares the performance of the Taiwanese manufacturing to the Taiwanese service industry. The special OEM / ODM mode (original equipment manufacturing / original design manufacturing) of the Taiwanese manufacturing industry gets special attention.

The discussions of the Taiwanese national innovation system provided some empirical characters of the Taiwanese national innovation. On the basis of the empirical literature we understand that manufacturing industries are the pillars of the Taiwanese national innovation. The industrial structure of Taiwan is mainly constituted by SMEs and the Taiwanese government provides strong guidance in the industrial development.

Yet, as discussed in section 2.2.1, the approach of national innovation system has several deficiencies. Such theoretical deficiencies influence the empirical analysis of the Taiwanese case in many aspects. First of all, both Hou and Gee (1993) and Balaquer et al (2008) have ignored the technological and sectoral differences within the Taiwanese national innovation system. Hou and Gee (1993) only discuss the evolution of the

overall industry in Taiwan. Even though Balaquer et al (2008) distinguish the Taiwanese manufacturing industry from the service industry, the book chapter doesn't provide detailed discussion about the sectoral differences under the manufacturing industry. Second, even though the Taiwanese government played a significant role in the development of the Taiwanese national innovation system, the role of the Taiwanese government is only discussed from purely economic and technological perspectives. The Taiwanese government is considered as a unified entity and the policy - making process within the Taiwanese government is not uncovered.

#### 2.4.2.1.2 The evolution of the Taiwanese national innovation system

In '*The evolving nature of Taiwan's national innovation system*', Dogson et al (2008) discuss the evolving nature of the Taiwanese national innovation system. From the authors' perspective, the national innovation system changes over time and the evolution of the national innovation system involves changing institutions and relationships within the system. By analyzing the new characters of the Taiwanese innovation network of biotechnology which do not exist in the Taiwanese innovation network of ICT, the authors tend to analyze the dynamics of the national innovation system in Taiwan.

The evolving characters of the Taiwanese innovation network of biotechnology, according to Dogson et al, refer to the evolving institutions, the evolving finance / investment patterns and the evolving research - industry links. The evolving institutions include the public research institutions and science parks. The Industrial Technology Research Institute which contribute a lot to the Taiwanese ICT sector, are emphasized. Besides, the Development Centre of Biotechnology and the National Health Research Institute are also mentioned in the paper. Furthermore, the Hsinchu Science

Park which clusters the majority of ICT companies is highly focused in the paper. The Biotechnology Plaza of Nakang Software Park, which clusters a large group of pharmaceutical companies and the Southern Taiwan Science Park, which clusters a group of agricultural companies are also discussed. For the evolving finance / investment patterns, these patterns include the firms' strategies and venture capital systems. On one hand, while the Taiwanese ICT companies use the downturn entry strategy to enter the market, the Taiwanese biotechnology related companies use new products to penetrate the market. On the other hand, while the venture capital system of the Taiwanese ICT sector is operated by private companies, the venture capital system of the Taiwanese biotechnology related sectors is driven by the government. For the evolving research - industry links, the links of Taiwanese biotechnology are different from the links of ICT. While the Taiwanese ICT companies transfer their technologies from MNCs, the Taiwanese biotechnology related companies usually transfer their technologies from universities. In summary, according to the new characters of the Taiwanese innovation network of biotechnology which do not exist in the Taiwanese innovation network of ICT, Dogson et al conclude that the Taiwanese national innovation system is under evolution.

Dogson et al provide some interesting observations about the Taiwanese innovation network of biotechnology. The authors notice that the development of the Taiwanese biotechnology is very different from ICT mode. Plural government institutions are involved in the Taiwanese development of biotechnology, and biotechnology companies are usually invested by the government. Since the local companies usually transfer their technologies from universities, the universities play important roles in the innovation of biotechnology. Indeed, the concept for the evolving characters of the innovation system contributes to our understanding of the dynamics of the innovation system in Taiwan. However, the paper seems to have three

important weak points.

First, out of the concept that there are technological and sectoral differences within a national innovation system, Dogson et al misunderstand the differences between the Taiwanese biotechnology and the Taiwanese ICT NSTIS as the characters of the evolving nature of the Taiwanese national innovation system. In fact, as we are going to show in Chapter 5, the developments of the Taiwanese biotechnology and related sectors have their own unique history. The Taiwanese biotechnology and related sectors do not evolve from the ICT sectors. Dogson et al use the Taiwanese biotechnology as an empirical case to explain the evolving nature of the Taiwanese national innovation system, which is not convincing.

Second, Dogson et al treat the Taiwanese biotechnology as one sector. Yet, as we are going to show in Chapter 5, biotechnology in Taiwan is in fact one technology which is adopted by three sectors including pharmaceuticals, agriculture and medical devices. Each sector adopted biotechnology in a very different context. The evolution of biotechnology was different from sector to sector. Therefore, it is insufficient to discuss the evolution of biotechnology in Taiwan without recognizing the sectoral differences. We will have detailed discussions about the development of the three biotechnology related sectors and the evolution of biotechnology in each of the three sectors in Taiwan in Chapter 5.

Third, Dogson et al look at the biotechnology in Taiwan through the lens of ICT. Some research organizations and science parks, such as the Industrial Technology Research Institute and the Hsinchu Science Park, which play important roles in the development of ICT but play very minor roles in biotechnology, are heavily emphasized. Yet, the important research organizations and science parks which never support ICT but play a key role

in the development of biotechnology are quite marginalized. This is the case of the Development Centre of Biotechnology, the National Health Research Institute, and the Biotechnology Plaza of Nakang Software Park.

#### 2.4.2.2 Taiwan and the literature of East Asian regional studies

Taiwan has been considered as one of the 'East Asian Tigers' due to its outstanding performance in the manufacturing and ICT industries. The literature of East Asian regional studies frequently compare Taiwan with other East Asian countries in terms of the historical progress in the high-tech industries, the industrial structures and the government's policies. Unlike the approach of national innovation systems which search for the general principles among countries belonging to different continents, regional studies usually consider the experiences of East Asian countries to be unique and only focus on the East Asian region. Since the ICT sector is still the most outstanding sector of Taiwan and other East Asian countries, regional studies usually emphasize the performance of the Taiwanese ICT sector and compare the Taiwanese ICT sector with other East Asian countries.

Mathews and Cho's book '*Tiger technology*' (2000) is the typical example of East Asian regional studies. In this book, the authors describe the historical progress of the Taiwanese semiconductor industries. Moreover, in Chu and Hill's book '*The East Asian high-tech drive*' (2006), Chu displays the statistical data of the Taiwanese manufacturing industries, the changing industrial structures of Taiwanese manufacturing industries, the Taiwanese government's industrial policies and the roles of universities in the national innovation. The problem of policy coordination within the Taiwanese government is discussed briefly and there is no further analysis for such policy issues.

The East Asian regional studies have collected some empirical data of Taiwan for further analysis, especially the data of the ICT sector. Nevertheless, the development of biotechnology and related sectors in Taiwan has seldom been mentioned. Why Taiwan has relatively high performance in the ICT sector, but relatively low performance in biotechnology related sectors? Are there any special reasons for such phenomena? Regional studies have not answered these questions yet.

#### 2.4.2.3 Taiwan and the literature of political science

The literature of political science which discusses the Taiwanese government belongs to two disciplines: comparative politics and public administration. Both disciplines are introduced below.

For the disciplines of comparative politics, the polity of Taiwan has been discussed by many scholars. Many political scientists of comparative politics consider the Taiwanese polity to be semi - presidential polity (Wang, 2002; Shih, 2004; Chen, 2005) because according to the Taiwanese Constitution, the President is the head of the state and the Prime Minister is the head of the Executive Yuan (the Cabinet). However, Wu (2000) has a very different point of view from other scholars. He claims that according to the Taiwanese Constitution the President is able to replace the Prime Minister any time without the permission from the Legislative Yuan (the Congress). Therefore, the Prime Minister is in fact the subordinate of the President and the President is the actual head of the executive branch. Wu then advocates that the Taiwanese polity is in fact presidential polity, rather than semi - presidential polity. According to the academic debates above, we adopt the opinion of Wu. From our point of view, since the President could replace the Prime Minister without the permission of the congress and treats



the Prime Minister as his / her subordinate, Taiwan should be considered a presidential polity rather than a semi - presidential polity. We will further analyze the impact of the Taiwanese presidential polity on the RTDI policy - making process in Chapter 6.

For the sub - discipline of public administration, the issues of policy coordination and the governance of the Taiwanese biotechnology related policies have been discussed by a few scholars. Wong (2005)

Figure 2.5 The institutional organizations of Taiwan's biotech innovation system

\*Source: Wong (2005)

analyzes the governance of the biotechnology innovation in Taiwan. As shown in Figure 2.5, Wong recognizes Taiwan's biotech innovation system. From his perspective, the Taiwanese government had once successfully directed the resources and the different actors of the state towards the development of ICT from top - down. However, in the development of biotechnology, the roles of the Taiwanese government were weakened considerably. The Taiwanese government tried to promote various policies to direct the development of biotechnology, such as increasing R&D expenditures, enhancing intellectual property protections, establishing the biotechnology cluster, investing biotechnology start - ups, refining regulations and so on. Yet, all the policies were promoted in the context of '*administrative decentralization*'. In the Executive Yuan, there were four ministries which claimed to be the key players for the development of biotechnology, i.e. the National Science Council (NSC), the Ministry of Economic Affairs (MOEA), the Department of Health (DOH) and the

Council of Agriculture (COA). Although the Science and Technology Advisory Group (STAG), was institutionally in charge of the setting priorities, the ministerial leaderships in the biotechnology policies were shared by four ministries. Wong further explains that there were in fact three factors which made the Taiwanese government incapable to coordinate biotechnology policies: (1) Market ambiguity: Bio - industries were multi - disciplinary by their nature and the market for bio - industry was ambiguous. Therefore, the policy makers were unable to effectively target the market winner and coordinate resources around it. (2) Ministerial contestation: The four ministries had different priorities for the development of biotechnology and competed for scarce resources and policy authority. (3) Absence of institutional leaderships: Even though the Science and Technology Advisory Group was in charge of coordinating biotechnology policies in Taiwan, its function of coordination was in fact very limited. In addition, Liu et al (2005) analyzed the network of stakeholders of the National Health Insurance.

Political scientists analyze the Taiwanese government and government policies from different perspectives. These strands of literature provide some initial discussions about the Taiwanese biotechnology related policies and help us to identify the institutions and actors which may influence the policy - making process of the Taiwanese government. For example, Wong (2005) provides a very interesting discussion about the governance of biotechnology in Taiwan. The institutional organizations of the Taiwanese biotech innovation system are identified. The problem of the coordination between the four ministries claimed to be responsible for the development of biotechnology is also interestingly discussed. Wong's paper provides a very important initial understanding of inter - ministerial coordination of biotechnology policies in Taiwan.

Yet, there are at least three limitations of the literature. First, different

strands of political science literature analyze the Taiwanese government and government policies from different perspectives; yet from our perspective different perspectives have to be integrated together in order to deepen the analysis of biotechnology and related sectoral policies in Taiwan. For example, besides the contestation of ministries, the congressmen under the presidential polity in Taiwan may also play important roles in shaping biotechnology and related sectoral policies. Yet, until now there is no literature to offer a synthetic discussion for the roles of both ministries and congressmen. Second, the policy - making process of the Taiwanese biotechnology and related sectoral policies remain blurred and there is no clear linkage between the policy - making process and the policy contents of the Taiwanese biotechnology related policies. Even though Wong (2006) has noticed the problems of policy coordination within the Taiwanese government, he does not link the ministerial contestation with the policy contents of specific policies. Moreover, Liu et al (2005) analyze the network of governance of the National Health Insurance. However, the authors do not clarify how the network of governance influences the policy contents of the Taiwanese National Health Insurance. Third, the literature of political science of Taiwan has not been linked with the approaches of innovation system. How does the policy - making process of the Taiwanese government influences the development of the Taiwanese biotechnology related NSTIS? Do the factors, such as the ministerial contestation described by Wong (2005), influence the development of biotechnology NSTIS in Taiwan? Are there sectoral differences between different biotechnology NSTIS? A clear answer for these questions has not yet to be found.

#### 2.4.2.4 Brief conclusion of the Taiwanese literature

The literature about the Taiwanese research provides some empirical analysis of Taiwan which contribute to our understanding towards our

empirical example; yet, there are two common insufficiencies of the empirical studies. Above all, even though the Taiwanese national innovation system has been studied, the sectoral and technological differences within the Taiwanese national innovation system have not been fully discussed. While the majority of literature focuses on the progress of manufacturing or ICT related sectors, the development of biotechnology and related sectors in Taiwan has been marginalized. The deeper and more precise empirical analysis of the Taiwanese biotechnology is lacking. Second, the discussions about the political nature and policy - making process of the Taiwanese government remain limited. The available literature is only able to discuss the roles of the Taiwanese government from different perspectives, but there is no literature to provide the comprehensive insights into the policy - making process of Taiwan.

Since both the discussions of the innovation systems of biotechnology in Taiwan and the policy - making process are limited, we choose the innovation systems and policies of the Taiwanese biotechnology and related sectors as our empirical examples. In Chapter 5, we will use the Taiwanese biotechnology and related sectoral innovation systems as the empirical examples of NSTIS. Moreover, in Chapter 6, we choose the Taiwanese biotechnology and related sectoral policies as our empirical cases to observe the RTDI policy - making process.

## **2.5 Conclusion**

In this chapter we reviewed three categories of literature which are related to the whole thesis, i.e. the approaches of innovation systems, the literature of political science and the empirical literature of biotechnology and Taiwan. The review of the existing literature helps us to discover the conceptual and empirical contributions of the existing literature. On the other hand, the

literature also helps us to establish our own conceptual framework and to analyze our empirical cases.

Based on the discussions of this chapter we are going to apply the conclusions derived from the existing literature for our analysis in the following chapters. In Chapter 3, we will establish our own conceptual framework according to the conclusion of the literature of political science. In Chapter 5, we will apply the concept of NSTIS which is derived from the literature of innovation systems for the analysis of the three biotechnology related NSTIS in Taiwan.

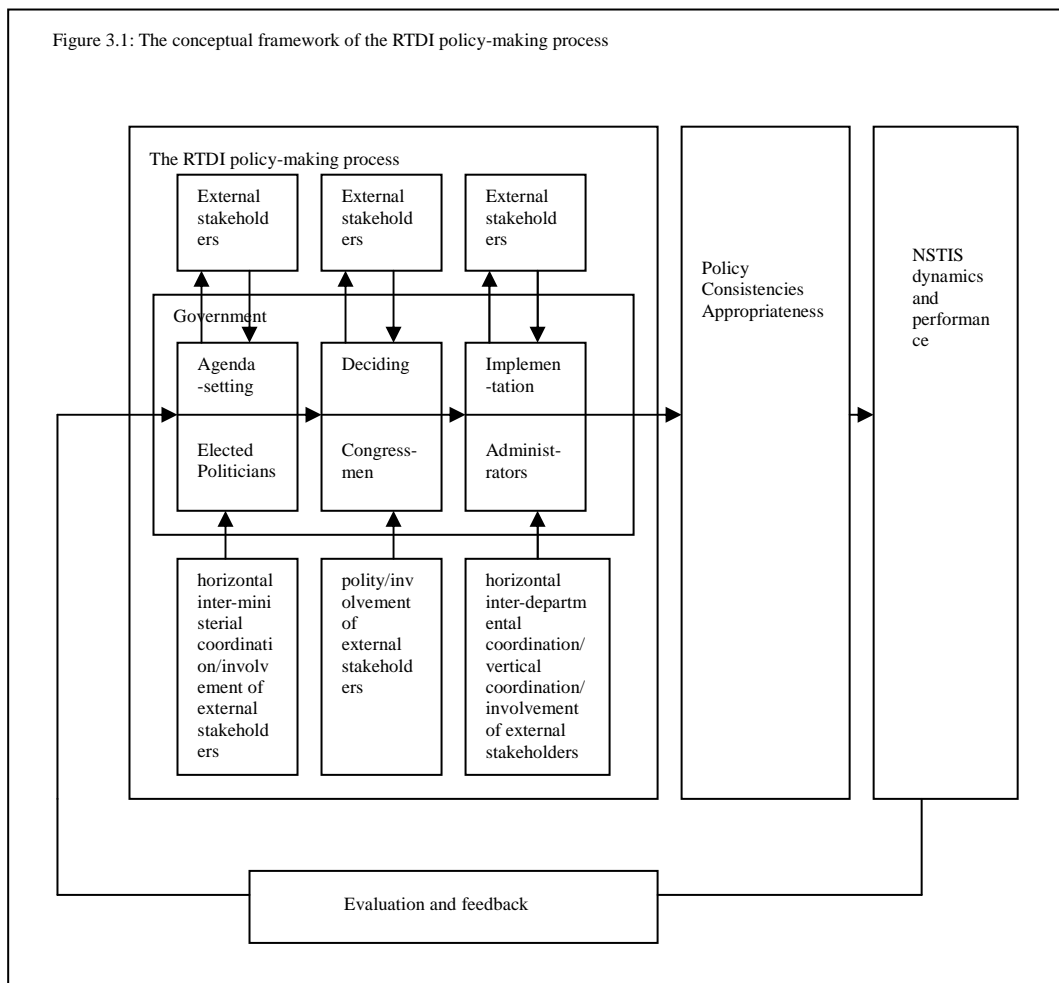
## **Chapter 3 Research questions and the conceptual framework of RTDI policy - making process**

### **3.1 Introduction**

The purpose of this chapter is to establish the research questions of the whole thesis and the conceptual framework of the RTDI policy - making process which is shown in Figure 3.1. The research questions and the conceptual framework are developed on the basis of the literature discussed in Chapter 2, i.e. the literature on innovation systems and literature on political science. However, before opening the detailed discussion of this chapter, we first introduce four closely interrelated theoretical blocks underlying the research questions and the conceptual framework and provide an overview for our conceptual framework.

The first theoretical block underlying the research questions and the conceptual framework is the approaches of innovation systems and the general roles of RTDI policies in the context of innovation systems. As discussed in section 2.2, Nelson (1993) and Lundvall (1992) contribute to the analysis of national innovation systems, while Freeman (1987) explains how governments promote technology and industrial policies to shape the national innovation systems through comparing the empirical cases of Japan and Britain; the OECD (1999) also describes how governments should positively support the development of the national innovation system through technology and innovation policies. Malerba (2004) looks at the dynamics of sectoral innovation systems and recommends that national institutions should match the specific characteristics of sectoral innovation systems and foster their further development. Furthermore, Carlsson (2004) and many other authors express the evolution of technological innovation systems, as well as the impact of national institutions on technological

innovation systems. Indeed, as described in section 2.2, national institutions shape the sectoral and technological innovation within the national border. Since we tend to look at how the national policies impact on a technology impinge upon sectors, we consider that the boundary of an innovation system which is drawn by a nation, a sector and a technology is the most suitable boundary for an innovation system. The configuration of a national, a sectoral and a technological innovation system is defined as the *national, sectoral and technological innovation system* (NSTIS). In fact, in the conceptual framework shown in Figure 3.1 we assume RTDI policies are made in the context of NSTIS. In addition, we adopt the concept of both Freeman and Malerba and assume that the dynamics of an innovation system is shaped by the government through the promotion of RTDI policies, as well as the provision of other framework conditions. From our point of view the government is responsible for making appropriate RTDI policies which not only match the specific dynamics and structures of an



innovation system, but also further shape and foster its development. The development of NSTIS includes the knowledge accumulation in a particular technological field, the network of actors and the particular set of products carried out by the NSTIS. RTDI policies that influence NSTIS can be characterized as being appropriate if they match the development of the NSTIS through supporting the underlying logic of knowledge accumulation and exploitation in a particular technological field, clustering the network of actors and encouraging the production and innovation of a particular set of products. We assume not only the policy objectives and policy instruments of RTDI policies, but once being implemented, these RTDI policies should generate appropriateness to the development of NSTIS. Appropriateness in this thesis refers to the ‘match’ between RTDI policies and the development of NSTIS which is able to be observed by some short-term effects caused by the RTDI policies<sup>3</sup>. Indeed, while some RTDI policies attend to the general national science and technology concerns, some others target the dynamics of specific sectors and technologies. We assume that the policies which

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<sup>3</sup> In other words, the concept of appropriateness has two aspects with different priorities. First of all, the concept prioritizes the importance of ‘match’, or we could also say the ‘fitness’, of RTDI policies towards the development of NSTIS. We recognize that a RTDI policy design should fit the general dynamics and the existing characteristics of a sector and a technology that shall be influenced. The policy should follow the principle processes that a sector and a technology demand and should not overwhelm the actors that are present in the given situation. For example, if there is no absorptive capacity in firms, the RTDI policy should consider to increase the absorptive capability of companies. Second, the concept of appropriateness treats the short-term effects, such as the quantitative economic indicators, caused by policies as a minor issue. The short-term effects are considered as an entry point for us to observe and analyze the match or fitness of RTDI policies. In another words, the short-term effects are considered as the attempts to assess if RTDI policies are promoted in a proposed direction.

Indeed, in our conceptual framework, we use the concept of appropriateness instead of effectiveness, because we are aware that there is ‘time-lag’ for every RTDI policy to generate long-term effectiveness, and all RTDI policies are promoted in an ‘open environment’ where the attributing effects caused by the RTDI policies are difficult to judge. It is in fact very difficult to link RTDI policy-making process with policy effectiveness since all actors in the reality involve in the policy-making process of RTDI policies without knowing the long-term effectiveness of these policies in the future. Actors who actually decide RTDI policies and involve in the policy-making process at best know the historical evolution of NSTIS in the past and the short-term effects of these policies. Under the circumstances, we recognize the concept of appropriateness is more applicable than effectiveness. Only under the condition that the RTDI policies could appropriately match the development of NSTIS in a short-term, these RTDI policies could generate positive long-term effectiveness. We will further operation the concept of appropriateness in section 6.3 when we analyze the appropriateness of our empirical cases, the National Programs and regulation policies.

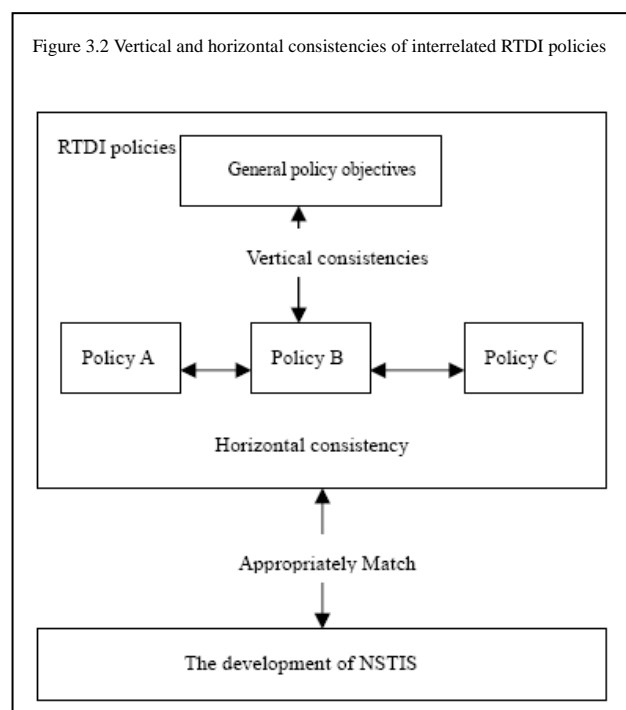


match the general national concern may not necessarily match the specific requirements and development of a particular NSTIS, and the policies which match the development of a particular sector and technology do not necessarily match the development of others. Indeed, the appropriateness of policies is a relative term and has different meaning in different nations, in different sectors and in different technologies. Therefore, under the context of NSTIS, we assume it is the responsibility of the government for making appropriate RTDI policies which specifically match the requirements and development of a particular NSTIS.

The second underlying theoretical block of our research questions and the conceptual framework has contributions by prominent scholars of public management. These scholars, such as Moge (1988), Six et al (2002), Peters (1998) and Braun (2008), agree that in order to spend public money most effectively and efficiently and maximize the positive support of government towards national development, the government should responsibly coordinate policies of different subunits and maintain the policies to be consistent, rather than fragmented. The improvement of the institutions inside the government is the key for the improvement of the coordination of policies. We fully agree with the scholars mentioned above. In the real world, policy objectives of policies are not always explicit but implicit. Even though the policy objectives of different policies are in many occasions fundamentally contradictory to each other and very difficult to be entirely consistent with each other, the government should maximize the opportunities to integrate different policies and thus minimize the wastes of public expenditures. Therefore, in the conceptual framework shown in Figure 3.1, we assume that during the RTDI policy - making process, a government is responsible for coordinating RTDI policies and maintaining the consistencies of RTDI policies. To improve the coordination of policies, the government is responsible for improving the institutions inside the

government. The coordination of policies, according to Peters (1998:296), is defined as the process in which RTDI policies are characterized by minimal redundancy and incoherence. The institutions inside the government, as defined in Chapter 2, refer to political organizations, political rules and practice. Moreover, consistencies of RTDI policies are defined vertically and horizontally, as shown in Figure 3.2. The vertical consistencies of policies are defined from two aspects. First, vertical consistencies refer to the conditions that the policy objectives of every single RTDI policy are vertically, not contradictory, even ideally complementary with the general policy objectives of the whole government. Second, the vertical consistencies of policies also refer to the conditions that the direction for the implementation of every single RTDI policy is vertically complementary with the general policy objectives of the whole government. Moreover, the horizontal consistency of RTDI policies means that the policy objectives and policy instruments of a set of interrelated RTDI policies are horizontally not contradictory, even ideally complementary with each other and offer no contradicting incentive structures which feed the dynamic development of the innovation system. In short, we assume it is the responsibility of the government to improve the institutions inside the government to coordinate and maintain the vertical and horizontal consistencies of RTDI policies during the policy - making process.

The third underlying theoretical block is established upon the literature of comparative



politics and governance. As we described in section 2.3.2, some scholars of comparative politics, such as Almond et al (1996), view a government as the core of a political system and focus on the internal institutions and actors which influence the government's policy - making process. On the other hand, as we described in section 2.3.3, the scholars of governance, such as Rhodes (1997) and Kooiman (1993a), consider the policy - making process as the process in which the government constantly interacts with the policy stakeholders involved in the network of governance. Indeed, both of the approaches imply the existence of the boundary of the government which distinguishes the inside and the outside world of the government. Both approaches also imply the importance of institutions which not only shape the relationship between actors inside the government, but also the interactions between the government and the actors outside the government. Almond et al (1996), influenced by both institutionalism and Easton (1965)'s theory of political system, consider institutions and actors as the components of the 'inside world' of the government and considers the activities of interest groups as the interest accumulation 'outside' the government. While Rhodes (1997:53) proposes that the network of governance covers both government and non - governmental actors and defines governance as 'self - organizing network', she has unreservedly implied the existence of the boundary of the government which distinguishes the government from non - governmental actors. In addition, she has also implicitly implied the structures and institutions which shape the interactions of actors in the governance network. According to the discussions above, in our conceptual framework shown in Figure 3.1, we assume the government itself is the core of the political system which is consisted of institutions and actors and is embedded in the network of governance formed by both governmental and non - governmental actors. The boundary of the government exists and separates the institutions and actors inside the government from actors outside the government. The actors

inside and the actors outside the government interact between them at all stages of the RTDI policy - making process. As pointed out by Almond, polity is a constitutional framework which not only shapes the institutions inside the government, but also the structures through which stakeholders outside the government can enter the policy realm. In short, we assume RTDI policies are made through the interactions between the government and the stakeholders outside the government which are shaped by institutions.

The fourth underlying theoretical block has contributions from the stagist approach. Stagists assume that the policy - making process can be divided into several stages, yet different proponents of this approach have different divisions for stages. For example, Parsons (1995:77) divides the policy - making process in seven stages, while May and Wildavsky (1978) only consider five stages of the policy - making process. However, as we discussed in section 2.3.3.4, we only discuss the stages which are considered to be important by more scholars. Therefore, our conceptual framework, as shown in Figure 3.1, only divides the RTDI policy - making process into four stages: agenda - setting, deciding, implementation and evaluation.

Based on the four theoretical blocks discussed above, we form the details of our research questions and the conceptual framework which are described in the following sections. Section 3.2 introduces the research questions of the whole thesis, and section 3.3 contains the detailed discussion of the conceptual framework of RTDI policy - making process. Section 3.4 is the conclusion of this chapter.

### **3.2 The research questions of the whole thesis**

In this section, we build up our research questions of the whole thesis. With

the acknowledgement that the boundary of the government exists, the research questions are established upon the variables inside and outside the government, which are supposed to influence the RTDI policy - making process. The variables inside the government are polity, horizontal coordination and vertical coordination, while the variable outside the government is the involvement of external stakeholders.

### 3.2.1 The research questions for the variables inside the government

Our research questions for the variables inside the government are built upon the literature of comparative politics and public management. The literature of comparative politics contributes to our research question of polity. Since our empirical example is situated within a presidential polity, we focus our discussion of polity on presidential polity only. Furthermore, the literature of public management contributes to our research questions of horizontal coordination and vertical coordination between actors inside the government.

#### 3.2.1.1 The research question for presidential polity

Presidential polity is established upon the principle of separation of powers. As it is described by Almond et al (1996: 134) and Hague and Harrop (2008:309-317, 329), under the presidential polity both the executive branch and the legislative branch are separately elected and authorized by people. The president directs the government, while the congress plays the roles to legislate, authorize the expenditures, scrutinize and oversee the government's policies. The president's policies must get approvals of the congress before being implemented. However, the personnel of the two branches are totally separated. Since both the president and the congress are elected for a fixed - term and no one is able to bring down another, the

presidential polity gives each branch some autonomy to make decisions by each own will.

The divided government under presidential polity is frequently discussed by the scholars of comparative politics. As we mentioned in section 2.3.2, the divided government, as defined by Elgie (2001:3), refers to the situation when ‘the president’s party fails to control a majority in at least one house of the legislature.’ While we refer to the president’s party to be the ruling party, the majority party controlling the congress is referred to be the opposition party.

In the divided government, as described by Weatherford (1994), the president is difficult to keep his / her policies fully approved by the congress. The congress, which is controlled by the opposition party, usually changes the contents of policy proposals provided by the president and breaks the consistencies of policies. As described by Smith et al (2006:275), the congress controlled by the opposition party in most cases has different policy priorities and disagrees with the president’s policy preferences. Since the congressmen, according to Monsma’s investigation for the congress of the United States (1969:142), only vote for their own party, in a divided government the majority of congressmen in most cases vote for the policies which are against the president’s policy preferences. As depicted by Samuels (2007), the ‘dead - lock’ between the congress and the president is possible to emerge in the divided government. Indeed, once the dead - lock emerges, as described by Weatherford (1994), Cox and McCubbins (2000) and Pfiffner (1994), the president should use his / her own leadership to persuade and to bargain with the congress.

However, the discussions of the divided government have seldom been applied for the analysis of RTDI policies. According to the existing

literature, such as Weatherford (1994), Cox and McCubbins (2000) and Pfiffner (1994), a divided government is hard to make consistent policies because the congress is supposed to break the policy consistencies. Yet, the available literature has not discussed how the divided government influences the consistencies of RTDI policies. Furthermore, once the contents of RTDI policies, in terms of policy objectives and policy instruments, are changed by the congressmen, the available literature does not express how the changes made by the congressmen influence the extent for the RTDI policies to appropriately match the development of NSTIS. Since the existing literature does not provide any answer for the relationships between the divided government and the consistencies and appropriateness of RTDI policies, here we get our first research question:

**Research question 1: How does a divided government under presidential polity influence the consistencies and appropriateness of RTDI policies?**

On the basis of the existing literature we assume that the congress controlled by the opposition party may have different priorities for RTDI policies and have incentives to change the contents of RTDI policy proposals through legislation, authorization of the expenditures and oversight of the government's policies. Once the contents of RTDI policy proposals are changed by the congress, the policy objectives of every single RTDI policy may be difficult to be vertically complementary with even contradictory to the general policy objectives and policy instruments of the whole government. The congress may also change the policy objectives of a set of interrelated RTDI policies not to be horizontally complementary and even be contradictory to each other and offer contradicting incentive structures to the innovation system. It is also possible that the congress has different policy preferences, policy priorities and may also have different judgment

for the appropriateness of RTDI policies. If such a situation occurs the president might need to extensively negotiate and if necessary compromise with the congress. Under such circumstances the judgment of policy appropriateness and the appropriateness of RTDI policies might become very difficult to be clearly defined, and the divided government can find it very hard to make appropriate RTDI policies which match the development of NSTIS.

#### 3.2.1.2 The research questions for actors' coordination inside the government

In the practice of presidential polity, although all policies are issued in the name of the president, it is in fact the cabinet which decides and implements the majority of policies. As it has been described by Moe (2005: 208) and Pfiffner (2005: 244), the practice in the United States is that the president only gives managerial directions in the broad sense to the cabinet, while it is the cabinet to implement policies towards the president's directions. Since the existing literature has identified the importance of the cabinet under the presidential polity, the coordination between actors in the cabinet is discussed in this section.

There are two levels of actors in the cabinet, elected politicians at cabinet level and the administrators on the agency level, and they have different impacts on RTDI policies. The coordination between actors is discussed in the following paragraphs.

Elected politicians on the cabinet level play the roles to decide and to coordinate the policy objectives and the policy instruments of a set of interrelated policies. The elected politicians, as defined by Kingdon (2003: 27), include the ministers of the cabinet and the heads of particular



departments who are directly or indirectly appointed by the president and are responsible for the president.

Among the elected politicians, ministers are especially essential in coordinating policy objectives and policy instruments and in maintaining the consistencies of policies; yet, it is difficult for ministers to achieve consensus for coordinating policies. As it has been depicted by Laver and Shepsle (1996: 30-32), the departmental egoism of each minister is very hard to avoid. Institutionally, each minister is the head of a major government department which has formal jurisdiction over a particular set of policy area. It is indeed the mission of each minister to lead his / her own department promoting policies in the particular policy area. Furthermore, the heavy workload of each minister makes him / her only able to concentrate on his / her own ministerial business and have little time and energy to concern policies which are outside his / her own departments' jurisdiction. In addition, since the resources in the majority of cases are allocated along the ministerial lines, the departmental egoism of each minister is even deepened due to resource allocation. In the field of RTDI policies, as Braun (2008:233) claims, the departmental egoism of ministers exists. From Braun's perspective, even though there are five institutional options which may be able to improve the coordination of RTDI policies, each institutional option is only feasible if the self - interested ministers are able to achieve the inter - ministerial coordination through inter - ministerial bargaining. Coordination only occurs if the benefits are higher than costs, there is no loser in the game and the identity and organizational routines of each ministry are respected. Indeed, even if Six et al (2006:30-31) clearly point out that collaborative organizational relationship is the precondition for policies to be consistent with each other, and the OECD (1999) describes that the government is responsible for coordinating RTDI policies in order to maximize its support to the development of the innovation system, the

establishment of inter - ministerial coordination is in fact very difficult to be achieved. Unless each minister is able to secure their ministries' benefits in the coordination, they have no incentives to coordinate.

However, the existing literature which discusses the inter - ministerial coordination provides no clear linkage between the horizontal inter - ministerial coordination and the consistencies of RTDI policies, as well as the linkage between horizontal inter - ministerial coordination and the appropriateness of RTDI policies. Since there are no straight linkages found within the existing literature, we get the initial query of our second research question: how does the horizontal inter - ministerial coordination influence the consistencies and appropriateness of RTDI policies? We assume if ministers are difficult to horizontally coordinate with each other, the general policy objectives of the whole government may be hard to be formulated, and it may also be difficult for the policy objectives of every single RTDI policy to be vertically complementary with the general policy objectives. Furthermore, if the ministers who decide the policies do not have sufficient consensus to coordinate a set of interrelated RTDI policies, the policy objectives and policy instruments of these RTDI policies may be difficult to be horizontally complementary with each other or may even contradict each other. In addition, we assume if ministers don't form a unified judgment for the appropriateness of RTDI policies, one minister may promote some policies which might be considered to be inappropriate by other ministers. As a result, it might be difficult for the cabinet as a whole to make a set of policies which appropriately match the development of a specific NSTIS and maximize the government support to it. Nevertheless, according to the literature discussed below not only ministers, but also administrators at the agency level have difficulties to coordinate with each other.

The administrators at the agency level play the role to implement the

contents of policies in order to realize policy objectives. Nevertheless, even if the horizontal coordination between administrators is essential for policies to be consistently and appropriately implemented, it is difficult for administrators to achieve the consensus to horizontally coordinate with each other. As it has been described by Elmore (1997:249, 261) when the institutions of bureaucracies become larger and more complex, the administrators in each agency only concentrate and specialize in the tasks of their agency. Departmental egoism of agencies is hard to avoid because departments tend to focus on their own sector only. Each agency with specific interests frequently competes for relative advantages in the exercise of power and the allocation of scarce resources. Six at al (2002) share the similar perspective, that within large bureaucracies most civil servants seek to maximize not only their budgets, but also the span of their control and influence. Indeed, administrators seek to shape the mode of the implementation of civil service in order to maximize their discretion. According to the analysis of Lindblom and Woodhouse (1993: 68), the effective coordination between agencies is only able to be achieved through agencies' mutual adjustment and bargaining. Commands from elected politicians which ask agencies to coordinate usually fail. In the context of RTDI policies, Braun (2008:235) claims that even though the improvement of the coordination at the agency level is one of the possible institutional options to improve policy coordination, unless agencies gain benefits or at least secure their benefits in the coordination, they have no incentives to coordinate with each other to implement RTDI policies.

However, the existing literature provides neither clear linkage between the horizontal inter - departmental coordination and the consistencies of RTDI policies, nor clear linkage between the horizontal inter - departmental coordination and the appropriateness of RTDI policies. Since there are not sufficient linkages found within the existing literature, according to the

discussions about administrators above, we get the advanced query for our second research question: how does the horizontal inter - departmental coordination influences the consistencies and appropriateness of RTDI policies? According to the discussions of the existing literature, we assume that if the administrators have difficulties to coordinate with each other horizontally, RTDI policies are likely to be implemented towards the directions which maximize the interests of implementation bodies. Yet, these directions for implementation may be neither vertically complementary with the policy objectives of a single RTDI policy, nor vertically complementary with even contradictory to the general policy objectives of the whole government. Furthermore, the directions of the implementation of a set of interrelated RTDI policies would not be horizontally complementary or even contradictory to each other, because the administrators who implement the policies do not have consensus to coordinate with each other for the implementation of these policies. In addition, we assume if the horizontal inter - departmental coordination between administrators fails, the administrators would be difficult to form a consensus which clearly recognizes the appropriateness of RTDI policies and to implement RTDI policies towards the direction to appropriately match the development of NSTIS. Once RTDI policies are implemented without administrators' clear recognition of appropriateness, after being implemented, the RTDI policies may be in fact difficult to appropriately match the development of NSTIS.

On the basis of the initial and advanced queries of the second research question, we establish our second research question as the following:

**Research question 2: How does the horizontal coordination between actors influence the consistencies and appropriateness of RTDI policies? The actors refer to both elected politicians and administrators.**

Besides the horizontal coordination, the vertical coordination between elected politicians and administrators also deeply influences the consistencies and appropriateness of RTDI policies; yet, vertical coordination is difficult to be achieved. When policy objectives and policy instruments, which are decided by elected politicians, are delegated to administrators for implementation, according to Hogwood and Gunn (1997) these policy objectives and policy instruments are hard to be ‘perfectly’ executed by administrators.

There are at least two reasons to explain why vertical coordination between the top and the down is difficult. First, as analyzed by Lindblom and Woodhouse (1993:69, 70), within the large bureaucracies, compared with the vast scope of administrators’ activities, elected politicians have only limited time which can be devoted to supervise the implementation of policies. While administrators, as observed by Almond et al (1996: 135), do many adjustments of policies, the majority of administrative adjustments are out of the scrutiny of elected politicians. Even if policy objectives and policy instruments are distorted when implemented, elected politicians are not able to fix the distortion spontaneously. Moreover, administrators have their own ‘organizational inertia’ which we define as the situation that administrators get used to the administrative routines too much and avoid to accept new changes. As described by Elmore (1997: 249), even if elected politicians intend to bring major changes in policies, these policies frequently suffer the implementation failure because the administrators keep doing what they did before. In the context of RTDI policies, we assume if elected politicians expect to make changes for RTDI policies, elected politicians must give administrators sufficient incentive to adjust and to implement these changes, or every new change of RTDI policies is likely to be implemented by bureaucratic routines and will most probably suffer

implementation failure.

However, the existing literature which discusses the vertical coordination between elected politicians and administrators provides no clear linkage between the vertical coordination and the consistencies of RTDI policies and no clear linkage between the vertical coordination and the appropriateness of RTDI policies. Since there are no direct linkages found within the existing literature, we get our third research question:

**Research question 3: How does vertical coordination between elected politicians and administrators influence the consistencies and appropriateness of RTDI policies?**

We assume if the vertical coordination between elected politicians and administrators is difficult to achieve, even if the policy objectives of every RTDI policy decided by elected politicians are vertically consistent with the general policy objectives of the whole government, the administrators may implement policies towards the directions which are not vertically complementary or may even be contradictory to the general policy objectives. Furthermore, even if the elected politicians have coordinated the policy objectives and the policy instruments of a set of interrelated RTDI policies to be horizontally complementary with each other, administrators may implement these policies towards the directions which are not horizontally complementary with even contradictory to other policy goals. In addition, we assume if vertical coordination is difficult to be achieved, even if the policy objectives and policy instruments decided by the elected politicians are appropriate, after being implemented by administrators the policies may be unable to match the development of NSTIS.

### 3.2.2 Research questions for the variable outside the government

Our research question for variables outside the government is mainly established upon the research of interest groups and scientists. According to the analysis of Kingdon (2003:45), actors outside the government refer to the participants who are without formal government positions but look into and involve in the policy - making process. These participants include interest groups, researchers and academics, media, parties and so on. However, not all participants are involved in the network of governance. We assume only the participants who perceive that their interests are influenced by policies are policy stakeholders. Moreover, since these policy stakeholders are external to the government, we also refer them as external stakeholders. Since the existing literature discussed in Chapter 2 has recognized the interest groups and academics as the most important external stakeholders, in this section we only discuss the characters of these two stakeholder groups.

Business interest groups which consist of companies are one of the most active external stakeholders involved in the policy - making process. The scholars of interest group research have high consensus that the incentives for interest groups to involve in the policy - making process is out of these groups' self - interests. For example, Chubb (1983: 22) describes that interest groups participate in the policy - making process in order to secure their benefits from government policies. Bennesen and Feldmann (2002:920) share similar opinions and describe that interest groups lobby the government in order to promote policies which fit their interests. Scott and Cornelius (2004: 36) also express that interest groups participate in the policy - making process in order to avoid policies which threaten and infringe their own interests.

The capabilities of interest groups to influence policies are different from one another. As depicted by Hrebenar and Scott (1982: 32), the potential lobbying strength of an interest group is influenced by its memberships. High respect, prestige and the status of memberships can be the key to the special access to policy makers. Scott (1997: 328-330) has more detailed description of the factors which influence the capabilities of interest groups. Not only the size of memberships, but also other characters of a group would increase its influence in the policy - making process. For example, a group with more financial resources, higher capabilities to build coalition with other groups, with longer history and better access to congressmen or policy makers is more influential to affect the policy preferences than others. Moreover, the ways the government is organized also influence the capabilities of interest groups to affect the policies. May et al (2005) compare the participation of interest groups in the policy - making process of Arctic policies in Canada with those in the United States. The authors conclude that the presidential polity of the United States in fact gives interest groups more opportunities to effect on the policies than the parliamentary polity of Canada. Steinmo and Watts (1995) share a similar perspective. Through analyzing the empirical case of the national health insurance in the United States, the two authors conclude that the presidential polity which allows interest groups to influence policies through lobbying the congress yields enormous power to interest groups. In short, the capabilities of interest groups to influence policies are different due to the unequal resources of each interest group and the different organizations of the government. Because of the divergent interests of the industry, the stronger voices among interest groups presented to the government do not always represent the general interests of the whole industry, but partial interests of particular larger and richer companies only.

In the context of RTDI policies, according to May et al (2005) participations



of interest groups in the policy - making process are able to positively increase government's understanding towards the interests of the whole sector and contribute to the coherence of policies or negatively affect policies in adverse. While Inzelt (2008) uses the empirical case of Hungary to explain how does the involvement of the private sector positively contribute to the government's policy - learning process of STI policies, Moguee (1988: 41) uses the empirical experiences of the United States' regulatory, tax and antitrust policies to argue that the diversity and the power of interest groups make it difficult to achieve the necessary consensus of establishing consistent innovation policies and stimulating innovations which are beneficial to all affected parties.

Based on the discussions on interest groups presented above, here we get the initial query of our fourth research question: how does the involvement of interest groups influence the consistencies and appropriateness of RTDI policies? We assume only the 'suitable involvement' of business interest groups should have positive influence on the consistencies and appropriateness of RTDI policies. What we define as 'suitable involvement' of business interest groups refers to the situation that the involved interest groups are able to represent the general interests of the whole industry and help the government to promote consistent and appropriate RTDI policies which match the development of the whole industry, rather than particular companies only. If the interest groups involved in the policy - making process are able to present the general interests of the whole industry to all elected politicians, congressmen and administrators, the involvement of interest groups would positively help the government as a whole to promote vertically and horizontally consistent policies. In addition, we also assume if interest groups are able to push the government to link the interests of the whole industry to RTDI policies, the involvement of these interest groups would ensure that the RTDI policies are decided and implemented with the

full knowledge about the conditions of the whole industry. Therefore, the likelihood of the appropriateness of the RTDI policies may increase and the involvement of these interest groups would increase the appropriateness of RTDI policies which match the development of NSTIS.

Besides interest groups, academics, who are also referred to be natural or social scientists, are other active external stakeholders involved in the RTDI policy - making process. As described by many scholars, scientists participate in RTDI policy - making process out of self - interests. For example, Tournon (1993: 91) depicts that scientists are heavily laced with professional self - interests. They are ambitious promoters and advisers of RTDI policies who seek to manipulate the decision - making process to get their projects approved and funded. Schooler (1971:218) and Hove (2007: 813) share similar opinion with Tournon that scientists – just as firms – are self - interested actors.

The capabilities of scientists to influence the RTDI policy - making process are different from one another. According to Schooler (1971:7-8), there are several factors to shape the influence of scientists in the policy - making process. The scientists who do not face the hostile competition of other scientists belong to a particular scientific field, have a higher degree of expertise in this field and therefore have higher influence than others. Schooler (1971:218) further points out that the scientific community is not unified but fragmented, pluralistic and constantly divided. In addition, the ways the government is organized also influence the capabilities of scientists to affect the policies. As depicted by Rich (2005:204-220), in the presidential polity the influence of scientists is high because they are able to affect policies from both sides of policy makers and the congress. In other words, as with industry, the capabilities of different scientists to influence the policies are different because of the unequal influence of each scientist

and the different ways for the government to be organized. Due to the fragmentation of the scientific community, the stronger voices among the scientific community do not necessarily represent the general interest of the whole scientific community, but the partial interests of particular scientists in a particular field only.

The participations of scientists in the policy - making process are able to positively increase or negatively reduce the government's understanding towards the interests of the whole scientific community. Pollitt (2006:260-261) considers scientists' positive impacts on policies because scientists play the roles to provide innovative solutions to existing problems, to help policy makers to clarify policy issues and so on. On the other hand, Tournon (1993:91) and Barker and Peters (1993: 9) point out the negative impact of scientists on RTDI policies. Tournon uses the empirical examples of French and German governments' policies of funding radiation facilities to explain how scientific advisors lead the states to be 'blind investors' in funding research. Barker and Peters also describe that if a government chooses to accept the status quo of advice too readily it harms the government's policy at an earlier stage of scientific development.

Based on the analysis about the role of scientists in the policy-making process as seen in the existing literature, here we get an advanced query of our fourth research question: how does the involvement of scientists influences the consistencies and appropriateness of RTDI policies? We assume only the 'suitable involvement' of academics would positively influence the consistencies and appropriateness of RTDI policies. The 'suitable involvement' of academics is defined as the situation that the involved academics are able to represent the general interests of the whole scientific community and help the government to promote consistent and appropriate RTDI policies which match the development of the whole

scientific community, rather than particular scientists only. From our point of view, if the scientists involved in the RTDI policy - making process could present the general interests of the whole scientific community to all related actors inside the government, the involvement of scientists would positively support the government and would promote the RTDI policies which are vertically and horizontally consistent. In addition, we also assume, if scientists could push the interests of the whole scientific community to link to RTDI policies, the involvement of these scientists could help the government to decide and implement RTDI policies with full knowledge of scientific community and therefore positively contribute to the appropriateness of RTDI policies.

According to our initial and advanced queries of the fourth research question, here we establish our fourth research question:

**Research question 4: How does the involvement of external stakeholders influence the consistencies and appropriateness of RTDI policies? The external stakeholders refer to both interest groups and scientists.**

### 3.2.3 Brief conclusion of the section

In this section we set up four research questions for the variables which are assumed to influence the consistencies and appropriateness of RTDI policies. Among the four queried variables, three variables are inside the government, i.e. polity, horizontal and vertical coordination of actors, while one variable is outside the government, the involvement of external stakeholders. While we refer the four queried variables to be the independent variables, we refer the two variables, consistency and appropriateness of RTDI policies, to be dependent variables. However, in the next section, we are going to link the

four independent variables to different stages of the RTDI policy - making process.

### **3.3 The conceptual framework of the RTDI policy - making process**

The purpose of this section is to identify different stages of RTDI policy - making process and to conceptualize the idea that each stage is influenced by different independent variables established above. We assume different stages of RTDI policy - making process are influenced by different independent variables because the governance of each stage is different. As we have described in section 3.1 in the conceptual framework shown in Figure 3.1, we only divided the RTDI policy - making process into four stages. Each of the stages is discussed in the following sections.

#### **3.3.1 The stage of agenda - setting**

The stage of agenda - setting, according to Kingdon (2003:196), is the stage for elected politicians to decide the agendas of policy proposals and bills. As we discussed in section 3.2.1.2, among the elected politicians ministers play key roles for the selection of policy agendas.

However, the different modes of interactions between elected politicians and external stakeholders have different impacts on the agendas of RTDI policies. As described by Smith et al (2006:284) and Kingdon (1993:49), the interactions between elected politicians and interest groups deeply influence the selection of RTDI policy agendas. On the other hand, as described by Pollitt (2006: 259, 262), Topf (1993:109) and Hove (2007:811), the interactions between elected politicians and academics also deeply influence the selection of RTDI policy agendas. Moreover, besides the direct interactions with external stakeholders, elected politicians, as described by

Chelimsky (1987), also indirectly learn the feedbacks and interests of external stakeholders through the evaluation of policies which have been previously promoted.

Indeed, we assume the stage of agenda - setting is the process of mutual persuasion between elected politicians and external stakeholders. While elected politicians persuade external stakeholders to accept their agendas, adopt new changes of policies, even sacrifice parts of the interests of these external stakeholders, external stakeholders also persuade elected politicians to link their own interests to RTDI policy agendas to maximize their own interests. The different extent for the interests of external stakeholders to be suitably involved in the RTDI policy agendas affects the extent for RTDI policy proposals and bills to be consistent with each other and appropriately match the development of NSTIS.

Furthermore, as discussed in section 3.2.1.2 different elected politicians belonging to different ministries, especially ministers, have different priorities for the selections of RTDI policy agendas, and it is important for different ministries to form a set of consistent RTDI policy proposals and bills through horizontal inter - ministerial coordination. The administrators, as described by Lindblom and Woodhouse (1993: 59), are frequently instructed by the elected politicians to draft up the policy agendas. However, since the administrators only draft up the agendas under the instructions of the elected politicians and it is the elected politicians who play the role to authorize the selections of the policy agendas, we consider that it is the elected politicians to play the most important role in deciding the agendas of RTDI policy proposals and bills. We assume that the different extent for the elected politicians of different ministries to horizontally coordinate with each other affects the extent for the cabinet as a whole to make consistent RTDI policy proposals and bills to appropriately match the development of

NSTIS.

In sum, the stage of agenda - setting is influenced by the interactions between elected politicians and the interactions between elected politicians and external stakeholders. Since elected politicians and external stakeholders are the most important actors to influence the stage, among our four independent variables, the horizontal coordination and the suitable involvement of external stakeholders are assumed to be the main independent variables which influence the consistencies and appropriateness of RTDI policies in this stage. How do the horizontal inter - ministerial coordination between elected politicians and the involvement of external stakeholders influence the consistencies and appropriateness of RTDI policies? We will discuss the question in Chapter 7 when we review our empirical cases of Taiwan.

### 3.3.3 The stage of deciding

The stage of deciding, according to our discussion in section 2.3.3.4, is the stage for congressmen to authorize RTDI policy proposals to become formal policies and to legislate bills to become laws. Since our empirical example belongs to the divided government, in this section we only discuss the stage of deciding of RTDI policies in the context of divided government. As described by Cox and McCubbins (2005: 1-16) and Weatherford (1994), under the divided government the schedules of the congress are controlled by the opposition party which has different policy preferences and in most cases disagrees with the president's policy priorities. The more the president is able to persuade the congressmen of the opposition party, the more the president is able to get his / her policies approved by the congress and to maintain the consistencies of his / her policies. The more the president is able to form a consensus with the congress for the appropriateness of RTDI

policies, the higher the possibilities for the divided government as a whole to make appropriate RTDI policies which match the development of NSTIS.

Furthermore, as we described in section 3.2.2 it is the interaction between the congressmen of the opposition party and external stakeholders that influence the judgment of the congressmen towards particular policy proposals and bills. According to Greenwald (1977: 194) and Goldstein (1999:36), the interactions between congressmen and interest groups deeply influence the judgment of congressmen towards particular policy proposals and bills. On the other hand, as described by Schooler (1971: 259-260) and Ricci (1993:165), the interactions between congressmen and academics also deeply influence the judgment of congressmen towards particular policy proposals and bills. In other words, as in the stage of agenda – setting, both interest groups and academics have access and influence the consistencies and appropriateness of RTDI policies.

In sum, the stage of deciding is influenced by the interactions between the congressmen and the president, as well as the interactions between the congressmen and external stakeholders. Since congressmen and external stakeholders are the most important actors to influence the stage, among our four independent variables, divided government and the involvement of external stakeholders are assumed to be the main variables which influence the consistencies and appropriateness of RTDI policies in this stage. How do the divided government and the suitable involvement of external stakeholders influence the consistencies and appropriateness of RTDI policies? We will discuss this question in Chapter 7.

### 3.3.4 The stage of implementation

The stage of implementation, according to Lane (1997), is the stage for



administrators to implement policies and to realize the policy objectives. As we discussed in section 3.2.1.2, administrators are difficult to horizontally coordinate with each other and tend to implement RTDI policies towards the directions which maximize their own interests. Yet, the directions may be neither consistent nor appropriate to the development of NSTIS. Moreover, even if RTDI policies decided by elected politicians are consistent and appropriate, administrators are difficult to ‘perfectly’ implement these policies because of their difficulties to vertically coordinate with elected politicians. Although the elected politicians may be able to correct the distortion of implementation, in fact, as described by Lindblom and Woodhouse (1993: 69), compared with the vast scope of administrative activities, the elected politicians only have limited time to devote to monitor the implementation of policies. Therefore, we consider that the administrators play the most important role in the implementation of RTDI policies. However, we assume not all RTDI policies get the same degree of implementation. Besides the vertical and horizontal coordination, different modes of interactions between administrators and external stakeholders make some RTDI policies better implemented than others.

Administrators interact with external stakeholders frequently during the implementation of policies. As depicted by Sabatier (1993) and Chubb (1983: 220), the interactions between administrators and interest groups deeply influence the extent for RTDI policies to be implemented. On the other hand, as described by Finegold (1995:30) and Pollitt (2006:262), the interactions between administrators and academics also deeply influence the extent for RTDI policies to be implemented. The involvement of external stakeholders in fact influences the directions of the implementation of RTDI policies.

In summary, the stage of implementation is influenced by the interactions

between administrators and elected politicians, the interactions between administrators, as well as the interactions between administrators and external stakeholders. Since the administrators on the agency level and external stakeholders are the most important actors to influence the stage, among our four independent variables, horizontal coordination, vertical coordination and the involvement of external stakeholders are assumed to be the main variables which influence the consistencies and appropriateness of RTDI policies in this stage. How do the horizontally inter - departmental coordination between administrators, the vertical coordination between elected politicians and administrators and the involvement of external stakeholders influence the consistencies and appropriateness of RTDI policies? We will discuss the question in Chapter 7.

### 3.3.5 The stage of evaluation

The stage of evaluation, according to Meyer-Krahmer (1988:121), Arnold (2004) and Miles and Cunningham (2006: 162), is the stage to examine and assess the effects of RTDI policies on the development of innovation systems. As depicted by Palumbo (1983b), the ideal evaluation should be done by neutral evaluators and as described by Parsons (1995:569), through the feedback loop, the results of evaluation become the new inputs of policy agendas in the new cycle. We assume if evaluations are able to be done properly and truly reflect the responses of external stakeholders towards policies, they contribute to the consistencies and appropriateness of new RTDI policies which are made in the new policy cycle.

However, in the stage of evaluation, since all of the RTDI policies are already implemented, we assume none of our independent variables are able to change the contents of RTDI policies to be more consistent or appropriately match the development of NSTIS. Yet, the proper evaluation

of policies will contribute to the new RTDI policies which are expected to be more consistent and appropriately match the development of NSTIS.

### **3.4 Conclusion**

In this chapter, we established the research questions for the whole thesis and the conceptual framework of the RTDI policy - making process. The research questions and the conceptual framework are established upon four independent variables and two dependent variables. The four independent variables are divided government, the horizontal coordination, the vertical coordination and the involvement of external stakeholders. The two dependent variables are consistencies and appropriateness of RTDI policies. In different stages of the RTDI policy - making process, there are different independent variables which have different impacts on the two dependent variables. How do the four independent variables influence the two dependent variables in different stages of the RTDI policy - making process? In order to answer the question we are going to apply the conceptual framework for analyzing the empirical cases in Taiwan in Chapter 6. Nevertheless, before opening the discussions of the empirical cases we first introduce our methodology for collecting the empirical data in the next chapter, Chapter 4.

## **Chapter 4 Methodology**

### **4.1 Introduction**

This chapter introduces the research methodology chosen and the research techniques designed to collect the empirical data in order to answer our research questions. In Chapter 2 we have established the concept of NSTIS and have explained the reasons why we choose the Taiwanese biotechnology and related sectoral policies as our empirical cases. Moreover, in Chapter 3 we have established the research questions and the conceptual framework of the whole thesis. Before we start to analyze the empirical cases of Taiwan through the perspectives of NSTIS and our conceptual framework in Chapter 5 and Chapter 6, in this chapter we firstly introduce our research design and the methods used to collect the empirical data.

Both the research methodology and research techniques intend to operationalize our definition of the two dependent variables of the conceptual framework, the consistencies and the appropriateness of RTDI policies. The consistencies of the RTDI policies, as defined in section 3.1, refer to both the vertical and horizontal consistencies. The vertical consistencies are defined by two aspects. The policy objectives of every RTDI policy are vertically complementary with the general policy objectives of the whole government; every RTDI policy is implemented towards the directions which are vertically complementary with these general policy objectives. The horizontal consistency refers to the conditions that the policy objectives and the policy instruments of a set of interrelated policies are not horizontally contradictory, even ideally complementary with each other. According to our definition of policy consistencies, empirical data are collected in order to identify the general policy objectives of the Taiwanese government, as well as the vertical and horizontal consistencies

between different policies. Moreover, the appropriate RTDI policies are defined as the policies which foster the development of a specific NSTIS in terms of supporting the underlying logic of knowledge accumulation and exploitation in a particular technological field, clustering actors' networks, and encouraging the production and innovation of a particular set of products. On the basis of the definition of the appropriateness, our data are collected in order to understand the appropriateness of the Taiwanese biotechnology and related sectoral policies on the development of the three biotechnology related NSTIS.

The chapter is structured in the following way. Section 4.2 discusses the research design, including the rationale of case studies, the analytical units and the selection of the cases. Section 4.3 describes the methods for the collection of data. Section 4.4 introduces the presentation and analysis of the data. Section 4.5 is the conclusion of the chapter.

## **4.2 Research design**

### **4.2.1 The rationale for case studies and multiple case study design**

This thesis adopts the case study as the most important methodology because we consider that the case study is able to properly address our research questions. As described by Yin (2009: 8), the research methodology should be chosen according to the types of research questions. Although there are a number of methodologies used in the social science research such as surveys, experiments and case studies, for the research questions which query 'how' and 'why', the case study is one of the most suitable methodologies to use. Since all our four research questions focus on 'how' the four independent variables influence the consistencies and appropriateness of the RTDI policies, we consider the case study is the most

suitable methodology to be adopted.

We adopt the research design of multiple case studies. As described by Herriot and Firestone (1983), the evidence derived from multiple case studies is usually recognized to be more persuasive than the single case study, and the overall research is thus regarded as more robust. We fully agree with Herriot and Firestone. In order to increase the persuasiveness of our thesis and fully explore the dynamics of the policy - making process, we adopt the 'two case design'. The analytical unit is introduced in the next section.

#### 4.2.2 The analytical unit and the selection of cases

The analytical unit used in the thesis is the policy. As described by Yin (2009: 29), the analytical units are selected according to the research topic. The possible analytical units include single individuals, programs, decision and so on. Among the possible analytical units, the policies are frequently chosen as analytical units for the comparisons with each other. For example, Ammons et al (2001) compare the performance of three programs implemented by the government of the United States, and Fernandez and Fabricant (2000) also compare two programs implemented by the government of Florida to support children. Since our focus is the policy - making process of RTDI policies, we consider the policies are the most suitable analytical units. Each policy is an analytical unit. In our 'two case design', each of the two cases refers to a specific policy.

In our 'two case design', the two cases are the National Program and the regulation policies; however, each of the two cases contains two to three mini - cases. In the case of the National Program there are three mini-cases, i.e. two National Programs directed to support the development of the

pharmaceutical sector and one National Program directed to support the development of the agricultural sector. In addition, the case of the regulation policies contains two mini - cases, the Law and the Management Act. Indeed, as we are going to show in Chapter 6 there were many biotechnology and related sectoral policies promoted by the Taiwanese government between 2000 and 2008. Instead of discussing every single policy, we only choose two cases and discuss them deeply. The National Program and the regulation policies are chosen as the two cases because of two reasons. First, both of the policies were promoted across different sectors. The National Programs were promoted to support the pharmaceutical and the agricultural sectors, and the regulation policies were directed towards all the three biotechnology and related sectors. Since a part of the theme of our thesis is the linkage between the policy - making process and the contents of RTDI policies, through comparing the two cases we are able to observe how the policy - making process embedded in the different context of NSTIS is shaped and how the shaped policy - making process makes the contents of RTDI policies towards different sectors to be different from each other. Second, both of the two policies have been promoted from 2000 to 2008. The appropriateness of each of the two policies has been continuously accumulated during the eight years. Since a part of the theme of our thesis is to analyze the appropriateness of RTDI policies, the two policies provide us excellent empirical examples to observe the accumulated appropriateness of both and to analyze it.

Five kinds of actors involved in the policy - making process of the two policies were approached and asked to identify their roles in the different stages of the two policies. The five kinds of actors, according to our discussion in Chapter 3, are represented by: three kinds of actors inside the government (elected politicians, congressmen of the opposition party and administrators) and two kinds of actors external to the government

(companies and scientists). The majority of interviewees are the five kinds of actors who have involved in the policy - making process of our two cases. However, we don't constrain ourselves in interviewing the actors involved in the two policies only. In order to explore the deeper underlying linkage between the two policies and other interrelated policies, we also interviewed several actors who were deeply involved in other interrelated policies but only indirectly involved in the policy - making process of the two policies, such as the actors involved in the business park policies which were the interrelated policies of the National Programs.

### **4.3 The collection of data**

The case studies, as described by Yanow (2007:422) and Hakim (2000:61), are based on multiple sources of data, including qualitative in-depth interviews, the analysis of documents and the quantitative data. Our case studies on the two policies are also based on multiple sources. Our methods to collect the first - hand resources and the second - hand resources are introduced below.

#### **4.3.1 The methods to collect first - hand resources**

##### **4.3.1.1 Interviews**

We adopt the qualitative methods to collect the first - hand resources. As described by Hakim (2000:34), the qualitative resources concern about actors' accounts of their attitudes, motivations, and behaviours. Sadovnik (2007:433) also describes that qualitative research is useful for describing complex phenomena in the public policies. However, from Yang's perspectives (2007: 349), the quantitative methods are used for demonstrating the relationships between the policy designs and policy



outcomes, for evaluating the magnitude of the effects of policies and for finding better alternatives. Since the focus of this thesis is about the actors' interactions, motivations and their behaviours in the policy - making process, we consider that the qualitative research methods are the most suitable methods for us to collect the first - hand resources. We also concern with the appropriateness of policies which, as we have describe in section 3.1, is more suitable to be demonstrated by the quantitative methods. The quantitative economic indicators which show the short-term effects of policies would help us to judge the extent for the policies to appropriately match the development of NSTIS. However, since some first - hand resources, such as the government documents, already provide the reliable quantitative data, we adopt the quantitative data from these first - hand resources rather than gathering the data by ourselves.

In - depth personal interview is the qualitative method for us to collect data. As recognized by McNabb (2002:94, 294), the in - depth personal interview is used frequently by the researchers of public policies to probe the detailed information. We also consider two functional reasons to conduct the in - depth interviews. First of all, all the interviewees we tended to interview, such as the elected politicians, congressmen and the managers in companies, are usually extremely busy. Personal interviews are more feasible to fit interviewees' busy schedules and to arrange a suitable time for interviews. Second, some information belonging to the interviewees may be sensitive, such as the interactions between the congressmen and companies. The personal interviews are the ideal conditions to secure the sensitive information of the interviewees. Under the conditions, the interviewees may be more willing to uncover their real intentions. Because of the two reasons in our thesis the in - depth personal interview is the main method to collect the qualitative data.

The identification of the interviewees is through two processes, the document based analysis and the snowballing sample survey. As suggested by Carlsson (2000), there are three methods to identify interviewees: (1) using proxy populations of a well defined sector, (2) document based analysis, and (3) snowballing sample survey. We adopt the document based analysis as our main method and adopt the snowballing sample survey as our minor method. The document based analysis is adopted as our main method to identify the interviewees. In the cases of both the National Programs and the regulation policies, many actors participated in the two policies are clearly listed on the official websites of these policies or on the official website of the implementation bodies of these policies. For example, each of the three National Programs has clearly listed the names of the elected politicians, the administrators, the academic representatives and the pharmaceutical and agricultural representatives who were involved in the policy - making process of the National Programs. Moreover, the meeting records of the Legislative Yuan also show the congressmen who have monitored the policy proposals of the National Programs and legislated the bills of the regulation policies. In fact, the official documents related to the two policies already help us to identify the majority of actors involved in the policy - making process of the two policies. Nevertheless, there are still some potential interviewees who are not listed on the documents. For these interviewees we use the snowballing sample survey to identify them. Since the network of governance of the two policies is relatively small and many interviewees know each other, the snowball technique is also effective. For example, the pharmaceutical and agricultural companies which transferred biotechnologies funded by the National Programs are not listed in the documents. Therefore, we ask the elected politicians and the administrators of the National Programs to help us identify these companies.

We have in sum interviewed 36 interviewees, and Table 4.1 shows the name

lists of our interviewees and their positions. As shown in the table there are five kinds of interviewees, the elected politicians, the congressmen of the opposition party, the administrators, the companies and the academics. In fact, the elected politicians and the administrators are selected from the ones who have decided or implemented the two policies. Since there are four ministries involved in the policy - making process of the two policies (the National Science Council, the Ministry of Economic Affairs, the Department of Health, the Council of Agriculture), we select our interviewees equally from the four ministries and make sure that the mission and attitudes of the actors of the four ministries are equally considered. Moreover, the congressmen of the opposition party, Kuomintang, are selected among the ones who have reviewed the policy proposals of the National Programs or authorized the bills of regulation policies from 2000 to 2008. In addition, academics are selected from the ones who have participated in the policy - making process of the National Programs, and the companies are selected according to the ecology of the three biotechnology related sectors. For the pharmaceutical sector, since both MNCs and local SMEs were involved in the policy - making process of the National Programs or the regulation policies and there were more SMEs playing active roles in the two policies, we interviewed 4 SMEs and 2 MNCs. For the agricultural sector, as long as the sector is composed of a large public company and local private SMEs, we interviewed 1 large public company and 5 SMEs. Moreover, for the medical device sector, since the sector is composed of local SMEs and the companies of Class II medical devices are especially active in the policy - making process of the regulation policies, we interviewed 3 local SMEs of Class II medical device.

All our interviews were semi - structured and guided by our conceptual framework. The semi - structured interviews were conducted because, as described by Legard et al (2006), they provide sufficient flexibility to let

Table 4.1 Interviewees in Taiwan				
Name	Code	Organization	Position	Dates of interviewing
<b>Elected politicians</b>				
Lee, Chong-chou	Intex1	Science and Technology Advisory Group	Director of Biotechnology Office	20/01/2009
Anonymous	Intex2	National Science Council	Ex-minister	15/05/2008
Anonymous	Intex3	Department of Health	Ex-minister	23/10/2008
Anonymous	Intex4	National Research Program for Genetic Medicine	Leader	19/04/2010
Anonymous	Intex5	National Science and Technology Program for Biotechnology and Pharmaceuticals	Leader	30/10/2008
Anonymous	Intex6	National Science and Technology Program for Bio agriculture	Leader	06/02/2009
<b>Congressmen of opposition party</b>				
Tsao, Shou-min	Intleg1	Legislative Yuan	Ex-congressmen of Kuomintang	08/05/2008
Lai, Shyh-Bao	Intleg2	Legislative Yuan	Congressmen of Kuomintang	03/11/2008
Anonymous	Intleg3	Legislative Yuan	Ex-congressmen of Kuomintang	05/03/2009
<b>Administrators</b>				
Chen, Jen-pin	Intad1	Pintung Agricultural Biotechnology, Council of Agriculture	Director General	19/11/2008
Chen, Chei-Hsiang	Intad2	One-stop-service for Biotechnology Industry, Ministry of Economic Affairs	Director	13/05/2008
Anonymous	Intad3	Incubator Center of Genomics, Academic Sinica	Associate specialist	27/10/2008
Anonymous	Intad4	National Research Program for Genetic Medicine	Project manager	13/04/2010
Anonymous	Intad5	National Science and Technology Program for Biotechnology and Pharmaceuticals	Officer	03/11/2008
Anonymous	Intad6	Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture	High level manager	09/06/2010
Chang, Ming-Lang	Intad7	Agriculture and Food Agency, Council of Agriculture	Project Director, Seed and Seedling Section	08/06/2010
Anonymous	Intad8	Food and Drug Administration, Department of Health (previously Bureau of Pharmaceutical Affairs)	High level manager	07/07/2010
<b>Federation</b>				
Anonymous	Intfed1	Secretary	Taiwan Bio Industry Organization	07/05/2008
<b>Firms</b>				
Anonymous	Intcommd1	Medical Device SME A	Assistant vice president	22/01/2009
Anonymous	Intcommd2	Medical Device SME B	Director, R&D Division	20/01/2009
Anonymous	Intcommd3	Medical Device SME C	Director of R&D Center	10/02/2009
Hsu, Ming-Chu	Intcomph1	Taigen Biotechnology	Chief Executive Officer	20/04/2010
Chien, Du-shieng	Intcomph2	Sunten Phytotech	Ex- Chief Executive Officer	16/04/2010
Tseng, Yun-long	Intcomph3	Taiwan Liposome Company	Director, R&D	01/19/2009
Anonymous	Intcomph4	Pharmaceutical SME A	President, R&D	03/02/2009
Anonymous	Intcomph5	Bayer Healthcare (Bayer Schering Pharma)	Head of general medicine	11/06/2008
Anonymous	Intcomph6	Pharmaceutical MNC A	Head of general medicine	01/09/2009
Jiang, Peter	Intcomag1	Hanaqua	Chief Executive Officer	29/10/2008
Anonymous	Intcomag2	Agricultural public company A	Director, R&D	08/04/2010
Anonymous	Intcomag3	Agricultural SME A	Chief Executive Officer	30/04/2010
Anonymous	Intcomag4	Agricultural SME B	Chief Executive Officer	29/04/2010
Tseng, Ming-Pao	Intcomag5	Advanced Green Biotechnology	Assistant Manager	12/26/2008
Lin, Fisher	Intcomag6	Taikong Corporation	Vice president R&D	10/02/2009
<b>Academics</b>				
Sun, Julie	Intac1	Taiwan Institute of Economic Research	Chief of Biotechnology Industry Study Center	08/05/2008
Anonymous	Intac2	National Taiwan University	Professor of Horticulture	24/10/2008
Wu, Yang-Chang	Intac3	Kaohsiung Medical University	Professor of natural products	23/02/2009

important issues to emerge while remain within the wild - range of parameters of the research boundary. In practice, we included a number of structured questions in each of the interviews and several additional questions which were tailored to the characters of the interviewees to make sure that each interview was able to add to the depth of our analysis. The initial questions asked the interviewees to provide a general overview of their roles in the two policies. The main part of the questions asked the interviewees to describe their interactions with other actors in the different stages of the policy - making process such as the occasions, the rationale and the modes of interactions. The interviewees were usually asked to illustrate some concrete examples. In addition, tailored questions were asked about each interviewee's accounts of his / her attitudes, motivations and behaviours in the policy - making process of the two policies.

All the interviews are recorded on MP3 players or computer software and typed to be transcripts. Each interview lasted between 30 minutes to 2 hours. The key information given by the interviewees was re-confirmed with the interviewees and analyzed together with other first - hand resources which are discussed in the next section.

#### 4.3.1.2 Government documents

The documents published by the Taiwanese government are very important for our analysis of the two cases. As described by McNabb (2002: 295), the study of the documents is undertaken to supplement the information acquired from interviews. According to our research theme, there are four kinds of documents which were published by the Taiwanese government that are very important for our analysis.

First of all, the official websites of the three National Programs and the ones

of the implementation bodies of the regulation policies are very important sources. Through these official websites we are able to find rich first - hand resources related to these two policies such as the name list of the actors involved in the two policies, the detailed contents of these two policies and the detailed clauses of the Law and the Management Act. These official websites not only support us to identify the proper interviewees, but also assist us to recognize the details of the two policies in terms of the concrete policy objectives and policy instruments.

Second, the yearbooks of the biotechnology and related sectors, which are edited by different ministries, are essential. The Ministry of Economic Affairs would publish three important yearbooks each year from 2000 to 2008, i.e. 'Year Book of Pharmaceutical Industry', 'Year Book of Medical Device' and 'Biotechnology Industry in Taiwan'. The three series of yearbooks have detailed records of the Taiwanese pharmaceutical and medical device sectoral development, as well as the technological achievements of the Taiwanese biotechnologies during 2000 to 2008. However, in the yearbooks edited by the Ministry of Economic Affairs, the agricultural sector only weighted a minor part in the yearbooks. Moreover, the National Science Council has published a series of 'Science and Technology Yearbook' from 2001 to 2008. The Yearbook has recorded the overall development of science and technologies in Taiwan. Since biotechnology is a part of the science and technology development in Taiwan, the development of biotechnology is also recorded. The Yearbook edited by the National Science Council also records some of the biotechnology and related sectoral policies promoted by the National Science Council, such as the progress and achievements of the National Programs. Furthermore, the National Science Council also irregularly publishes documents to discuss the Taiwanese agricultural policies and technological achievements of agriculture, like the 'Strategic planning on

the development of Taiwan agricultural biotechnology industry' (STRIC, 2006). However, there is not a yearbook especially edited for the agriculture sector.

Third, the meeting records of Legislative Yuan from 2000 to 2008 are also important. They are usually published on the official website of the Legislative Yuan. Through the meeting records of Legislative Yuan, the interactions between the elected politicians and the congressmen of the opposition party are able to be clearly understood. Especially when we tend to analyze the process of deciding and the authorization of the two policies, the meeting records play an important role in our analysis.

Fourth, the historical archives which were published by the Taiwanese government during the 1950s to the 1990s played an important role for us to understand the historical evolution of the three Taiwanese biotechnology related NSTIS. The historical archives are usually the pieces of policy proposals, the documents exchanged between the universities and the government, as well as the formally decided policies. These pieces of archives extensively contribute to our understanding towards the history of the three biotechnology related NSTIS, especially the historical evolution of the biotechnology and related sectoral policies, which is going to be further discussed in Chapter 5.

#### 4.3.2 The methods to collect second - hand resources

The second - hand resources play relatively minor roles in our research. As we have shown in Chapter 2 the literature related to the Taiwanese biotechnology and sectoral policies is very limited. Besides a few journal articles which we have discussed in Chapter 2, the most important second - hand resource is the historical records related to the three biotechnology

related NSTIS, such as the ‘The history of pharmacology in Taiwan’, ‘The history of Medical College in National Taiwan University’ and so on. We will further discuss the literature in Chapter 5.

#### **4.4 Conclusion**

The data collected according to the research design will be further analyzed in Chapter 5 and Chapter 6. While we use the historical archives to analyze the evolution of the three biotechnology related NSTIS in Chapter 5, in Chapter 6 we will intensively use the data collected from the interviews to analyze the policy - making process of the two policies.



## **Chapter 5 The history of the three biotechnology NSTIS in Taiwan**

### **5.1 Introduction**

In Chapter 2, we reviewed the three approaches of innovation systems, i.e. the national, the sectoral and the technological innovation systems. While the approaches of the national innovation system adopt the national border as the boundary of an innovation system, the approach of technological innovation system draws the boundary of the innovation system by a particular knowledge field, and the approach of sectoral innovation system recognises the innovation system boundary as a set of products. The configuration of the three innovation systems, as defined in Chapter 2, is the *national sectoral and technological innovation system* (NSTIS).

On the basis of our analysis of NSTIS in Chapter 2, in this chapter we will apply the concept of NSTIS for the analysis of the three biotechnology related NSTIS in Taiwan from 1945 to 2000. Biotechnology in Taiwan indeed co-evolved with different sectors in different modes. Each sector provided contrasting opportunities for the development of biotechnology and was supported by different types of policies. As we are going to show within this chapter, the governance of each of the three sectors was quite distinctive to each other. Through analyzing the history of the three biotechnology NSTIS, we expect to gain deeper understanding towards the different types of policies required by the different biotechnology related NSTIS. The historical background is especially important for us to judge the appropriateness of the biotechnology and related policies between 2000 and 2008.

We use the year 1945 and the year 1982 as the two milestones to divide the

history of each three NSTIS into two periods: from 1945 to 1982 and from 1982 to 2000. 1945 was the year for the Japanese government to officially return Taiwan to the government of the Republic of China (ROC). After 1945, Taiwan started to have its own independent history. The Taiwanese government announced its biotechnology related policies for the first time in 1982. After 1982, Taiwan started to have biotechnology related policies. Since the general history of Taiwan is essential for us to understand the evolution of the three NSTIS, we briefly discuss the general historical background of Taiwan below.

The formal name of Taiwan internationally is the Republic of China. From 1890 to 1945, Taiwan was colonised by Japan. After World War II, in 1945, as a defeated nation, Japan was forced to return Taiwan to the government of the Republic of China, led by Kuomintang. According to the international laws, Taiwan became a part of the Republic of China after 1945. However, soon after Taiwan was returned, Kuomintang lost its battles with the Chinese Communist Party in mainland China. In 1949, the Chinese Communist Party successfully set up the central government of the People's Republic of China (PRC) in Beijing, and in the same year, Kuomintang moved the central government of the Republic of China to Taipei, Taiwan. During 1949 to 1996, Taiwan was ruled by Kuomintang with one-party and a semi-autocratic system. In 1996, Taiwan had the first general presidential election and the first general congressional election. Since Kuomintang won both of the elections in 1996, Taiwan was continuously ruled by the one-party system until 2000.

This chapter discusses the history of the three biotechnology related NSTIS in turn. Section 5.2 portrays the development of the pharmaceutical NSTIS, and section 5.3 focuses on the agricultural NSTIS. The development of medical device NSTIS is discussed in section 5.4. Section 5.5 is the

conclusion of the chapter.

## **5.2 The evolution of the pharmaceutical sector**

### **5.2.1 From pre-1945 to 1982**

#### **5.2.1.1 Ecology of firms**

The pharmaceutical technology of Taiwan was originally introduced by Japan. Since 1931, some Japanese pharmaceutical companies set up factories in Taiwan to produce pharmaceutical intermediaries and supply the demands of the Japanese army. When Taiwan was returned to the Republic of China in 1945, there were 312 factories all over the island (Zheng, 2001: 195). The government of the Republic of China then unified the 312 factories to be one national pharmaceutical company, Taiwan Pharmaceutical Company (台灣省醫療物品公司). Later, because of the financial deficits, the Taiwan Pharmaceutical Company gradually sold all of its factories to different private firms (DCB, 2003: 208). The sector, which was once institutionally unified by the public sector, was then split by the private companies.

Local private companies were gradually developed, and some small local private pharmacies used the rough facilities to synthesise simple pharmaceutical intermediaries in their backyards since the colonisation of Japan (Zheng, 2001: 196). These small local pharmacies were gradually developed to be small family-operated factories. Moreover, since the government of the Republic of China moved its central government from China to Taiwan, some Chinese pharmaceutical companies also followed the government and relocated their factories in Taiwan around 1950. Both the original Taiwanese companies and the newly immigrated Chinese

companies were limited in employees and capitals. Some firms with higher capabilities were able to get technology transfers from the Japanese or German companies and manufactured the pharmaceutical intermediaries with higher qualities (Ding, 2001: 232). Yet, the majority of local companies had very limited capital and technological capabilities to develop complex products but manufactured low-end intermediaries that had high similarities. Besides manufacturing intermediaries, some local firms imported higher end intermediaries from abroad and processed them as generic medicines. However, whether it was the companies of pharmaceutical intermediaries or those of generic medicines, their products overlapped. The knowledge base of all these firms was chemical engineering, as biotechnology was not introduced to the pharmaceutical sector. In addition, because of the small size of these companies, they were unable to innovate or to export their products but competed with each other in the domestic market on a price-base. Knowledge transfer and collaboration between companies was minimal. Competition was the mainstream for the interactions of these companies.

Only after 1960, multinational pharmaceutical giants who were attracted by the government's policies and the low cost of manufacturing began to invest in Taiwan. Most of these MNCs were from Japan and the United States, such as Takeda Pharmaceuticals (from Japan) and Pfizer (from the United States). The MNCs brought advantageous manufacturing technologies to Taiwan, particularly the technologies of chemical engineering for pharmaceuticals. With the advantages of technologies and marketing capabilities, MNCs shared more than 50% of the domestic market (Zheng, 2001: 203).

A very minor sub-sector of the pharmaceutical sector was Chinese herbal medicine; the local SMEs that were moved from China were the pillars of

this sub-sector. In fact, during the colonisation of Japan, due to political reasons, the development of Chinese herbal medicines was strictly constrained. Only after 1949, when some Chinese herbal pharmacies followed the government of the Republic of China and moved their pharmacies from China to Taiwan, Taiwan started to use Chinese herbal medicines. Later, these Chinese herbal pharmacies gradually set up herbal factories (DCB, 2003: 219)<sup>4</sup>.

The main business of the herbal factories was to use modern machinery facilities to process the herbs to create customised Chinese herbal medicines. Herbs were decocted, pounded and kneaded by modern machinery facilities. Multiple herbs were mixed together by a fixed proportion and became one medicine. Because of lacking the technologies of extraction, these herbs were usually used by their whole entities. Biotechnology was not yet applied for the manufacturing of Chinese herbal medicines. Furthermore, the functions of each herb were not surveyed in detail by the scientific methods. The knowledge accumulated for the functions of each herb was based on the records of traditional Chinese pharmacopoeias. The products produced by the herbal factories were the herbal medicines, which were well recorded in the pharmacopoeias rather than the newly innovative ones. The quality controls in these herbal factories were not stable. The majority of these factories targeted the domestic market and rarely exported their products overseas.

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<sup>4</sup> Chinese have used herbs as medicines and health food for five thousand years. The knowledge accumulation through the history was rich. The knowledge also widely spread to adjacent countries, including Japan and Korea. Compared with herbal medicine, Chinese have only used Western pharmacology for a hundred years. The traditional Chinese herbal medicines were usually compound prescriptions. In other words, the doctor would use multiple herbs for one disease. The portion of each herb depended on the conditions of each patient. So the traditional Chinese herbal medicine was very personal. Ways to take the Chinese herbal medicine include decocting medicinal herbs, pounding the herbs to powder and kneading the herbal powders to make pills. Only under the scientific trends from Westerners, the Chinese herbal medicine factories started to produce customised herbal medicines, including powders and pills.

#### 5.2.1.2 Knowledge accumulation and the academic community

The Taiwanese branch of Imperial University, which was changed to be National Taiwan University after 1945, was the first university of Taiwan and the medical college of the university was the first academic institution doing pharmaceutical research. The university was set up by the Japanese government, yet, during the colonisation of Japan, there was no pharmaceutical college in Taiwan. Also there was no academic institution to train the pharmaceutical experts. Indeed, the first generation of pharmacists was the Taiwanese students trained in Japan. These Taiwanese pharmacists introduced the pharmaceutical knowledge from Japan to Taiwan (Zheng, 2001).

After 1949, some Chinese universities followed the government of the Republic of China to Taiwan and rebuilt their campuses in the island; some Taiwanese universities also set up locally. The Chinese universities included the National Defense Medical Centre. The Taiwanese universities included the Taipei Medical University, the Kaohsiung Medical University and the China Medical University.

During 1949 to 1966, there were six pharmaceutical colleges built within these universities (Zheng, 2001: 3). However, during this period, the main purpose of pharmaceutical education was to train qualified pharmacists. The research within the universities was rare. Only some particular universities, such as the National Taiwan University, did some initial research about pharmaceuticals, including the chemical medicines and Chinese herbal medicines (NTU, 2000: 49). Biotechnology was not formally introduced to the universities that were doing pharmaceutical research. Moreover, while the universities gradually accumulated fundamental knowledge related to chemical pharmaceuticals and Chinese herbal medicines, the knowledge

was not transferred to the pharmaceutical companies that emphasised manufacturing. Indeed, the only occasion for the scholars in the universities to practice their knowledge was to help the government set up regulation policies in order to control the qualities of pharmaceuticals (Zheng, 2001:203), especially the qualities of medicines.

#### 5.2.1.3 National institutions and related policies

During this period, the Taiwanese government was led by Kuomintang and operated the one-party and semi-autocratic system. There was no historical evidence showing that the government consulted related stakeholders before making any decisions. The main purpose of policies was to encourage and to control the manufacturing activities of pharmaceutical sector. The main policies promoted by the government were the regulation policies and policies attracting FDI. The minor policies promoted by the government were the R&D policies. Each policy is discussed below.

The regulation policies were especially promoted to control the manufacturing of medicines. To upgrade the manufacturing technologies of local SMEs, in 1960, the government committee led by the Ministry of Economic Affairs formally announced the ‘Taiwanese Standard for Pharmaceutical Manufacturing’ (台灣省製藥工廠設廠標準). This standard classified the pharmaceutical factories into three classes. The ones that fall into the lower two classes were told to improve their manufacturing facilities or close down. Such policies forced the factories to upgrade their manufacturing facilities (Zheng, 2001: 201). Ten years after the promotion of the Standard, in 1970, the Law was legislated to control the manufacturing activities of pharmaceutical factories and the quality of medicines, especially the ones manufactured by the local SMEs. Yet, the regulations for Chinese herbal medicines were quite marginalised. In 1971,

the Department of Health formed the Committee on Chinese Medicine and Pharmacy under the Department. But the committee was formed only to answer the queries related to Chinese herbal medicines (Zheng, 2001: 240). There was, in fact, no regulation for the product of Chinese herbs.

The FDI policies were extensively promoted to attract the foreign investments in the pharmaceutical sector. To increase the manufacturing capabilities of the pharmaceutical sector, in 1950 the government launched the ‘Statute for Encouraging Foreign Direct Investment’ (獎勵外人投資條例, abolished in 1990). In 1961, the government further announced the ‘Clause for Foreign Investment in Pharmaceutical Intermediaries’ (國外廠商來台設廠或與我國藥廠技術合作製造維他命等四類藥品注意事項). Thus, multinational pharmaceutical companies would receive a tax reduction if they manufactured intermediaries in Taiwan or transferred technologies to local pharmaceutical firms. Moreover, as long as the MNCs manufactured their products in Taiwan, their products would be considered to be domestic products. Yet, if the MNCs imported the foreign produced pharmaceuticals to Taiwan, these imported products were rigorously regulated (Zheng, 2001: 202).

The R&D policies at the time were quite marginalised compared with the regulation and FDI policies. In 1973, the National Science Council and the Department of Health funded some firms to synthesise several pharmaceutical intermediaries to be new intermediaries. But only a few of these new intermediaries were produced on a large scale (DCB, 2003: 201).

To sum up, during this period, while the production of pharmaceutical intermediaries and generic medicines was the main business of the pharmaceutical sector, the policies also focused on regulating or supporting



the manufacturing of the pharmaceutical companies, especially on the manufacturing of medicines. The main knowledge base of the pharmaceutical sector was chemical engineering. The development of Chinese herbal medicines at the time was quite marginalised both by the pharmaceutical companies and by the government's policies.

#### 5.2.2 From 1982 to 2000

The pharmaceutical sector gradually used the knowledge base of Chinese herbal medicines to develop new herbaceous medicines during this period. Modern biotechnology was used by the pharmaceutical sector to extract herbal compositions.

##### 5.2.2.1 Ecology of firms

From 1982 to 2000, the ecology of the pharmaceutical sector had radical change. With the rising cost of manufacturing in Taiwan and the free trade of pharmaceuticals, pharmaceutical MNCs gradually sold their manufacturing facilities to local companies in the 1990s (DCB, 2003: 209). After these sales, MNCs kept only their marketing divisions in Taiwan to deal with the issue of importing of medicines and local SMEs gradually became the main force of manufacturing.

The main business of local firms did not change so much. Most of the local SMEs manufactured pharmaceutical intermediaries or generic medicines. To fit the new regulation of 'Good Manufacturing Practice' (GMP), the manufacturing technologies of local SMEs have been upgraded. Yet, the manufacturing technology used by local SMEs was chemical engineering rather than biotechnology. Because of their lack of capability to innovate or to export, most of the firms still targeted the domestic market and competed

with each other on a price base. According to the statistical data in 1995, the sales of local SMEs shared 31% of the domestic market, while MNCs shared 38%, and the imported medicines shared 31% (Zheng, 2001: 194).

The development of Chinese herbal medicines was relatively quick compared with medicines. With the trend to manufacture Chinese herbal medicines by scientific methods, the companies of Chinese herbal medicines gradually followed the rules of the Good Manufacturing Practice to manufacture their products and sold these products in the domestic market. Moreover, some companies of Chinese herbal medicines have started to establish the networks with academics to develop new herbaceous medicines (DCB, 2003: 226). At the time, the strict regulation for clinical trials was gradually applied for developing new herbal medicines. Since the Taiwanese government had no regulations to review the license of the new medicines, all the companies of Chinese herbal medicines followed the regulations of the United States' Food and Drug Administration (FDA). Each traditional Chinese herbal medicine was made by multiple compositions of different herbs. Yet, to fit the regulation of the United States' FDA, each new herbaceous medicine was made by a single composition extracted from a particular herb. Indeed, the companies that invested in the innovation of Chinese herbal medicines only did detailed research related to these single herbal extracts. Modern biotechnology was applied for extracting the functional ingredients of the herbs. Furthermore, modern biochemistry, which was introduced by the scientists trained in the United States, was applied for the deeper analysis of the medical functions of single herbal extracts, such as the chemical activities of the herbal extracts. Yet, there was no new herbaceous medicine successfully developed during this period.

#### 5.2.2.2 Knowledge accumulation and the academic community

Since the 1980s, the pharmaceutical research within the academic community was developed more and more. Unlike the old generation of pharmaceutical researchers, who were trained by the Japanese system, the younger generation was trained by the United States' system and transferred pharmaceutical related knowledge (such as molecular biotechnology and biochemistry) from the United States to Taiwan. These scholars trained by the United States gradually became the pillars of academic community in pharmaceutical schools. In 1980s, the main function of the pharmaceutical school was still training qualified pharmacists. With the gradually matured environment for the pharmaceutical research, some universities, like National Taiwan University, started to provide postgraduate degrees in the early 1990s and trained local pharmaceutical researchers (Zheng, 2001: 80, 81).

There has been initial research for small molecular medicines and Chinese herbal medicines within the academic community since the 1980s. For the research of small molecular medicines, the National Science Council usually funded this research and the research interests of individual scholars chose the research topics. Collaborations between different academics were rare. Even though the scientists had related research interests, they had very limited cooperation with each other. For the research of Chinese herbal medicines, out of the demand of regulation, the Department of Health funded Kaohsiung Medical University and Taipei Medical University to survey the herbs of Taiwan (Zheng, 2001: 242). But such surveys were just to serve the policy expectations and were not considered to be commercialized.

During 1980s, universities had limited interactions with the industry, and it

was public funded research organizations under the Ministry of Economic Affairs who played the roles as intermediary organizations between the universities and industry. Due to the regulation policy of the human resources of academics, the interactions between the universities and pharmaceutical firms were forbidden. The Taiwanese government in fact set up major institutional constraints in the commercialisation of university research. Since universities were not supposed to directly interact with firms, the Development Centre of Biotechnology of the Ministry of Economic Affairs was set up in 1984 to apply the small molecular research from the universities for developing new medicines and then transfer such technologies to local firms. However, because the majority of pharmaceutical companies that manufactured pharmaceutical intermediaries or generic medicines were unable or unwilling to develop new medicines, the Development Centre of Biotechnology gradually became the research centre for developing pharmaceutical intermediaries (Ding, 2001: 229). The condition only changed after the late 1990s when more firms tried to develop new herbaceous medicines. Besides, the Industrial Technology Research Institute under the Ministry of Economic Affairs has helped local SMEs upgrade their manufacturing facilities in order to fit the regulation of Good Manufacturing Practice.

#### 5.2.2.3 National institutions and related policies

During 1980s and the early 1990s, the Taiwanese government still operated the one-party and semi-autocratic system led by Kuomintang. But with the trend of democratisation and the participation in the World Trade Organisation (WTO), the Taiwanese government gradually needed to involve the interests of external stakeholders and the game rules of international institutions within the policies. Taiwan had the first general presidential and congressional elections in 1996. Since Kuomintang won

both of the elections, the Taiwanese government was able to continue all the policies promoted before. The legislative branch, the Legislative Yuan, remained stable and the executive branch was still the main body making decisions. The policies gradually encouraged the innovation within the pharmaceutical sector. The main policies promoted during this period included the 'Eight Key Industries', the R&D policies, regulation policies and the National Health Insurance. Each of the policies is discussed below.

The 'Eight Key Industries' announced in 1982 was the first biotechnology policy promoted by the Taiwanese government. The Taiwanese government for the first time recognized biotechnology as one of the eight key industries in which government should invest more resources. However, according to the contents of the Eight Key Industries, the development of biotechnology was almost equal to the development of pharmaceutical sector whose knowledge base was chemical engineering rather than biotechnology. Moreover, besides announcing they would invest more in biotechnology, the government in fact didn't promote any concrete policies under the framework of the Eight Key Industries<sup>5</sup>.

The R&D policies were also extensively promoted during this period. Two years after the announcement of the Eight Key Industries, the Ministry of Economic Affairs set up the Development Centre of Biotechnology in 1984<sup>6</sup>. The Ministry allocated the majority of its R&D resources to the Industrial Technology Research Institute and the Development Centre of Biotechnology to play the intermediary roles between universities and pharmaceutical companies. However, the majority of technologies transferred were chemical engineering rather than biotechnology. Moreover, the National Science Council continued funding fundamental biological

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<sup>5</sup> See Taiwan's Biotechnology Policy and Promotion Status:  
<http://www.bpipo.org.tw/en/policy.html>

<sup>6</sup> See the mission of the Development Centre of Biotechnology: <http://www.dcb.org.tw/>

research in the universities. In practice, the universities funded by the National Science Council did not necessarily have connections with the research organizations under the Ministry of Economic Affairs since the knowledge base of the two kinds of institutions was different. Only after 1998, with the initiation of the National Programs, the Taiwanese government started to integrate the pieces of research dispersed in different universities and research organizations together. Furthermore, the focus of R&D policies was also changed. Originally the government only encouraged the production of pharmaceutical intermediaries. But after 1998, the government started to recognise Chinese herbal medicine as the pillar of the pharmaceutical sector and encouraged the development of new herbaceous medicines. From the perspective of the government at the time, the knowledge accumulation of bio-pharmaceuticals in Taiwan was too weak to compete with developed countries. But the Taiwanese had strong knowledge base of Chinese herbal medicines<sup>7</sup>. As such, Taiwan should fully use the advantages of Chinese herbs to develop the pharmaceutical sector. We will further discuss the policies related to Chinese herbal medicines in Chapter 6.

The regulation policies were also extensively promoted. In 1982, the Department of Health and the Ministry of Economic Affairs formally launched the regulations of Good Manufacturing Practice and forced the local SMEs to upgrade the manufacturing capabilities. The pharmaceutical firms originally objected to the policy. Later since the government has persuaded the representatives of the pharmaceutical associations, the associations became the assistant of the government to urge their members to accept the policy of the government (Zheng, 2001: 193, 229). The majority of local SMEs finally accepted the regulation of Good

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<sup>7</sup> See the introduction to the background of The National Science and Technology Program for Biotechnology and Pharmaceuticals:  
[http://npbp.m-w.com.tw/tw/pageContent.php?id=11&catalog\\_id=0](http://npbp.m-w.com.tw/tw/pageContent.php?id=11&catalog_id=0)

Manufacturing Practice. In addition, the Patent Act was amended in 1985 and 1994 under the pressure of the United States' 'Trade Act of 1974' and the pressures of the pharmaceutical MNCs from the United States. The Taiwanese Patent Act, which only offered protections to the patents of pharmaceutical process, was forced to extend its protection to the patents of pharmaceutical products (Ding, 2001: 228).

The National Health Insurance was promoted in 1996 under the Department of Health. More than 90% of the medical institutions were covered by the health insurance system<sup>8</sup>. Because of the reimbursement of medicines, the government became the largest buyer of medicines in the domestic market. The policy brought major change in the domestic market. The National Health Insurance reimbursed higher prices for the new or patented medicines than the generic medicines. The policy in fact seriously squeezed the interests of domestic pharmaceutical companies.

The policies of international trade were also promoted. Tariff was used as the policy instrument in the early 1980s to develop pharmaceutical intermediaries. In 1981, the Ministry of Economic Affairs consulted the Department of Health, the National Science Council, pharmaceutical companies and academics and announced the 'Administrative Rules of Encouraging Production of Pharmaceutical Intermediaries' (促進國內原料藥實施要點). These rules temperately upgraded the tariff of pharmaceutical intermediaries to 10% and adopted the fast routes for the approvals of manufacturing. The policy was promoted from 1982 until 1994. After 1994, because of preparing for the application of WTO, the policy was suspended (Zheng, 2001: 213).

As such, during this period, the development of the pharmaceutical sector in

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<sup>8</sup> See the National Health Insurance Profile

1980s and 1990s had dramatic differences. In the 1980s, the knowledge accumulation within the sector was in the manufacturing of pharmaceutical intermediaries and generic medicines. Even though the Taiwanese government announced to support biotechnology in 1982 in the Eight Key Industries, the government indeed tended to encourage pharmaceutical sector to adopt more chemical engineering rather than biotechnology. Only after late 1990s, the sector gradually started to discover new herbaceous medicines and configure the Western-based knowledge of biology and biochemistry with the traditional Chinese knowledge of herbs. The policy focus also turned from pharmaceutical intermediaries to new medicines. The government's policies gradually turned to encourage the development of new herbal medicines rather than merely the manufacturing of pharmaceutical intermediaries and generic medicines.

### **5.3 The evolution of agricultural sector**

The agricultural innovation system in Taiwan could be categorized into four sorts: seed, food industry, pesticide industry and fertilizer industry.

#### **5.3.1 From pre-1945 to 1982**

During this period, rice and sugar were the two most important agricultural products for exporting. Traditional biotechnology of hybridization was applied for the seed innovation, while the industries of food, pesticide and fertilizer remained to use the knowledge base of machinery processing.

##### **5.3.1.1 Agricultural innovation system**

The Taiwanese innovation system of seeds was originally set up by the Japanese government and further developed by the government of the



Republic of China in 1945. The research organizations within the Agricultural Experiments Station system, including the Agriculture Research Institute and the Agricultural Experiments Stations, were the most important organizations for seed innovation. These research organizations were fully funded by the Japanese government before 1945 and by the government of the Republic of China after 1945. Indeed, since the Japanese colonization, to feed the population of Japan, the Japanese government has introduced the seeds of the Japanese rice to Taiwan. To plant the Japanese rice under the subtropical climate of Taiwan, the research organizations of the Agricultural Experiments Station system (typically shortened to be the Agricultural Stations) used the traditional biotechnology of hybridization to improve the genes of Japanese rice by the genes of the Taiwanese rice. Japonica which looked and tasted like Japanese rice but grew well under the subtropical climate of Taiwan was the representative of the new rice. Moreover, not only rice, the experts of Agricultural Stations also did genetic research of subtropical fruits and vegetables, such as sugar cane and tea. In addition, besides doing research, the Agricultural Stations also trained some of the Taiwanese students within these organizations (Lin, 1995:2). After Taiwan was returned to the Republic of China in 1945, the government of the Republic of China replaced the Japanese government to fully fund the Agricultural Stations. After 1949, except the original Taiwanese experts, some Chinese experts who followed the government of the Republic of China and migrated from China to Taiwan also became the pillars of the researchers in the Agricultural Stations. The knowledge of hybridization which was accumulated by the Japanese scientists was further developed by the Taiwanese experts (Su, 2004:18), especially in the rice research.

After the seeds were innovated by the Agricultural Stations, the Agricultural Stations should pass the seeds to the Farmers' Association. The Farmers' Association was founded by the Japanese government to control the

production activities of farmers. One of the main responsibilities of the Farmers' Association was to disseminate the seeds of the Agricultural Stations to individual farmers. After 1945, the government of the Republic of China substituted the Japanese government to govern the Farmers' Association (Liu, 1996:188). While every farmer held a small farm and did intensive cultivation within the small area, these farmers got the seeds through the Farmers' Association for free. Indeed, in the innovation system of seeds, farmers were treated as the pure producers who had only limited knowledge accumulation related to cultivation. The experiences of farmers seldom fed back to the Agricultural Stations. It was the constraint of the innovation system of seeds to let the experts of the Agricultural Stations to understand the experiences of the cultivation and to improve the next generation of seeds. Furthermore, most of the crops, especially rice, were exported to foreign markets. Farmers who cultivated to serve the overseas demands got rewards only from the sales of their harvests. However, the rewards for farmers were only sufficient for their survivals but not sufficient for them to reinvest in the seed innovation.

There were some small local private seed companies which played supplementary roles in the innovation of seeds. These companies usually aimed at innovating the specific kinds of seeds and sold these seeds to farmers. For example, Known-You Seed Cooperation was the company which particularly innovated the seeds of watermelons (Cai, 2007). The technology used by the private companies to improve the genes of seeds was the traditional biotechnology of hybridization which was also used by the Agricultural Stations. However, compared with the public funded Agricultural Stations, the private SMEs were only able to play minor roles in the seed innovation. Moreover, through the Taiwanese agricultural history, multinational companies, such as Monsanto, played no role in the seed innovation.

Besides seeds, the industries of food, pesticide and fertilizer also developed (Chang, 1982:237, 255). The market of each industry was different. Plantation white sugar was central to the food processing industry. Taiwan Sugar Corporation which was set up by the Japanese government in 1900 and later fully invested by the government of the Republic of China was not only the public but also the first and the largest agricultural company in Taiwan. The company's original business was to process sugar cane by modern machinery facilities and exported to foreign markets. Later, the company expanded its business to the production of chemical pesticides and fertilizers (TSC, 2006), and the majority of its products of chemical pesticides and fertilizers served with the domestic demands. Furthermore, there were also some local small and medium companies of food, pesticide and fertilizer surrounded Taiwan Sugar Corporation. They usually target the domestic markets which were not yet dominated by Taiwan Sugar Corporation, and a few of the private companies started to use biotechnology to improve their products. For example, Wei-chuan has used the technology of fermentation to produce monosodium glutamate (Lee and Hua, 2004:114) and exported to overseas markets. Yet, compared with Taiwan Sugar Corporation, these private companies only played auxiliary roles in the innovation of food, pesticides and fertilizers.

#### 5.3.1.2 Knowledge accumulation and the academic community

The Agricultural College of Imperial University which was changed to be National Taiwan University after 1945 was built up by the Japanese government and was the most important academic institution doing fundamental agricultural research; and the Agricultural Stations were the most important research institutions doing applied agricultural research. The headquarters of the Agricultural Stations was first built up next to National

Taiwan University. The traditional biotechnology of hybridization was frequently applied for the agricultural research. The innovation network was established between the university and the Agricultural Stations. Through the flow of personnel, knowledge was transferred between the university and the Agricultural Stations. In fact, many graduates trained by National Taiwan University took important positions in the Agricultural Stations. Moreover, some graduates from National Taiwan University also worked in Taiwan Sugar Corporation and supported the industry of plantation sugar (Su, 2004:18).

In the early 1970s, the headquarters of the Agricultural Stations were moved from the north to the middle of Taiwan, and the new headquarters was next to the Agricultural College of Chung-hsing University. The Agricultural College of Chung-hsing University which was once an agricultural vocational school became another important academic institution for agricultural research (Lin, 1995:3; Su, 2004:18).

#### 5.3.1.3 Government and governance during this period

The Taiwanese government was the one-party and the semi-autocratic system during this period. The agricultural policies were promoted totally from top-down, and there was no evidence to show that there were private organizations involved in the governance of agricultural policies. In fact, all the main organizations involved in the governance of the agricultural sector and the agricultural innovation were the public organizations. The public Agricultural Stations mainly did the agricultural research and the Farmers' Association, who were managed by the government, managed the production of the farmers. Even the industry of agricultural processing was dominated by the publicly-owned company, Taiwan Sugar Corporation.

The main purpose of the agricultural policies at the time was to produce agricultural products as much as possible within the limited areas of cultivation. The majority of the agricultural products were exported to earn the foreign exchanges to support the development of the manufacturing industries, such as electronic engineering. Only after 1970, when the manufacturing industries were well developed, the policy objectives of the agricultural policies were turned to upgrade the living standard of farmers (Chang, 1982: 238-239). Indeed, even though biotechnology was heavily used in the agricultural sector, there was no policy to particularly encourage the development of agricultural biotechnology. The main policies promoted by the Taiwanese government included R&D and regulation policies. The two policies are discussed below.

The R&D policies for the agriculture were promoted by multiple ministries to increase the production of crops. The agricultural research within the universities was mainly funded by the National Science Council, and the research within the Agricultural Stations was at the time co-funded by the National Science Council and the Council of Agriculture. The Farmers' Association was managed by the Ministry of Domestic, and the farms were managed by the Council of Agriculture. In fact, the agricultural sector was governed by multiple ministries since the very early stage of its development.

Multiple ministries also promoted the regulation of agriculture, especially the regulation of food, chemical pesticides and chemical fertilizers. The Ministry of Economic Affairs promoted the Factory Rules (legislated in 1969) to control the manufacturing and quality of food, pesticides and fertilizers. The Council of Agriculture also regulated the production of pesticide through the Management Act (legislated in 1972). The regulation for the manufacturing of pesticides and fertilizers in fact overlapped to each

other.

In sum, during this period, agricultural sector was highly dominated by the public sector. The innovation system of seeds extensively used the traditional biotechnology of hybridization to improve the genes of seeds and produced the seeds to serve the foreign markets. The industries of food, pesticide and fertilizer had limited adoption of biotechnology and targeted the domestic demands.

### 5.3.2 From 1982 to 2000

The modern biotechnology of genetic modification was used in the innovation of seeds during this period. The traditional biotechnology of hybridization continued being applied for the innovation of both seeds and livestock. The companies of food, pesticide and fertilizer have gradually adopted modern biotechnology for processing their products.

#### 5.3.2.1 Agricultural innovation system during this period

The institutions for the innovation system of seeds didn't have much change during 1980 to 2000; and these institutions were expanded for the innovation of new species of livestock, including farm animals and aquaculture. The Agricultural Stations were still the most important organizations doing applied agricultural research and transferred the innovated seeds and younglings to farmers. Besides using the traditional biotechnology of hybridization to innovate the new kinds of subtropical crops and new species of livestock, with the development of molecular biology after 1980s, the Agricultural Stations also started to do the experiments of genetic modification to improve the genes of seeds,

especially the seeds of rice and subtropical fruits. The modern biotechnology of genetic modification was transmitted from the United States to Taiwan through the Taiwanese scientists trained in the United States. In 1997, the genetic modified papayas which were innovated by the Taiwanese scientists and were successfully grown in the trial fields were the milestones of the development of genetic modification. Indeed, all papayas were cultivated in the south of Taiwan under the subtropical climate. Since the old kinds of papayas were easy to be infected by parasites, their genes were modified to make the crop parasite-resistant. However, because of the regulations of the Taiwanese government, even though the genetic modified papayas were successfully innovated, they were not allowed to be cultivated in the normal farms. Moreover, besides the innovation of seeds and livestock, the Agricultural Stations have expanded their research to the modern biotechnology of fermentation and applied the research for the development of bio-pesticides and bio-fertilizers. Since 1987, bio-fertilizer has been formally used in the farms (STRIC, 2005:31, 33). Yet, all the technologies innovated by the Agricultural Stations were not commercialized but transferred to the Farmers' Association. Through the Farmers' Association, these technologies were passed to farmers for free.

The small private companies also started to invest in the innovation of genetic modification products. Since the 1990s, some local SMEs transferred the modern biotechnology of genetic modification from the academic institutions and started to produce genetic modification organism (GMO), especially the non-edible GMO. For example, Taikong which was a trade company selling ornamental fish has coordinated with National Taiwan University to develop GM ornamental fish since 1990s<sup>9</sup>. However, there was not yet any new GM product successfully innovated by the private companies.

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<sup>9</sup> See the statement of Taikong: [http://www.azoo.com.tw/azoo\\_tw/instruction/004.php](http://www.azoo.com.tw/azoo_tw/instruction/004.php).

For industries of food, pesticide and fertilizer, the main change was the market. The sugar industry which traditionally targeted overseas demand turned to focus on the domestic market, while the industries of pesticide and fertilizer remained to target the domestic demands. On one hand, since sugar was no longer the main products for exporting, Taiwan Sugar Corporation started to transform itself to be a multi-faceted agricultural company and adopted biotechnology in its multiple divisions, such as food-processing, the cultivation of orchids and fermentation products (Su, 2004:17). Yet, the company kept manufacturing chemical pesticides and fertilizers rather than bio-pesticides and bio-fertilizers. On the other hand, after 1990s, some local food companies also began to cooperate with academic institutions and adopted biotechnology in food-processing. For example, Grape King set up its own research center for biotechnology in 1992. United and President has collaborated with the Academic Sinica to develop the biotechnology of microscopic fermentation (Lee and Hua, 2004:98,116,130). However, the knowledge spill-over from academic community to the industry was still limited, and technology transfer was not institutionalized.

#### 5.3.2.2 Knowledge accumulation and academic community

During 1980 to 2000, the Taiwanese scientists who were trained in the universities of the United States introduced the concept and technologies of molecular biotechnology from the United States to the Taiwanese universities. The introduction of molecular biotechnology greatly increased the depth of basic agricultural research in the universities. The majority of the research of genetic modification done within the universities was funded by the National Science Council. Once the universities had done the basic research, the results of the basic research were further developed by the scientists in the Agricultural Stations (Su, 2004:18, 20). Since the



universities were not supposed to directly interact with the agricultural companies during this period, the technology transfers from the universities to the agricultural sector was rare. Moreover, the research topics were chosen according to the research interests of individual scholars. The overlapping topics were done by different universities spontaneously, and different scientific teams had very little coordination with each other.

Besides universities, the personnel and labs of the Agricultural Stations were expanded since 1980s. As long as agricultural products were no longer export-oriented, the mission of the Agricultural Stations was changed to upgrade the quality rather than the quantity of primary production to fit the domestic demands. In 1990s, with the preparation for the participation of WTO and the free trade of agricultural products, the Agricultural Stations was further pushed to develop the agricultural technologies which were able to increase the competitiveness of the primary domestic products in the domestic market (Wong, 1998:96-98). Within this context, the Agricultural Stations have set up the Agriculture Gene Resources Center to create a microbial gene bank, including the genes of both hybrid and GM seeds. All the seeds were not commercialized. While the hybrid seeds were disseminated to farmers for free, the GM seeds were stored in the storage device of the Agricultural Stations and not allowed to be formally planted in the normal farms. Even if holding the rich database of gene resources, the services of the Agricultural Stations merely charged the cost of handling and shipping (Su, 2004:18).

#### 5.3.2.3 Government and governance during this period

Since 1980s, with the trend of political democratization and economic free trade, the Taiwanese government gradually included the interests of external stakeholders. Yet, the agriculture sector which was highly controlled by the

government was still dominated by the policies, and the interests of external stakeholders stayed weak during this period. The main policies promoted by the government included R&D and regulation policies. Each policy is discussed below.

The R&D policies of agriculture were considered to be a part of the agricultural policies rather than a part of the innovation policies of biotechnology during 1982 to 2000. In 1982, even though the government announced the Eight Key Industries to further support the development of biotechnology, the meaning of biotechnology was equal to the pharmaceutical sector, and agricultural biotechnology was not included. Indeed, since 1980s, as long as agricultural products were no longer export-oriented and served the domestic demands only, the agricultural sector was gradually recognized as the sector with low productivity. While the government's resources were intensively allocated to the development of ICT, resources allocated to the agricultural sector were relatively limited. Although the government continued supporting R&D in bio-agriculture, the main policy purpose was merely to increase the welfare of farmers (Chang, 2004:151). The R&D funding of the Council of Agriculture even decreased in 1990s (Wong, 1998:115), and the same time, the Farmers' Insurance was promoted. Moreover, because the R&D policies of agriculture were treated as a kind of welfare policy, the agricultural biotechnologies innovated by the public universities and research organizations were transferred to farmers on a non-profit base. Only until late 1990s, the issue of the commercialization of bio-agricultural technologies was raised. With the promotion of the National Science and Technology Program for Bio-agriculture, the commercialization of bio-agriculture gradually became the core of the policy.

Another important policy promoted by the government was regulation.

Since 1980, ‘GM Safety Rules’<sup>10</sup> have been implemented in the labs. Yet, besides field trials, none of the GM seeds were allowed to be traded in the domestic market.

To sum up, before 2000, the Taiwanese government only encouraged the development of bio-agriculture through agricultural policies. What was labeled as the biotechnology policies didn’t cover the agricultural sector. The traditional biotechnology of hybridization was highly developed, and the modern biotechnology of GM was widely applied in the agricultural academic institutions. Yet, even though the technological level of the agricultural sector was very high, due to the policies, these technologies were commercialized to a limited extent. Such conditions only started to change after late 1990s.

#### **5.4 The evolution of the medical device sector**

The technologies used by the medical device sector were the same as the technologies used by the industries of textile, plastic, machinery and electronic engineering. Before late 1990s, medical device was not recognized as an independent sector but the supplementary sub-sectors of the industries of textile, plastic, machinery and electronic engineering. Only after 1990s, medical device was gradually recognized as an independent sector and thus gained more attentions of firms and the government.

##### **5.4.1 From 1945 to 1982**

The main business of the medical device sector during this period was the

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<sup>10</sup> See the Official website of Council of Agriculture:  
<http://www.coa.gov.tw/view.php?catid=7661>.

production of Class I medical device on the bases of textile and plastic technologies.

#### 5.4.1.1 Knowledge base and the development of the sector

The initial development of the Taiwanese medical device sector was embedded in the development of textile and plastic industries. Medical cotton and swab were the most important medical devices produced by the textile industry. Under the context of the Cold War, to back up the Republic of China (at the time 'Free China') as the frontline to defend the expansion of the People's Republic of China (at the time 'Communists China'), the government of the United States aided the government of the Republic of China lots of American cottons to develop economy. Since swab was one of the textiles which Taiwan was lacking, local SMEs were encouraged by the government to import textile machines to process cottons given by the government to be swabs (Zheng and Xu, 2005:108-109). Originally these SMEs only aimed at the domestic market. However, with the improvement of textile machines, the products of medical cottons and swabs were gradually exported (CCRA, 1983:1-2). In addition, the plastic industry which intensively used the technologies of chemical engineering was also rapidly developed during this period. The plastic medical devices, like surgical dressings, plastic catheters and syringes, were manufactured by the local SMEs and exported to the foreign markets (Shen, 1996:5). However, all the textile and plastic products were just the applications of existing technologies for medical utilities. These products which were usually categorized as the Class I medical devices which were the low value-added products and competed with similar products in the international market on a price-base. Most of the firms only focused on manufacturing. They only accumulated some knowledge related to manufacturing but had limited capabilities for innovation. Competition was the main mode of interaction

between companies, and there was no record to show that these firms started to form R&D alliance during this period.

Besides the technologies of textile and plastic, the technologies of machinery were also used by the medical device sector. The Taiwanese machinery industry was established by the Japanese government before 1945. After Taiwan was returned to the government of the Republic of China in 1945, the government unified all the large factories of Japan to be two public companies, Taiwan Machinery Company (台灣機械公司) and Taiwan Shipping Company. Besides the large factories, some small Japanese factories were sold to the local Taiwanese private SMEs. In addition, after 1949, some Chinese machinery companies also followed the government of the Republic of China and moved their factories to Taiwan. However, compared with the private companies, the public companies actually held more resources and had higher technologies. The knowledge of the machinery technologies was spilled over from the public to the private companies through technology transfers (Zheng and Xu, 2005:104-105). The main products related to medical devices which were produced by these companies were metal-processing and machinery components. Although during this period, the machinery industry didn't produce any medical devices, the industry set up the bases of the development of medical device sector later.

The development of the electronic engineering industry also contributed to the development of medical devices. Since 1960, attracted by the government's policies, some multinational giants of electronic engineering started to invest in the manufacturing facilities in Taiwan. These MNCs included Philips (from Netherlands), General Engine (from the United States), Motorola (from the United States) and Hitachi (from Japan). At the same time, some local SMEs also set up their factories to process electronic

components or assembled electronic components to be end products. The majority of the electronic products were exported to overseas market. The main products at the time were the voice recorders, television and calculating machines (MOEA, 1977). Although electronic engineering should be one of the technological bases of medical devices, especially the Class II electronic medical devices, there was no evidence to show that some firms already applied the technologies of electronic engineering for medical devices.

#### 5.4.1.2 The role of the universities and public research institute

For the textile and plastic industries, since the knowledge for manufacturing was accumulated within the industries, the universities only played roles to supply well educated human resources; however, the universities and public research institutes played much more significant roles in machinery and electronic engineering industries. The Metal Industries Research and Development was set up by the Ministry of Economic Affairs in 1977 with the funding of United Nation. The Center was responsible for upgrading the technologies of metal machines and for transferring the technologies to the local firms (Zheng and Xu, 2005:115). Moreover, National Chiao-tung University which had strong research capabilities in electronic engineering played important roles in understanding the technologies through ‘reverse engineering’, in helping local companies develop new products, and lending firms expensive instruments (Lee, 1998:315-318). The Industrial Technology Research Institute which was built up by the Ministry of Economic Affairs was responsible for transforming the basic research in the universities to be applied technologies and transferred these technologies to the firms. However, during this period, the technologies of electronic engineering were only applied for the electronic equipments, such as television, rather than electronic medical devices.

#### 5.4.1.3 Government and policies during this period

Since 1945, the Taiwanese government which was the one-party and semi-autocratic system applied top-down approach for the development of the industries of textile, plastic, machinery and electronic engineering; the main policies promoted were R&D policies, regulation and the policies attracting FDI. For the R&D policies, the Development Center of Metal Industry and the Industrial Technology Research Institute were set up by the Ministry of Economic Affairs to do research related to manufacturing process and to help the firms to upgrade their manufacturing technologies in order to increase their international competitiveness. For the regulation policies, the Law which was legislated in 1970 also regulated the manufacturing of medical devices. For the policies attracting FDI, the ‘Statute for Encouraging Foreign Direct Investment’ promoted by the Ministry of Economic Affairs were to encourage FDI, especially FDI in electronic engineering. Yet, the main target of this policy was the daily-used electronic equipments rather than electronic medical device.

As such, from 1945 to 1980, the products of medical device sector were medical cotton, swab, surgical dressings, plastic catheters and syringes. The majority of these products were only belonging to Class I products. The market and demand was from overseas. In fact there were no policies specifically to support the development medical devices. The technologies of machinery or electronic engineering were gradually developed, but the applications of these two technologies for medical devices were at the time limited.

#### 5.4.2 From 1982 to 2000

The medical device sector adopted more advanced technology from machinery and electronic engineering industries during this period.

##### 5.4.2.1 Knowledge base and the development of the sector

After 1980, the companies of Class I medical devices, such as medical cotton, swab, and surgical dressings continued improving their manufacturing technologies in such products. Their knowledge base was still textile and plastic technologies. The demand was from overseas market. Since these firms were all small and rarely cooperated for the innovation of more advanced technologies, their investments in R&D were just able to do innovation on the manufacturing process. Until as late as 1996, the Class I products still shared a portion of the overall national production of medical devices (Shen, 1995:6).

The greater technological achievements in the medical device sector were the progress of machinery and electronic engineering. The local SMEs in the machinery industry were encouraged by the Ministry of Economic Affairs to form the Precision Machinery Research Center with the government in 1993. The main mission of the Research Center was to help machinery firms to upgrade their technological level in precision machines (Zheng and Xu, 2005:193). Yet, the development of medical precision machine was only the minor part of the mission of the center. Furthermore, on the basis of the technological progress from 1960 to 1980, the industry of electronic engineering had great advancement after 1980s. However, the technology of electronic engineering was strongly encouraged by the government to be further developed to be semiconductors, personal computers, and notebooks. In other words, the knowledge accumulation of electronic engineering was



developed into ICT rather than electronic medical devices. Both local firms and multinational companies heavily invested in the R&D and manufacturing facilities of integrated circuit (IC), semiconductors and so on. Even if ICT and electronic medical devices had related technological base, compared with the competitive and matured ICT cluster, the sector of electronic medical device was only treated as the marginal sub-sector of ICT. On the one hand, the large competitive local ICT companies, such as Acer, Asus and Taiwan Semiconductor Manufacturing Corporation, never invested in electronic medical device between 1980 and 2000<sup>11</sup>. On the other hand, the multinational ICT giants which were also the giants of electronic medical device (such as Philips) didn't invest in the electronic medical device in Taiwan but kept their investments in the ICT industries only.

In fact, from 1980 to 2000, Class II electronic medical devices Class II medical devices were developed peripherally to the ICT cluster. At the time, the companies producing electronic medical devices were the local SMEs which were set up around late 1980s and 1990s (DIT, 2009). After 2000, these local SMEs became the pillars and most competitive companies in the whole medical device sector. The main business of these local medical device SMEs was to fabricate developed machinery and/or electronic engineering technologies and applied these technologies for medical devices. The knowledge accumulation of the firms of electronic medical devices was mainly in the technology field of ICT. Biotechnology was not used by these firms. With the trend that multinational large manufacturers of electronic medical device gradually concentrated on higher value added products and outsourced manufacturing of lower profit products, the Taiwanese local SMEs then cooperated with the multinational manufactures to manufacture

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<sup>11</sup> Only after the financial tsunami in the end of 2008, some local ICT companies which suffered the bottleneck in the sales of personal computers and notebooks started to invest in electronic medical device.

the lower profit products. The main products included electronic wheelchairs and beds, electronic blood pressure meters, dentists' apparatuses, X-ray machines and so on (Shen, 1995:6). The majority of such products were exported to foreign markets. Besides doing outsourced manufacturing, some local SMEs also started to sell the products by their own brands. Moreover, the development of biochips led to the beginning of the medical device sector starting to combine ICT with biotechnology. The companies of biochips were all new SMEs set up around 1990s. For example, DR. Chip used molecular biotechnology to extract, amplify and hybrid nucleic acid on a DNA microarray chip. Such microchip was used for DNA sequencing to detect food bacteria, agricultural pathogens and human papillomavirus (HPV)<sup>12</sup>.

#### 5.4.2.2 The roles of universities and public research institutes

Universities didn't play significant roles in the innovation of medical devices. Since the medical device companies which adopted the technologies of textile and plastic mainly accumulated their technologies through the experiences of manufacturing, and the academics who focused on the basic research had relatively very limited supports to these companies. Furthermore, for the companies of electronic medical device, as long as the main business of these companies was only to fabricate relatively mature technologies, not all the companies of electronic medical device needed or expected the technology transfers from universities. In addition, the universities also concentrated the majority of their resources on the technologies of ICT rather than on the medical devices. Therefore, the innovation network between universities and the medical device companies was not well established. Only after 1990s, when more start-ups in the

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<sup>12</sup> See the Official website of Dr. Chip:  
<http://www.bio-drchip.com.tw/HOME2ENG/06index.asp>.

medical device sector tried to promote higher value-added products and searched for the development of advanced technologies, the universities played more important roles in technology transfers.

In fact, it was the public research organizations that started to play more significant roles in technology transfers. The Metal Industries Research and Development Center which helped machinery firms to fit the standard of ISO 9000 and to gain CE certification indirectly helped the companies of electronic medical devices to link with the international standard (Zheng and Xu, 2005:193). Moreover, the Industrial Technology Research Institute supported by the Ministry of Economic Affairs also increased its roles in transferring technologies to medical device companies. The Institute even helped local SMEs to form the R&D consortiums to innovate the advanced technologies of medical devices. In 1998, the Institute assembled six SMEs to form the R&D consortium of biochips. The consortium which was called Clinical Biochips Industrialization Consortium was to explore the potential of microarray technology and was the most successful consortium supported by the Institute<sup>13</sup>.

#### 5.4.2.3 Government and policies during this period

Even though the Taiwanese government was relatively open after 1980s, without influential association and outstanding performance, the participation of the companies of medical devices in the policy-making was limited. Indeed, until 1990, there were no clear policies specifically developed for medical device companies. The main roles of the government were to subsidize the R&D expenditures of the companies and to regulate the manufacturing of medical devices. Each role of the government is introduced as the following.

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<sup>13</sup> See the Official website of the Consortium: <http://www.bel-series.org.tw/cbic/About/>

The main role of the government was to subsidize the R&D expenditures of the medical device companies. Since the Taiwanese government recognized biotechnology as one of the key industries for future development in 1982, the medical device sector was not considered to be a part of biotechnology industries. The development of the medical device sector was considered to be the business which may add value to the products of the 'traditional industrial sectors', including textile, plastic, machinery and low end electronic engineering. Therefore, the innovation activities of local medical device SMEs were mainly funded by the Ministry of Economic Affairs through the projects which encouraged the traditional industries to upgrade their technologies. Only after 1990, medical device was gradually considered to be a part of the development of biotechnology in Taiwan. Yet, besides the R&D subsidies provided by the Ministry of Economic Affairs, the Taiwanese government as a whole didn't promote more sophisticated policies which particularly encouraged the development of medical device sector.

The minor role of the government was regulation. The Law which was executed by the Department of Health was amended to follow the standard of the United States' FDA and European Unions' CE and announced that the medical devices should fit the standard of ISO.

In sum, while the development of the medical device sector was mainly based on the technologies of textile, plastic, machinery and electronic engineering, there was no government's policies to encourage the medical device sector to adopt biotechnology. Indeed, the medical device sector was not seriously considered by the government to be a part of the development of biotechnology. Only after 2000, the production of the medical device

sector was formally calculated as a part of the biotechnology related industries. Yet, besides biochips which combined the technology of electronic engineering with biotechnology, the majority of the Taiwanese medical devices didn't apply biotechnology for their products.

## **5.5 Conclusion**

In this chapter, through analyzing the historical evolution of the three NSTIS, we clearly identify how biotechnology intersected with the three sectors within the national boundary of Taiwan. Indeed, the three sectors were very different from one another and possessed contrasting modes for absorbing biotechnology. Furthermore, the development of each of the three sectors and biotechnology was heavily shaped by the Taiwanese national institutions.

For the pharmaceutical sector, local SMEs have been the pillars for innovation and manufacturing. Multinational companies were only once involved in the manufacturing activities of the sector. After multinational companies extensively withdrew their investments, there were almost no large firms involved in the manufacturing and innovation of the pharmaceutical sector. Furthermore, for both local SMEs and MNCs in Taiwan, the main knowledge base was chemical engineering. Modern biotechnology was only introduced to the pharmaceutical sector after 1980s and used to analyze the extracts and the medical functions of herbs. Yet, the main knowledge base for the development of the new herbaceous medicines was the traditional knowledge of Chinese herbal medicines. Originally the Taiwanese government only purposed to encourage and to control the manufacturing of medicines. Later after 1990s, the policies gradually turned to encourage the innovation of new pharmaceuticals, especially new herbal medicines.

For the agricultural sector, the public sector, including public research institutions and public owned company, has been the most important participant in innovation. Local private companies only played minor roles in the agricultural innovations, and MNCs played no role. In addition, rice and subtropical species (including fruits, vegetables and ornamental fish) have been chosen as the targets of genetic modification. These targets reflected the climate and species of Taiwan. Taiwan introduced the traditional biotechnology of hybridization and the modern biotechnology of genetic modification in the early stages of the development of these two technologies. Yet, even if the agricultural sector accumulated rich knowledge of modern and traditional biotechnology, the Taiwanese government mainly supported the agricultural sector through agricultural policies. The government only started to encourage the commercialization of agricultural biotechnology in the late 1990s.

For the medical device sector, the main pillars of innovation have been local SMEs. The most competitive companies belonged to the companies of Class II electronic medical devices. Knowledge accumulation of these companies was based on the Taiwanese ICT industries. Biochips, which integrated biotechnology and electronic engineering, reflected the Taiwanese national strength in ICT. Until the 1990s, the Taiwanese government in fact had no specific policies to support the development of the medical device sector and to encourage the sector to absorb biotechnology.

In fact, the different evolution of the three biotechnology NSTIS offers us a very different context for thinking about policies. Different NSTIS was developed by different modes and shaped by different types of biotechnology and related sectoral policies. Indeed, as the dynamics of each biotechnology related NSTIS was different, each NSTIS needed different

appropriate policies to support its development. However, in this chapter, we have not discussed the different types of policies required by each of the three NSTIS. On the basis of the discussions in this chapter, in the next chapter, Chapter 6, we will further judge the appropriateness of the Taiwanese biotechnology and related sectoral policies, as well as the policy-making process which shapes the consistencies and appropriateness of these policies.

## **Chapter 6 The policy - making process of the Taiwanese biotechnology and related sectoral policies (2000 - 2008)**

### **6.1 Introduction**

In this chapter we propose to open the ‘black – box’ of the policy - making process of the Taiwanese biotechnology and related sectoral policies. On the basis of our discussion about the evolution of the three biotechnology related NSTIS in Taiwan from 1945 to 2000, this chapter will focus on the period from 2000 to 2008 and describes the influence of the policy - making process on the consistencies and appropriateness of the Taiwanese biotechnology and related sectoral policies. However, as described in Chapter 4, there were many policies promoted by the Taiwanese government between 2000 and 2008. For the reasons described in Chapter 4, we only selected the National Programs and the regulation policies - in terms of the Law and the Management Act - as our empirical cases and discuss these two cases deeply.

In order to open the black - box of the policy - making process of the two policies, in this chapter, we will apply the conceptual framework established in Chapter 3 for our empirical discussions. As we have already described in Chapter 3, our research questions and conceptual framework are built upon four independent variables and two dependent variables. The four independent variables are divided government, horizontal coordination, vertical coordination and the involvement of external stakeholders. The two dependent variables are the consistencies and appropriateness of RTDI policies. As we have assumed in Chapter 3, during the policy - making process the four independent variables would influence the two dependent variables. Moreover, we assume that the policy - making process can be divided into four stages. Each stage of the policy - making process is



influenced by different independent variables and shapes the two dependent variables in different ways. In this chapter we will frequently refer to the definitions of the key concepts defined in Chapter 3. In addition, since the data collected through the fieldwork is essential to the analysis, in this chapter we will frequently quote the codes of our interviewees, which are shown in Table 4.1.

This chapter is structured as follows: in section 6.2 we will provide an overview for the contents of the National Programs and the regulation policies and emphasize the vertical and horizontal consistencies of these two policies. Section 6.3 continues the historical discussion in Chapter 5 and focuses on the appropriateness of the two policies. Section 6.4 emphasizes the policy - making process of the two policies. Section 6.5 is the conclusion of the chapter.

## **6.2 Overview of the contents of the National Programs and regulation policies**

The section gives an overview of the policy contents of the three National Programs and the regulation policies, in terms of the Law and the Management Act, and discusses the consistencies of the two policies. The consistencies of policies, as we have defined in section 3.1, refer to both vertical and horizontal consistencies. Besides, the Promotion Plan for the Biotechnology Industry (hereafter referred to as the Promotion Plan), which revealed the general policy objectives of the whole government and other policies which were closely interrelated to the two cases, such as the Mid-term R&D Plans (typically shortened to be the Mid-term Plans), are very important for us to judge the consistencies of the two policies. Therefore, we also review the Promotion Plan and the interrelated policies.

The structure of the Taiwanese biotechnology and related sectoral policies, the contents of the policies and the ministries responsible for these policies are displayed in Figure 6.1, Table 6.1 and Figure 6.2. Figure 6.1 shows the structure of the Taiwanese biotechnology and related sectoral policies and reveals the positions of the two cases in the structure of the biotechnology policies. As shown in the figure, the Promotion Plan was the framework which was above the four types of policies, i.e. R&D policies, part of the regulation policies, part of the business park policies and the ‘Statute for the Development Biotechnology New Drug Industry’. However, another four types of policies (i.e. part of the regulation policies, part of the business park policies, national health insurance and international trade policies) were outside the framework of the Promotion Plan. Among our two cases, the three National Programs and the new clauses of the Law were under the framework of the Promotion Plan, while the majority of the clauses of the Law and the Management Act were not. The contents of the two policies, the Promotion Plan and some closely related policies are summarized in Table 6.1. In addition, the two cases and all other interrelated biotechnology and related sectoral policies were decided and implemented by four ministries (i.e. the National Science Council, the Ministry of Economic Affairs, the Department of Health, and the Council of Agriculture). Since the institutional structure of the four ministries is very important for us to understand the contents and the policy - making process of the two cases, we also show in Figure 6.2 the institutional structure of the four ministries and their positions in the executive branch. As shown in the figure, the National Science Council was the coordinator to collaborate the other three ministries for promoting the National Programs, while the Department of Health was the only ministry to execute the Law and the Council of Agriculture was the only ministry to execute the Management Act. The roles of each ministry and their subordinate implementation bodies in the policy - making process will be further discussed in section 6.4. In the following

paragraphs we only emphasize the discussion of the contents of the Promotion Plan and the two cases.

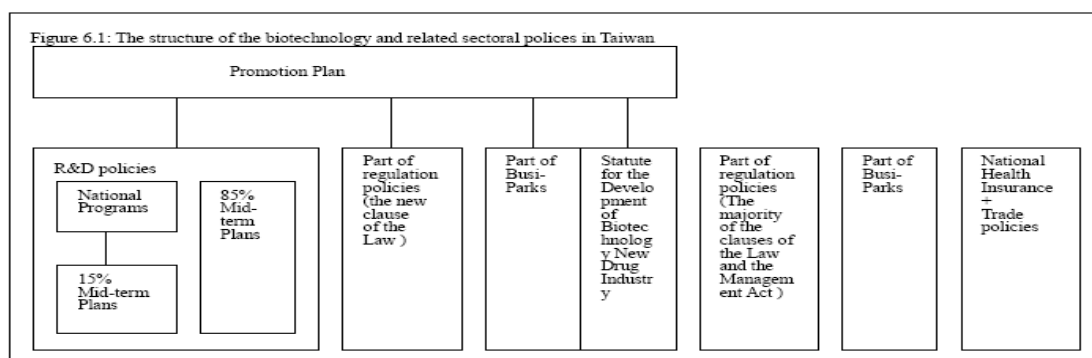
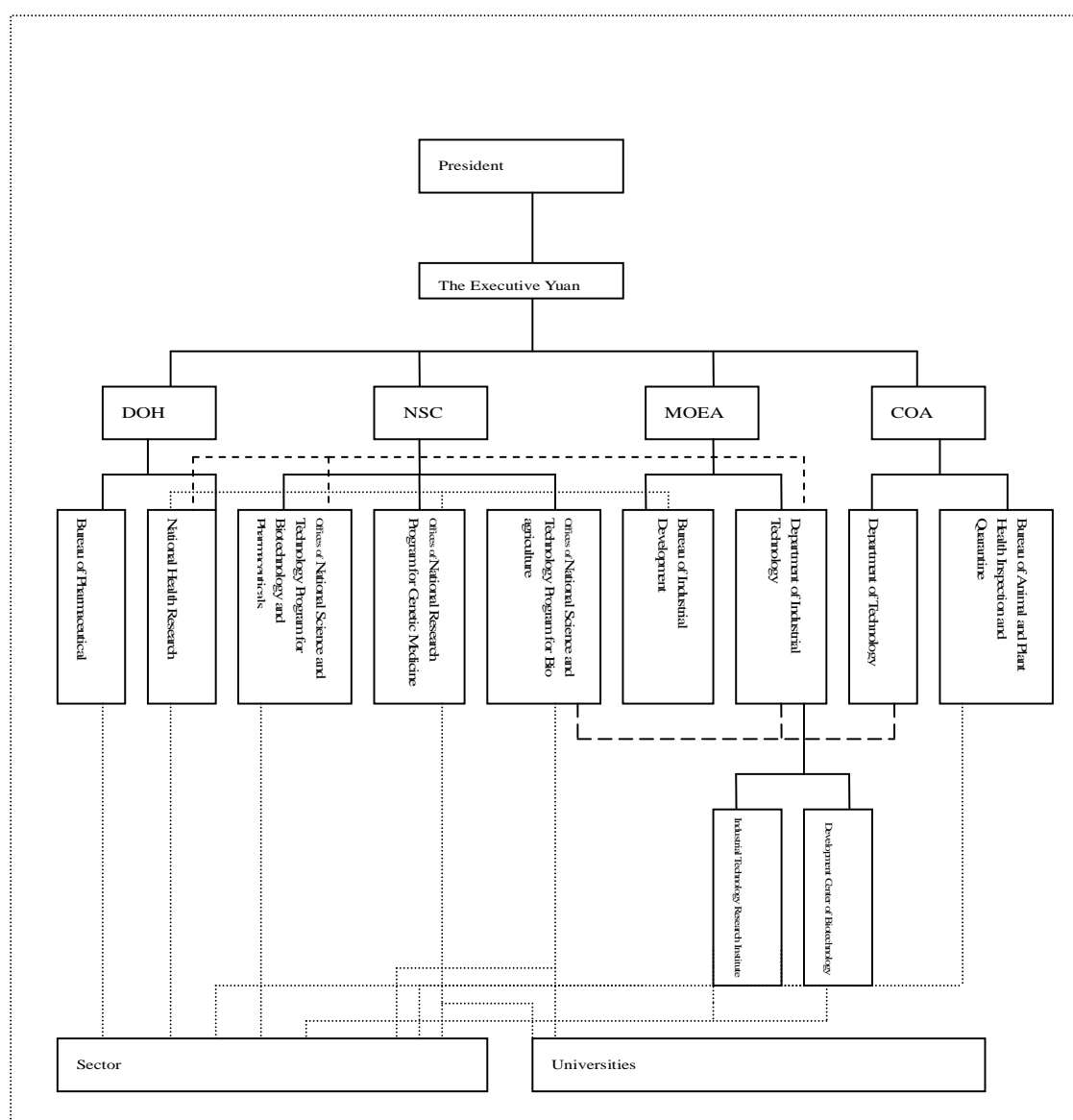


Figure 6.2 The institutions of the four ministries of the executive branch in Taiwan



Abbreviation: NSC= the National Science Council, MOEA= the Ministry of Economic Affairs, COA= the Council of Agriculture, DOH= the Department of Health

Policy names	Policy type	Policy contents
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The Promotion Plan for the Biotechnology Industry	<b>Overall Highest Principal of biotech policies</b>	<ul style="list-style-type: none"> <li>* Ministries: NSC, MOEA, DOH, COA</li> <li>* Year of promotion: 1995 (revised in 2003)</li> <li>* Policy objectives: to establish Taiwan to be the leading Asian center for biotechnology innovation, manufacturing and operations</li> <li>* Policy instruments: (1) funding biotechnology research, (2) facilitating technology transfer and commercialization, (3) developing and refining regulations and laws, (4) training talents, (5) attracting domestic and foreign investments (6) offering marketing services</li> </ul>
National Research Program for Genomic Medicine	<b>R&amp;D</b>	<ul style="list-style-type: none"> <li>* Ministries: NSC (coordinator), MOEA, DOH</li> <li>* Year of promotion: 2002</li> <li>* Policy objectives: to 'integrate limited resources, to capitalize the knowledge embodied in the human genome in order to promote medical research in Taiwan and also to act as an initiator for the local biomedical industry'</li> <li>* Policy instruments: funding</li> <li>* Targets: the research of genetic therapies for cancers, infectious diseases and highly heritable diseases</li> </ul>
National Science and Technology Program for Biotechnology and Pharmaceuticals	<b>R&amp;D</b>	<ul style="list-style-type: none"> <li>* Ministries: NSC (coordinator), COA, MOEA</li> <li>* Year of promotion: 2000</li> <li>* Policy objectives: to 'fully utilize all existing R&amp;D resources to develop cutting-edge agricultural biotechnology in the Asian-Pacific regions, to develop value-added agricultural products and to direct academic/industrial interaction and cooperation'</li> <li>* Policy instruments: funding</li> <li>* Targets: 15 bio-agricultural products, such as genetic modified orchids, animal vaccines etc.</li> </ul>
National Science and Technology Program for Bio-agriculture	<b>R&amp;D</b>	<ul style="list-style-type: none"> <li>* Ministries: NSC (coordinator), MOEA, DOH</li> <li>* Year of promotion: 2001</li> <li>* Policy objectives: to 'gather all the allocated funding related to biotechnology and drug R&amp;D of the National Science Council, the Ministry of Economic Affairs and the Department of Health to integrate the co-operation among industry, government, academics and the institutes'</li> <li>* Policy instruments: funding</li> <li>* Targets: the research of new chemical medicines, new protein of pharmaceutical intermediaries, and new Chinese herbal medicines which may be able to heal the four diseases among Taiwanese citizens, including cancer, diabetes, cardiovascular, and neurological diseases</li> </ul>
Mid-term R&D Plans	<b>R&amp;D</b>	<ul style="list-style-type: none"> <li>* Ministries: NSC, MOEA, DOH, COA</li> <li>* Year of promotion: 1960</li> <li>* Policy objectives: <ul style="list-style-type: none"> <li>※ NSC: 'support advanced fundamental biological research in the academic community, to develop outstanding researchers and to improve the infrastructure of research in universities'</li> <li>※ MOEA: to 'encourage domestic SMEs to invest in biotechnology, to build up competitive biotechnology clusters and to support advanced applied biotechnological research' (National Applied Research Laboratories, 2008: 463,464).</li> <li>※ COA: to 'enhance the competitiveness of domestic agricultural products in the domestic and international markets' (National Applied Research Laboratories, 2008: 463,464).</li> <li>※ DOH: 'to support the bio-pharmaceutical research in the research organizations and companies which were searching for the therapies for the common diseases of citizens' (National Applied Research Laboratories, 2008: 463,464).</li> </ul> </li> <li>* Policy instruments: funding</li> </ul>
The Law of Pharmaceutical Affairs	<b>Regulation</b>	<ul style="list-style-type: none"> <li>* Ministries: DOH (Bureau of Pharmaceutical Affairs)</li> <li>* Year of promotion: 1970</li> <li>* Policy objectives: to 'regulate the safeties of pharmaceutical affairs'</li> <li>* Policy instruments: penalties</li> <li>* Policy purpose of the new clauses: encourage innovation of new medicines</li> <li>* Policy instruments of the new clauses: license and protection</li> </ul>
Agro-pesticides Management Act	<b>Regulation</b>	<ul style="list-style-type: none"> <li>* Ministries: COA (Bureau of Animal and Plant Health Inspection and Quarantine)</li> <li>* Year of promotion: 1972</li> <li>* Policy objectives: to 'strengthen the management of pesticides'</li> <li>* Policy instruments: penalties and license</li> </ul>
Factory Rules	<b>Regulation</b>	<ul style="list-style-type: none"> <li>* Ministries: MOEA (Bureau of Industrial Development)</li> <li>* Year of promotion: 1969</li> <li>* Policy objectives: to regulate manufacturing activities of factories</li> <li>* Policy instruments: license</li> </ul>
Abbreviation: NSC= the National Science Council, MOEA= the Ministry of Economic Affairs, COA= the Council of Agriculture, DOH= the Department of Health		

<sup>14</sup> See National Science Council Mid-term R&D Plans:  
[http://210.241.21.133/DOC/2406/PLAN\\_10\\_20051103162406193.htm](http://210.241.21.133/DOC/2406/PLAN_10_20051103162406193.htm).

The Promotion Plan<sup>15</sup> defined the general policy objectives of the Taiwanese government. It was first decided by the Executive Yuan in 1995 and was further revised in 2003. According to the Promotion Plan the Taiwanese government recognized that the ‘global biotechnology industry would quickly grow in the future and would essentially contribute to the Taiwanese national competitiveness’. Therefore, the general policy objective of the government was to establish Taiwan as ‘the leading Asian center for biotechnology innovation, manufacturing and operations’. All the policies under the framework of the Promotion Plan were promoted as the policy instruments to fulfil the general policy objectives of the Promotion Plan. However, as already shown in Figure 6.1, the Promotion Plan was only over a part of the biotechnology and related sectoral policies in Taiwan. For the policies outside the Promotion Plan, such as the Management Act and the majority of the clauses of the Law, the Taiwanese government in fact had no institution to direct them to be consistent with the Promotion Plan.

The National Programs, as shown in Figure 6.1, were the policy framework over 15 % of the Mid-term Plans of the four ministries. As shown in Table 6.1 each of the four ministries promoted its own Mid-term Plan. Since the Mid-term Plan of each of the four ministries had different policy objectives and had limited connection with the other (see below, section 6.4.), the National Programs were promoted during 2000 to 2002 to make the policy objectives and policy instruments of the 15 % Mid-term Plans of the four ministries to be horizontally complementary to each other. Moreover, the policy objectives of the National Programs were vertically consistent with the general policy objectives of the Promotion Plan. Indeed, two National Programs were directed towards the pharmaceutical sector (also referred to

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<sup>15</sup> See the Promotion Plan for the Biotechnology Industry:  
[http://www.biopharm.org.tw/promoption\\_program/promoption\\_program.html](http://www.biopharm.org.tw/promoption_program/promoption_program.html).

be the ‘two pharmaceutical National Programs’) and only one National Program was directed towards the agricultural sector (also referred to be the ‘agricultural National Program’). As shown in Table 6.1 the ‘National Research Program for Genetic Medicine’ and the ‘National Science and Technology Program for Biotechnology and Pharmaceuticals’ were the two National Programs funding bio - pharmaceutical research and supporting the growth of local pharmaceutical SMEs. The detailed policy objectives of the two National Programs are shown in Table 6.1<sup>16</sup> and the policy instruments of both of the two National Programs were funding. While the National Science Council was responsible for funding the fundamental bio - pharmaceutical research in the universities, the Department of Health should fund clinical trials, and the Ministry of Economic Affairs should fund local pharmaceutical companies to transfer the results from the projects funded by the National Programs. In addition, the ‘National Science and Technology Program for Bio agriculture’ was the only National Program funding bio - agricultural research and supporting the development of local agricultural SMEs<sup>17</sup>. The policy objectives of the National Program are shown in Table 6.1 and the policy instruments of the National Program were also funding. The National Science Council was responsible for funding bio - agricultural research in universities, the Council of Agriculture and the Ministry of Economic Affairs should fund local agricultural SMEs to transfer the bio - agricultural research from universities.

Furthermore, the Law and the Management Act were promoted to regulate the safety of pharmaceuticals, medical devices and food. The policy objective of the Law<sup>18</sup> is shown in Table 6.1, and the policy instruments were penalties. These initial policy objectives and the policy instruments,

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<sup>16</sup> See the goal of National Research Program for Genomic Medicine: <http://nrpgm.sinica.edu.tw/en/content.php?cat=agtc>. See the Official website of the Program: <http://npbp.m-w.com.tw/en/index.php>.

<sup>17</sup> See the Official website of the Program: <http://nstpab.sinica.edu.tw/english.php>.

<sup>18</sup> See the Law of Pharmaceutical Affairs: <http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT01.asp?lsid=FL013783>

which, as described in section 5.2.1.3, were promoted in 1970 before the announcement of the Promotion Plan, remained outside the framework of the Promotion Plan. Only after 2000 in order to achieve the general policy objectives of the Promotion Plan and to encourage the innovation of new pharmaceuticals, the Department of Health executed new clauses of the Law, such as the licenses of new medicines and pharmaceutical data exclusivity<sup>19</sup>. The policy instruments of the new clauses were license and protection. Only the new clauses of the Law were promoted under the framework of the Promotion Plan. In addition, the policy objective of the Management Act is shown in Table 6.1 and the policy instruments of penalties and license. The Management Act, which, as described in section 5.3.1.3, was legislated in 1972, remained outside the framework of the Promotion Plan after 2000. According to the Management Act, the pesticide factories should get the first manufacturing license through the ‘Factory Rules’ executed by the Ministry of Economic Affairs and should get the second licenses from the Council of Agriculture, through the Management Act.

In fact, the National Programs and the two regulation policies under consideration here (the Law and the Management Act) were not consistent with each other. While the policy objectives of the National Programs tended to encourage the innovation of pharmaceuticals and agricultural products and to realize the general policy objectives of the Promotion Plan, the policy objectives of the regulation policies did not prioritize the development of biotechnology and were not vertically complementary to the Promotion Plan. In addition, the policy instruments of the two policies also had potential inconsistencies. While the National Programs used the policy instruments of funding to support the development of pharmaceutical and agricultural sectors, the policy instruments of the regulation policies, license

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<sup>19</sup> See the Official website of the Council for Economic Planning and Development: <http://www.cepd.gov.tw/m1.aspx?sNo=0004392>

and penalties may increase the difficulties of innovation and made the obstacles for the development of biotechnology related sectors. Once the policy instruments of the two policies were promoted together, the appropriateness of the two policies is the central topic of section 6.3.

### **6.3 The evolution of the three biotechnology related sectors and the appropriateness of the National Programs and regulation policies from 2000 to 2008**

In this section we will discuss the evolution of the three Taiwanese biotechnology related NSTIS and the appropriateness of the National Programs and the regulation policies. As we have described in section 3.1 the appropriateness of the RTDI policies is a relative term and different from sectors, technologies and nations. The three biotechnology related NSTIS, as we have briefly mentioned in the end of Chapter 5, in fact needed different appropriate policies. In the following sections, we will first discuss the evolution of the pharmaceutical sector and the appropriateness of the two policies, and afterwards discuss that of the agricultural sector and the medical device sector.

#### **6.3.1 The pharmaceutical sector**

##### **6.3.1.1 The ecology of firms**

Between 2000 and 2008, local SMEs were the pillars of innovation and manufacturing activities in the pharmaceutical sector. The pharmaceutical MNCs, which had started to sell their manufacturing facilities to local SMEs since the 1990s, sold out their manufacturing facilities. In the beginning of the 2000s the MNCs only operated their marketing divisions in Taiwan (Cho, 2001).



The main business of local pharmaceutical companies was still manufacturing pharmaceutical intermediaries and generic medicines. The knowledge base of these firms was chemical engineering rather than biotechnology. The knowledge accumulation of these companies was in manufacturing activities. However, the majority of firms still lacked resources to do innovation. They mainly targeted the domestic market and competed with each other on a price - base. With limited technological capabilities, these firms' pharmaceutical products were hard to export to foreign markets (Development Center of Biotechnology, 2007: 585-586).

The most significant ecological change of the pharmaceutical sector was the emergence of new bio - pharmaceutical companies. Compared with the local companies which focused on manufacturing pharmaceutical intermediaries and genetic medicines, the new bio - pharmaceutical companies had much stronger research capabilities for biotechnology and pharmaceuticals and concentrated on the innovation of new bio – pharmaceuticals. Since the knowledge accumulation of these new bio - pharmaceutical SMEs was still too weak to compete with MNCs, they usually focused on the innovation of Me-Too medicines, rather than new medicines. Furthermore, due to the smallness and limited marketing capabilities of these new companies they usually targeted the sales of the domestic market (Ho, 2004: 28, 63).

The companies of Chinese herbal medicines also made obvious progress during this period. While the majority of companies of Chinese herbal medicines still emphasized the manufacturing activities of traditional herbal medicines (Development Center of Biotechnology, 2004: 184), some larger companies started to invest in the innovation of new herbaceous medicines. In addition, a group of new companies of Chinese herbal medicines were set up in the late 1990s and at the beginning of the 2000s (Ho, 2004: 220).

Since these new companies were established, they emphasized the innovation of new herbaceous medicines. In fact, new companies and also larger ones, of Chinese herbal medicines, had frequent interactions with academics. The main knowledge base of all these companies was the historical records of Chinese herbs. Modern biotechnology was mainly used by the companies to test the reliability of the historical records, to analyze the functional genes of herbs and to discover the effects of herbal genes on human cells. The new herbaceous medicines usually used a single extract of a specific herb. Strict clinical trials were widely adopted in the innovation of new herbal medicines (Department of Biotechnology, 2005: 244-246). However, due to the smallness and limited marketing capabilities of these companies, they usually targeted the demands of domestic market only.

While biotechnology gradually spilled over in the pharmaceutical sector, the two pharmaceutical related National Programs also tended to facilitate pharmaceutical companies to absorb biotechnology and to develop new medicines; yet, most of the pharmaceutical companies were quite indifferent to the two National Programs (see below, section 6.3.1.3). In fact, the two National Programs which targeted the new biotechnological or chemical pharmaceuticals didn't fit the manufacturing business of the firms of intermediaries and generic medicine whose knowledge base was the chemical engineering. While the majority of these companies were not incentivized by the two National Programs to do pharmaceutical innovation, only few larger companies of intermediaries and generic medicines, which were willing to invest in the innovation of new or Me-too medicines, transferred biotechnologies from the two National Programs (National Science Council, 2004). For example, Taiwan Tong Yang, which was one of the largest companies of generic medicine in Taiwan, transferred Thalidomide (a new chemical medicine for anti - liver cancer) from the National Science and Technology Program for Biotechnology and

Pharmaceuticals and continued doing Phase III clinical trials (National Science Council, 2004). Besides, it was in fact the new bio - pharmaceutical companies and the companies of Chinese herbal medicines to benefit most from the two National Programs. With stronger research capabilities these companies were more willing to transfer the biotechnologies from the two National Programs. For instance, PhytoHealth and SunTen Phototech have cooperated in the innovation of PDC-748 (a new herbal medicine of tussis) and received full funding from the National Science and Technology Program for Biotechnology and Pharmaceuticals to continue Phase II clinical trials<sup>20</sup>.

We have interviewed three pharmaceutical companies which transferred biotechnologies funded by the National Science and Technology Program for Biotechnology and Pharmaceuticals, including one larger (SunTen Phototech) and one new company of Chinese herbal medicines (Pharmaceutical SME A), as well as one new bio - pharmaceutical company (Taiwan Liposome Company). All of the companies which transferred biotechnologies supported by the National Science and Technology Program for Biotechnology and Pharmaceuticals considered that the National Program positively encouraged them to cooperate with academics and positively increased their capabilities of innovation. However, besides SunTen Phototech which has not expressed its difficulties, the other two companies expressed that after they transferred the biotechnologies they found it very hard to continuously innovate the bio - pharmaceutical products due to the regulations. As described by the director of R&D of Taiwan Liposome Company (Intcomph3), the company transferred biotechnologies from the National Program for the innovation of new bio - pharmaceuticals, yet the regulatory body, the Bureau of Pharmaceutical

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<sup>20</sup> See the Official website of SunTen Phototech:  
[http://www.stpt.com.tw/eng/rd\\_pdc748.php](http://www.stpt.com.tw/eng/rd_pdc748.php).

Affairs under the Department of Health, which implemented the Law, was quite conservative to issue the company license for clinical trials. Furthermore, the president of R&D of another new company of Chinese herbal medicines (Intcomph4) expressed almost the same experience. The company transferred the biotechnologies funded by the National Program for the innovation of new herbaceous medicines. Yet, because the Bureau of Pharmaceutical Affairs was conservative to issue the company license for clinical trials, the clinical trials of the company were slowed down.

#### 6.3.1.2 The knowledge accumulation and the academic community

The roles of universities dramatically changed after 2000. Before that universities were not allowed to directly interact with pharmaceutical firms. Yet, after 2000, universities were encouraged by the policies, such as the Mid-term Plans of the four ministries and the National Programs, to transfer biotechnologies to pharmaceutical companies as much as possible. Since the majority of local pharmaceutical SMEs were too small to do pharmaceutical related research by themselves, universities in fact burdened the responsibilities to do the majority of research, including the research of small molecule medicine, bio - pharmaceuticals and Chinese herbal medicines. The majority of research topics were chosen according to the research interests of individual scientists. However, with the promotion of the two pharmaceutical National Programs, the scientists with related research interests were gradually encouraged to establish networks with each other and to join research which emphasized the targets of the two National Programs.

Besides universities, the public research organizations under the Ministry of Economic Affairs and the Department of Health were also involved in the innovation of bio - pharmaceuticals and tended to play intermediary roles

between universities and pharmaceutical companies. All of these research organizations, including the Industrial Technology Research Institute, the Development Center of Biotechnology and the National Health Research Institute, tended to transform the basic research from the universities to become applied research, and quickly to transfer the applied research to the pharmaceutical companies. The roles of these research organizations will be further discussed in section 6.4.

Even if the two National Programs have been directed to encourage academics within the universities to transfer biotechnologies to pharmaceutical companies as much as possible, not many academics were incentivized and the results of the majority of the research funded by the two National Programs remained in universities, rather than transferred to the pharmaceutical sector. As described by a professor of Chinese herbal medicines involved in the National Science and Technology Program for Biotechnology and Pharmaceuticals (Intac3), the two National Programs incentivized some scientists to collaborate with each other and to join research projects which focused on the pharmaceutical research of the four selected diseases. Moreover, from his perspective the National Programs also aroused the entrepreneurships of some academics and increased the incentives of these academics to transfer their technologies to pharmaceutical companies. However, as described by the leader of the National Research Program for Genetic Medicine (Intex4), besides a small group of scientists, many scientists funded by the National Program were very reluctant to transfer their results to pharmaceutical companies. In other words, many academics were still not incentivized by the two National Programs to transfer the technology.

### 6.3.1.3 The roles of the government: the appropriateness of the National Programs and the Law

In this section we discuss the roles of the Taiwanese government through analyzing the appropriateness of the National Programs and the Law. In the following paragraphs we will discuss the appropriateness of National Programs and the Law first, and the appropriateness of the two policies afterwards.

The policy objectives and the policy instruments of the National Research Program for Genetic Medicine, as we are going to show below, were appropriate; yet, once being implemented, the National Program did not generate appropriate support to the pharmaceutical NSTIS. As we have described in Table 6.1 the policy objectives of the National Program were ‘to integrate limited resources’, ‘to capitalize on the knowledge embodied in the human genome’, and ‘to act as an initiator for the local biomedical industry’. The extent for the National Program to ‘integrate the limited resources’ will be discussed in section 6.4.2.4. However, the National Program which tended to ‘capitalize on the knowledge’ and ‘to act as an initiator for the local biomedical industry’ in fact tended to support the knowledge accumulation in genetic research and to cluster the networks between academics and companies. As discussed in section 2.4.1, modern biotechnology is science - based and developed through interactions of actors in the network, i.e. scientists and companies. As the universities still did the majority of research and the local pharmaceutical SMEs lacked resources to fund their own innovations, the intended clustering of networks between the university and industry, in order to accelerate the technology diffusion from the universities to companies and to support the knowledge accumulation in the companies, was indeed appropriate for the Taiwanese pharmaceutical NSTIS. The policy instruments which funded both

universities and pharmaceutical companies to explore and accumulate knowledge of genetic therapies were also appropriate.

Yet, the National Program was not effective. Because of the time-lags of the National Program, we are unable to observe the long-term effects of the National Program. However, some economic indicators, such as the number of papers publishes from the results of the projects funded by the Natioanl Program, are able to show short-term effects which are clearly caused by the National Program. These short- term effects are able to help us to observe the extent for

the National Program to appropriately match the pharmaceutical NSTIS. Table 6.2 shows the economic index

Table 6.2: The performance of National Research Program for Genomic Medicine and numbers of pharmaceutical companies from 2002 to 2007						
Year	Papers published	Patent applied	Patent obtained	Technology transfer	Talents educated	Number of pharmaceutical companies
2002	86	3	3	0	299	425
2003	222	21	7	2	376	429
2004	354	48	9	5	419	414
2005	531	11	6	1	338	419
2006	216	7	10	10	600	328
2007	402	14	11	15	340	321
* Sources: Science and technology Yearbook (2008), Biotechnology Industry in Taiwan (from 2001 to 2009)						

of the National Program published by the National Science Council in terms of papers published, patent applied, patent obtained, technology transfer, talents educated and number of pharmaceutical companies. On the basis of the statistical data shown in Table 6.2, in each year from 2002 to 2007 the National Program only transferred 0 to 15 biotechnologies to the pharmaceutical sector. The number of companies which transferred biotechnologies funded by the National Program only shared 0 % to 4.6 % of the total of pharmaceutical companies. Under the condition that more than 95 % of pharmaceutical companies did not transfer biotechnologies funded by the National Program, it was hard for the National Program to claim that it was successful ‘to act as an initiator for the local biomedical industry’. Furthermore, from 2002 to 2007 in each year the National

Program only obtained 3 - 11 patents. The extent for the National Program to 'capitalize on the knowledge embodies in the human genome' was in fact very limited. Nevertheless, besides the quantitative economic index, we also collected some qualitative data through our interviews with the leader of the National Program (Intex4) and the project manager in the Office of the National Program (Intad4). According to the interviewees the National Program did encourage some scientists to do outstanding genetic research and encouraged a small group of scientists and a small number of pharmaceutical companies to collaborate with each other through technology transfer. In another words, the National Program, to some extent, appropriately encouraged the knowledge exploitation of biotechnology in universities and encouraged some academics and pharmaceutical companies to cluster networks. Although in the short term the economic index didn't show the appropriateness of the National Program, in the long term the National Program may be able to appropriately support the development of pharmaceutical NSTIS in the future. In summary, the policy objectives and policy instruments of the National Program were appropriate, yet after being implemented, at least in the short term, the National Program had very limited support to the pharmaceutical NSTIS.

The policy objectives and policy instruments of the National Science and Technology Program for Biotechnology and Pharmaceuticals, as shown below, were also appropriate; yet, the National Program generated very limited appropriate support for the development of pharmaceutical NSTIS. As we have described in Table 6.1 the policy objectives of the National Program were to 'gather all the allocated funding related to biotechnology and drug R&D' of the three ministries and 'to integrate the co-operation among industry, government, academics and the institutes'. The extent for the National Program to 'gather all the allocated funding' will be discussed in section 6.4.2.4. As the modern biotechnology was developed through



interactions of actors and both scientists and companies are important in the innovation of biotechnology, the National Program, which sought 'to integrate the co-operation among industry, government, academics and the institutes', in fact tended to cluster networks between different actors. The policy instruments of the National Program which funded both the academics and pharmaceutical companies in order to encourage interactions and the knowledge accumulation of bio - pharmaceuticals on both sides were also appropriate. However, on the basis of the quantitative economic index published in the Science and Technology Year Book (2008:348-362), from 2005 to 2007 the National Program has totally transferred 10 biotechnologies to the pharmaceutical sector. The number of pharmaceutical companies which transferred biotechnologies funded by the National Program only weighted 4 % of the total number of pharmaceutical companies. Under the condition that more than 95 % of the pharmaceutical companies didn't transfer technologies funded by the National Program, it was difficult for the National Program to claim that it successfully encouraged the cooperation between the academics and industry. Besides, we have collected the qualitative data through the interviews with the leader (Intex5), the officer of the National Program (Intad5), the pharmaceutical companies (Intcomph2, Intcomph3, Intcomph4) and the academic (Intac3) involved in the National Program. According to those interviewees, the National Program did encourage the collaboration between some academics and a small number of pharmaceutical companies. Even if in the short term the economic index didn't show the appropriate effect, in the long term the National Program may be able to appropriately support the development of pharmaceutical NSTIS. In sum, the policy objectives and policy instruments of the National Program were appropriate, but the National Program generated limited appropriate effect on the pharmaceutical NSTIS, at least in the short term.

The policy objective and the policy instruments of the Law, as we are going to show below, were inappropriate and only the policy purpose and the policy instruments of the new clauses of the Law were appropriate; once all clauses of the Law being implemented, the Law didn't generate appropriate support to the pharmaceutical NSTIS. The policy objective of the Law, as described in Table 6.1, which intended to 'regulate the safeties of pharmaceutical affairs' through penalties, in fact had no intention to support the knowledge accumulation, to cluster actors or to encourage the innovation of pharmaceutical products. As we have discussed in section 5.2.1.3, the majority of the clauses of the Law legislated in 1970 in order to control the manufacturing and the quality of medicines. From 1970 to 2000, the policy objective and the policy instruments of the Law were not changed. Only after 2000 the new clauses of the Law were legislated to follow the general policy objectives of the Promotion Plan and to encourage local pharmaceutical companies to be involved in the innovation of new pharmaceuticals and new bio – pharmaceuticals. The policy purpose of the new clauses of the Law was appropriate, because the involvement of the pharmaceutical companies facilitated the knowledge diffusion of modern biotechnology in the pharmaceutical sector. Moreover, the policy instruments of the new clauses which licensed and protected the data exclusivity of the new pharmaceuticals and new bio - pharmaceuticals also encouraged the involvement of pharmaceutical companies in the innovation of modern biotechnology and were appropriate. Yet, once being implemented, according to the descriptions of the director of R&D of Taiwan Liposome Company and the president of R&D of Pharmaceutical SME A (Intcomph3, Intcomph4), the implementation body of the Law was conservative to issue the license for clinical trials and to some extent, discouraged the pharmaceutical companies to innovate new pharmaceuticals. In other words, even if the policy purpose and policy instruments of the new clauses of the Law were appropriate, once being implemented, the new

clauses didn't appropriately support the development of the pharmaceutical NSTIS. We will further discuss the implementation of the Law in section 6.4.3.3.

While the two National Programs and the Law were promoted together, according to our interviews with the three pharmaceutical companies which transferred the biotechnologies from the project funded by the two National Programs, the limited appropriateness of the two National Programs was, to some extent, reduced by the promotion of the Law. After the promotion of the two policies, the Taiwanese government in fact had no obvious appropriate support to the development of pharmaceutical NSTIS. We will further discuss this issue in section 6.4.

### 6.3.2 The agricultural sector

#### 6.3.2.1 The agricultural innovation system during this period

The innovation system of seeds and livestock was gradually transformed during this period. The Agriculture Stations still played significant roles in the innovation of new seeds and new species of livestock. Traditional biotechnology of hybridization was adopted by these public research organizations to improve the genes of both seeds and livestock, and the modern biotechnology of genetic modification was only used to improve the genes of the seeds. Through the Farmers' Association, the majority of the innovated seeds and the youngling of new livestock which were improved by the traditional biotechnology of hybridization were given to farmers for free. Nevertheless, the seeds improved by modern biotechnology of genetic modification were cultivated in field trials only and were not allowed to be disseminated outside the research organizations.

Private SMEs still played supplementary roles in the innovations of seeds and livestock. Even though the knowledge for the genetic modification of seeds has been plentifully accumulated in public research organizations and universities for many years, larger private seed companies, such as Knownyou<sup>21</sup>, insisted to use the traditional biotechnology of hybridization to improve the genes of the seeds. The main reason for this was the market. Since these private seed companies tended to export their seeds to foreign markets such as Japan and South East Asian countries, these companies tended to strictly keep their products as ‘no GM’ seeds (Intex6). In fact, it was the new agricultural SMEs set up after 2000 and the agricultural trade companies to invest in the innovation of GMO, especially in the non - edible GMO. For example, Taikong, an agricultural trade company, started to sell its first GM products in 2001<sup>22</sup>.

In the industries of food, pesticide and fertilizer, both the public company and the private companies adopted biotechnology in their products. Taiwan Sugar Corporation was still public and the largest company of food, pesticides and fertilizers. Modern biotechnology was used by the corporation to extract the functional ingredients from Chinese herbs and further process these herbal ingredients into herbal food<sup>23</sup>. The knowledge base of the herbal food was totally the same as the knowledge base of Chinese herbal medicines. Without doing strict clinical trials, the corporation only sold its herbal products as herbal food, rather than Chinese herbal medicines and supplied the domestic demands. Besides, the private

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<sup>21</sup> See the Official website of Knownyou:  
<http://www.knownyou.com/index.jsp?bodyinclude=aboutusbody6.jsp&knownyounews=knownyounews2.jsp>.

<sup>22</sup> See the interview with the CEO of Taikong:  
[http://www.biotaiwan.org.tw/download/structure4/%E5%8A%89%E7%BF%A0%E7%8E%B2/%E5%B0%88%E8%A8%AA%E9%82%B0%E6%B8%AF%E7%A7%91%E6%8A%80%E8%82%A1%E4%BB%BD%E6%9C%89%E9%99%90%E5%85%AC%E5%8F%B8\(200809\).pdf](http://www.biotaiwan.org.tw/download/structure4/%E5%8A%89%E7%BF%A0%E7%8E%B2/%E5%B0%88%E8%A8%AA%E9%82%B0%E6%B8%AF%E7%A7%91%E6%8A%80%E8%82%A1%E4%BB%BD%E6%9C%89%E9%99%90%E5%85%AC%E5%8F%B8(200809).pdf)

<sup>23</sup> See the information of the products of Taiwan Sugar Corporation:  
[http://www.taisugar.com.tw/chinese/ProductsInfo\\_index.aspx?n=10026](http://www.taisugar.com.tw/chinese/ProductsInfo_index.aspx?n=10026)

food companies also used biotechnology in the innovation of herbal food<sup>24</sup>. Moreover, the new companies of pesticides and fertilizers which were set up after 2000 continuously utilized biotechnologies in their products of bio - pesticides and bio - fertilizers (STRIC, 2006: 31). The majority of these firms targeted the domestic market. However, some of the firms gradually started to search for opportunities in the foreign markets, including Japan, EU, China and South East Asian countries (Intcomag5).

While modern biotechnology, such as the technologies of genetic modification and extraction, gradually spilled over in the agricultural sector, the National Science and Technology Program for Bio agriculture also tended to facilitate agricultural companies to absorb biotechnology; yet, only part of the companies were eager to transfer biotechnologies from the National Program. For the companies of seeds and livestock, the National Program, which targeted the modern biotechnologies of genetic modification rather than traditional hybridization, did not get much support from larger companies. As described by the CEO of Agricultural SME B (Intcomag4), since the governments of Taiwan and South East Asian countries didn't allow the trade of GM seeds, the company didn't see the market. Therefore, the company had no incentives to transfer the biotechnology of GM and invest in the innovation of GM seeds. Indeed, it was the new agricultural companies or the agricultural trade companies which were willing to invest in the innovation of GMO to benefit most from the National Program. For example, Taikong was funded by the National Program to innovate GM ornamental fish (Intcomag6). In addition, for the companies of food, pesticides and fertilizers, all public and private companies which were willing to invest in the innovations of herbal food, bio - pesticides and bio - fertilizers were benefitted by the National Program. For example, an Agricultural public company A was funded by the National

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<sup>24</sup> See the websites of Simpson: <http://simpsonbioteche.so-buy.com/front/bin/home.phtml>.

Program to cultivate gentians in Taiwan. Gentian was the herb which originally grew in China and was imported to Taiwan. Since gentian was frequently used by the Taiwanese companies of food and Chinese herbal medicines, the National Program hoped that the company would plant the herb in Taiwan and reduced the reliance on China (Intcomag2). Moreover, Advanced Green Biotechnology was also funded by the National Program to innovate the manufacturing process of bio - pesticides and bio - fertilizers (Intcomag5).

We have interviewed three companies which transferred biotechnologies within the National Program, including one company of the innovation of GMO (Taikong), one public company of food, pesticides and fertilizers (Agricultural public company A), and one private company of bio - pesticides and bio - fertilizers (Advanced Green Biotechnology). All three companies expressed that even though they transferred biotechnologies funded by the National Program, they suffered great difficulties for commercialization because of the regulation policies for food safety. As described by the vice - president of R&D of Taikong (Intcomag6), the Taiwanese government had no regulations for non - edible GMO, and the international regulations were not applicable in Taiwan. The company was only able to sell its GM ornamental fish in the domestic market. Yet, because the company got no licenses in Taiwan, it was impossible to get licenses from the government of EU countries and Japan. The company was then totally excluded from the main international markets. Moreover, as described by the Director of R&D of the public company of food, pesticides and fertilizers (Intcomag2), even though the company was funded by the National Program and successfully cultivated gentian in Taiwan, the company was forbidden by the Council of Chinese Herbal Medicine under the Department of Health to sell its products. According to the perspective of the Council, the historical records of the herb were based on the ones

grown in China. The company was unable to demonstrate if the herbs cultivated in Taiwan had the same functions as the ones grown in China. Therefore, the sale of the gentian cultivated in Taiwan was forbidden. Furthermore, as expressed by the Assistant Manager of Advanced Green Biotechnology (Intcomag5), even though the company has transferred the biotechnologies of fermentation funded by the National Program to manufacture bio - pesticides and bio - fertilizers, the company was unable to get a license from the Bureau of Animal and Plant Health Inspection and Quarantine to manufacture its products in Taiwan. According to the Management Act, the company should provide the data of toxicology to the Bureau. Since the company was unable to provide sufficient data, it got no license. The company finally gave up all the manufacturing activities in Taiwan and turned to manufacture in South East Asian countries. In sum, the agricultural companies which transferred biotechnology funded by the National Program in fact encountered various problems of commercialization because of different agricultural regulations. Instead of discussing the policy - making process of various agricultural regulation policies, we will discuss the case of the Management Act in-depth in section 6.4.

#### 6.3.2.2 The knowledge accumulation and the academic community

The universities gradually established a network with agricultural companies during 2000 to 2008. Before 2000 universities were not expected to directly interact with agricultural companies. However, after 2000 universities were encouraged by policies, such as Mid-term Plan of the Council of Agriculture and the agricultural National Program, to transfer biotechnologies to private agricultural companies as much as possible. While the knowledge of modern biotechnology was quickly accumulated within universities, the research topics of the majority of research were

decided by the research interests of individual scientists. With the promotion of the National Program after 2000, the scientists in the universities were gradually encouraged to establish networks with each other and to join research projects.

The Agriculture Stations continued accumulating the knowledge of modern agricultural biotechnology. However, the National Program gradually changed the roles of these public research organizations in the innovation system of seeds. Before the promotion of the National Program all the seeds and livestock innovated by the public research organizations were transferred to farmers for free. Yet, after the promotion of the National Program, as long as the Agriculture Stations joined in the projects funded by the National Program, the biotechnologies innovated by Agriculture Stations should be sold to private companies rather than transferred to farmers for free. In addition, farmers were gradually encouraged to buy the seeds and new species of livestock from private companies, such as the seeds of GM orchid.

Even though the National Program encouraged academics to transfer their technologies to agricultural companies, many results of the research projects funded by the National Program were kept in the universities. As described by a professor of horticulture involved in the National Program (Intac2), the National Program indeed encouraged collaborative research projects across universities. Yet, from his perspective, the National Program was not very different from the research projects which purely encouraged academics to do fundamental bio - agricultural research. As also acknowledged by the leader of the National Program (Intex6), in practice, many results of the research projects funded by the National Program were still in universities rather than transferred to agricultural companies.



### 6.3.2.3 The roles of the government: the appropriateness of the National Program and the Management Act

The roles of the Taiwanese government were judged by the appropriateness of the National Program and the Management Act. In the following paragraphs we discuss the appropriateness of the National Programs and the Management Act first, and then discuss the appropriateness of the two policies.

The  
National  
Science  
and  
Technolog  
y Program  
for Bio  
agriculture,  
as

Table 6.3: The performance of National Science and Technology Program for Bio agriculture from 2003 to 2007

Year	Papers published	Patent obtained	Technology transfer	Academic conferences	Number of agricultural companies
2003	246	5	2	10	63
2004	413	4	11	7	57
2005	202	9	29	15	73
2006	286	9	18	30	--
2007	392	13	22	27	--

\* Sources: Science and technology Yearbook (2008), Biotechnology Industry in Taiwan (from 2001 to 2009)

discussed below, had appropriate objectives and policy instruments, and after being implemented, the National Program, to some extent, generated appropriate support to the development of agricultural NSTIS. As we have described in Table 6.1, the policy objectives of the National Program were to ‘fully utilize all the existing R&D resources to develop cutting-edge agricultural biotechnology in the Asian-Pacific regions’, ‘to develop value-added agricultural products’ and ‘to direct academic / industrial interaction and cooperation’. The extent for the National Program to ‘fully utilize all existing R&D resources’ will be discussed in section 6.4. However, the National Program, which aimed to develop value - added agricultural products and to direct academic / industrial interaction and cooperation, in fact intended to encourage the innovation of agricultural products and to

cluster the networks between actors. The interactions between actors, including scientists and agricultural companies, are important for the innovation of modern biotechnology. The agricultural sector was strongly guided by the public sector. Yet, the private agricultural companies played more and more important roles in the innovation and commercialization of agricultural biotechnology. Since the universities in Taiwan have accumulated rich knowledge of modern biotechnology and the majority of private agricultural companies were too small to do R&D by themselves, the policy objectives of the National Program which tended to cluster networks between universities and companies in order to accelerate the knowledge accumulation within the agricultural SMEs indeed appropriately matched the development of agricultural NSTIS in Taiwan. The policy instruments of the National Program which funded both the universities and agricultural companies were appropriate, because the policy instruments encouraged the knowledge accumulation of modern biotechnology of both of the actors. Yet, after being implemented, the National Program didn't fully achieve its policy objectives. Table 6.3 shows the economic index of the National Program published by the National Science Council in terms of the numbers of papers published, patent obtained, technology transfer, academics conferences and the agricultural companies. As shown in the table from 2003 to 2007, every year, the National Program transferred 7 to 29 biotechnologies to agricultural companies. The number of agricultural firms which got technology transfers weighted as much as 3 to 40 % of the overall agricultural companies. Under the condition that in the particular years there were 40 % agricultural companies that transferred biotechnologies from the research projects funded by the National Program, the National Program, to some extent effective, 'to direct academic/industrial interaction and cooperation'. There was no clear economic index to show the extent for the agricultural companies to 'develop value - added agricultural products'. Therefore, we are unable to judge if the National Program achieved its

policy objective to ‘develop value-added agricultural products’ or not. However, besides the economic index, we also collected qualitative data through our interviews. According to our interviews with the leader of the National Program (Intex6), three agricultural companies (Intcomag2, Intcomag5, Intcomag6) and one academic (Intac3) involved in the National Program, all the interviewees explained that the National Program positively encouraged their coordination with each other. Therefore, in the long term, such cooperation between academics and industry may contribute to the agricultural NSTIS to develop value - added products. In short, after being implemented, the National Program did not perfectly realize its policy objectives, but to some extent, appropriately matched the development of agricultural NSTIS.

The Management Act, as we are going to analyze below, didn’t process appropriate policy objectives and policy instruments and generate appropriate supports. As we have described in Table 6.1, the Management Act was to ‘strengthen the management of pesticides’ through the policy instruments of penalties and license. As we have described in section 5.3.1.3, the Management Act was legislated in 1972 to control the quality of chemical pesticide. At the time, there was no bio-pesticide. However, the Management Act was not adjusted for the development of bio-pesticide. The policy objective and policy instruments in fact had no intention to support the knowledge accumulation and diffusion of modern biotechnology in the agricultural sector. Once being implemented, according to the descriptions of our interviews with the Assistant manager of Advanced Green Biotechnology (Intcomag5), the Management Act in fact increased the barriers of cooperation between actors and discouraged the innovation of the bio - pesticides.

While the National Program and the Management Act were promoted

together, on the basis of our interviews, the appropriateness of the National Program, which in general was appropriate to the dynamics of the agricultural sector, was to some extent reduced by the promotion of the Management Act. After the promotion of the two policies the Taiwanese government in fact had only limited appropriate support to the development of agricultural NSTIS.

### 6.3.3 The medical device sector

#### 6.3.3.1 Knowledge base and the development of the sector

Between 2000 and 2008 the local SMEs of Class I medical devices (such as swabs, surgery dressing and injection) still played important roles within the medical device sector. The main knowledge base of these companies was still the technologies of textile, plastic, machinery and ICT. Biotechnology was seldom adopted by these companies. The main business of these companies was manufacturing, and the majority of these companies' products were exported to foreign markets. These firms usually competed with each other on a price - base. To reduce the cost of manufacturing, some companies of Class I medical devices, such as the companies of surgery gloves, have moved their factories to China (Industrial Technology Research Institute, 2007: 1-5).

The companies with the fastest growth within the medical device sector were the local SMEs of Class II electronic medical devices. The main knowledge base of these firms was machinery and electronic engineering. The main business of the firms of Class II medical devices was manufacturing higher value - added equipments which were outsourced by MNCs. The main products included electronic blood pressure meters, electronic sugar meters, electronic wheelchairs and so on. The majority of

the products were exported to foreign markets. Besides manufacturing, parts of firms have developed more and more mature capabilities to sell the products by their own brands and do research in their companies. Nevertheless, the collaboration between firms was rare. The majority of Class II medical device companies competed severely with each other, not only in the domestic market, but also in the overseas markets. Moreover, to minimize the cost of manufacturing, lots of companies started to move the lower end manufacturing activities to China (Industrial Technology Research Institute, 2007: 1-5). Besides the companies of biochips (like Dr. Chip and Pharlanx) which integrated ICT and biotechnology together, the majority of the companies of Class II medical device didn't adopt biotechnology in their products.

While the companies of medical devices had only limited applications of biotechnology, there was no National Program to facilitate medical device companies to absorb biotechnology; and only the Law was promoted to regulate the safety of the medical devices. We have interviewed three local SMEs of Class II medical devices which have been involved in the promotion of the Law and its affiliated administrative rules. Only the Assistant vice - president of Medical Device SME A (Intcommd1) expressed that the Law did not increase any obstacles for the company's business. The Directors of R&D of the other two medical device companies (Intcommd2, Intcommd3) have both explained that the Law has increased their obstacles for commercializing their products. As described by the Director of R&D of Medical Device SME B (Intcommd2), the Bureau of Pharmaceutical Affairs under the Department of Health checked the quality of every single electronic thermometer of the company. The affiliated administrative rules of the Law not only seriously delayed the timing for commercialization, but also heavily increased the costs of the company. A similar perspective was shared by the Director of R&D of Medical Device SME C (Intcommd3).

His opinion was that the Bureau of Pharmaceutical Affairs was quite conservative to issue licenses to the new products of Class II medical devices. Therefore, the company's sales in the domestic market were seriously delayed.

#### 6.3.3.2 The roles of universities and public research institutes

The universities which focused on the basic research didn't play significant roles in the innovation of Class I medical devices, but had more and more collaboration with the companies of Class II medical devices (Industrial Technology Research Institute, 2007: 4-7). Through technology transfer the knowledge of ICT and machinery accumulated in the universities was gradually spilled over to the medical device sector.

Besides, the public research organizations also accelerated the technology transfer to Class II medical device companies. The roles of the Metal Industrial and Development Center were progressively changed. Before 2001 the companies of Class II medical devices were only indirectly supported by the Center through the projects of supporting machinery companies. However, after 2001, the Center has recognized the importance of the development of Class II medical devices. The Center then set up a new branch in the Southern Taiwan Science Park and organized six SMEs to form a new R&D consortium to innovate man - made gums<sup>25</sup>. In addition, the Industrial Technology Research Institute under the Ministry of Economic Affairs continued supporting the R&D consortium of six biochip companies, the 'Clinical Biochips Industrialization Consortium'<sup>26</sup>.

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<sup>25</sup> See the Official website of Metal Industrial and Development Center: <http://www.mirdc.org.tw/manual/History01.aspx?sty=01>. And the news of the Center: [http://www.mirdc.org.tw/news/News01\\_detail.aspx?Type=1&cond=1354&Source=1&sty=02](http://www.mirdc.org.tw/news/News01_detail.aspx?Type=1&cond=1354&Source=1&sty=02).

<sup>26</sup> See the Official website of the Consortium: <http://www.bel-series.org.tw/cbic/About/>.

#### 6.3.3.3 The role of the government and the appropriateness of the Law

In this section the roles of the Taiwanese government are analyzed by the appropriateness the Law and its affiliated administrative rules. As we have described in section 6.3.1.3, the policy objective and policy instruments of the Law in fact had no intention to encourage the innovation of modern biotechnology and to cluster the network of actors. Even though the Law was amended to add new clauses to support the development of the pharmaceutical sector, the Law was not amended during 2000 to 2008 to match the development of the medical device sector. According to the interviews of the Director of R&D of Medical device SME A and SME B (Intcommd2 and Intcommd3), the Law and its affiliated administrative rules in fact discouraged some of the medical device companies to innovate new medical device products and commercialize these products. Therefore, for the medical device sector, the support of the Law remained inappropriate and thus did not have appropriate supports to the sector.

### **6.4 The policy-making process of National Programs and regulation policies**

#### 6.4.1 Introduction

According to our discussion in section 6.2 and section 6.3, the policy objectives and the policy instruments of the National Programs and the regulation policies were not consistent with each other; and once being implemented together, the two policies did not point in the same direction, and they were very difficult to generate appropriate supports to the development of the three NSTIS. Since we assume that the policy-making process is the root which shapes the consistencies and appropriateness of the two policies, in this section, we will apply the conceptual framework

established in Chapter 3 for opening the black-box of the policy-making process of the two policies. However, before we do this, we will first identify the institutions and actors inside and outside the government which influence the policy-making process.

Inside the Taiwanese government, from 2000 to 2008, the government was the divided government, and the actors inside the government included the elected politicians, the congressmen of the opposition party, and the administrators in the four ministries. While the position of the President was held by the Democratic Progressive Party, the majority of the Legislative Yuan (the congress) was controlled by the opposition party, Kuomintang. It was very difficult to get approvals in the congress for the policy proposals issued in the name of the President. Furthermore, within the executive branch, as we are going to show in the following sections, it was in fact the cabinet rather than the president to make the significant decisions of the biotechnology and related sectoral policies. Nevertheless, the horizontal coordination within the cabinet was difficult, and the vertical coordination between the elected politicians and administrators was also insufficient.

Outside the government, each of the three biotechnology related NSTIS had different external stakeholders. The pharmaceutical sector had eight pharmaceutical associations<sup>27</sup>, and only one had MNCs as members while the other seven were composed of local SMEs. The scientists embedded in the pharmaceutical NSTIS included the academics working in the universities and doing the research of bio-pharmaceuticals and Chinese herbal medicines. The agricultural sector, until 2008, had no influential association operating on a national base, and the scientists in the agricultural

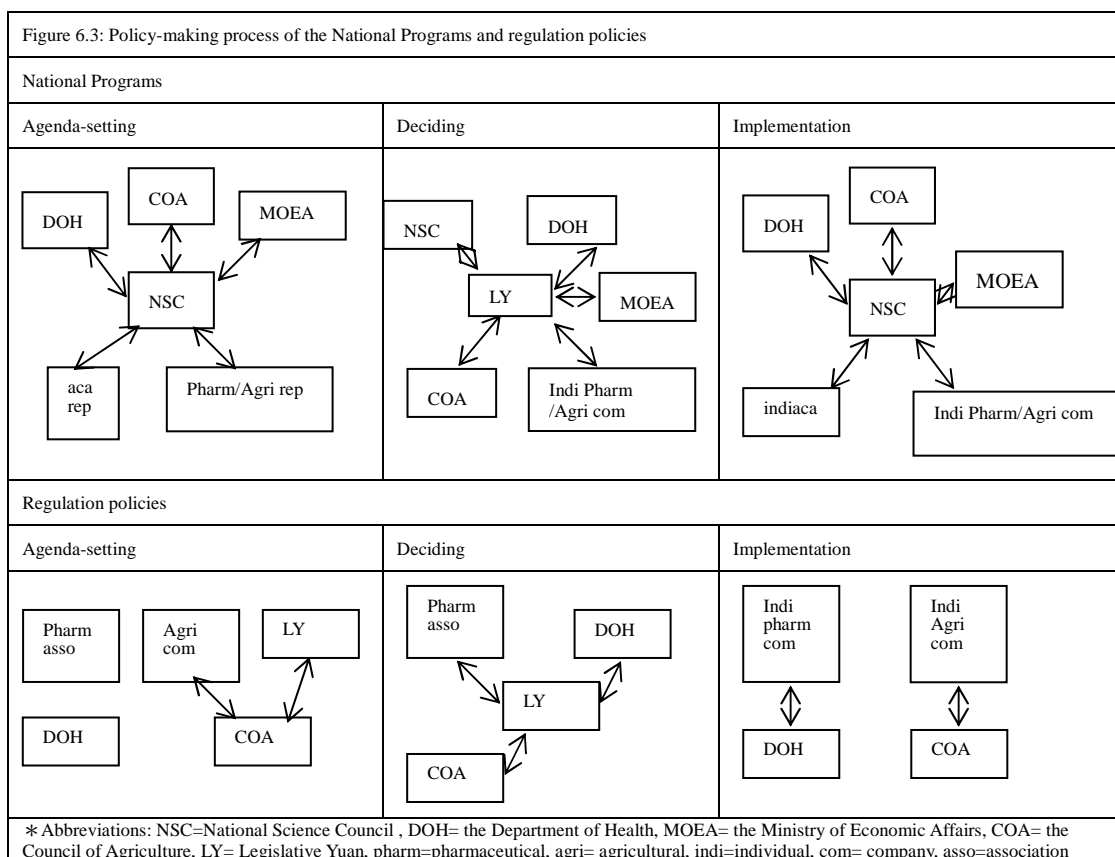
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<sup>27</sup> including the International Research-based Pharmaceutical Manufacturers Association, Taipei Pharmaceutical Agents and Distributors's Association, Taiwan Pharmaceutical Manufacturer's Association, Chinese Association for Pharmaceutical Agents, National Pharmaceutical Chinese Association, Chinese Pharmaceutical Manufacture and Development Association, Taiwan Generic Pharmaceutical Association, and Taiwan Pharmaceutical Marketing and Management Association.



NSTIS included the ones working in the universities or in the public research organizations and doing the research of genetic modification and so on. Finally, the medical device sector had only one association, Taiwan Medical and Biotech Industry Association which was composed of local SMEs.

In the following sections, we will discuss the policy-making process of the National Programs first and discuss which of the regulation policies afterwards. Since the institutional structure of the four ministries shown in Figure 6.2 is useful for us to understand the policy-making process, we will frequently refer to the Figure. Moreover, on the basis of our discussions in section 3.3, we divide the policy-making process of the two policies into four stages, agenda-setting, deciding, implementation and evaluation. The political institutions of the policy-making process of the two policies are shown in Figure 6.3, and the details of the policy-making process are discussed in the following sections.



## 6.4.2 The cases of the National Programs

### 6.4.2.1 The stage of the agenda-setting

#### 6.4.2.1.1 Introduction of the stage

The stage of agenda-setting of the three National Programs was the stage for the leaders of the National Programs to decide the agendas of the policy proposals of these National Programs. According to our discussion in section 3.3.2, the stage of agenda-setting is deeply influence by two independent variables, the horizontal inter-ministerial coordination and the involvement of external stakeholders. In this section, we will focus on the influence of the two independent variables on the consistencies and appropriateness of the three National Programs.

The leaders of the three National Programs indeed were the most important elected politicians to decide the agendas of the National Programs, even though the agendas of the National Programs were first initiated on the ministerial level. As described by the Minister of the National Science Council (Intex2), it was the Minister of the Council to initiate the agendas of the three National Programs. The main purposes of the National Programs were to better integrate the R&D resources of the Mid-term Plans of the four ministries and to invest these resources in the research which had the potential to be transferred to the industries. According to the proposition of the Minister of the Council, each ministry should appropriate 15% budgets of its own Mid-term Plan to the National Programs. The National Science Council was responsible for coordinating the other three ministries to form the inter-ministerial consensus for the policy objectives and the policy instruments of the National Programs and to horizontally coordinate with

each other under the framework of the National Programs. As the policies under the Promotion Plan, the policy objectives of the National Programs should be vertically complementary or at least not contradict to the general policy objectives of the Promotion Plan. The proposition of the Minister of the National Science Council, as described by the Minister of the Council (Intex2), got the agreement of other Ministers. Moreover, since pharmaceuticals and agriculture were considered to be the two sectors with the highest potential for future growth, the inter-ministerial consensus was achieved that the resources of the National Programs should be invested in the bio-pharmaceutical and bio-agricultural research and the results of the research should be transferred to local pharmaceutical and agricultural SMEs. However, as expressed by the Minister of the Council (Intex2), the Ministers of the four ministries only decided the general directions for the National Programs. In practice, it was the leaders of each National Program to decide the detailed agendas of each National Program, including the concrete policy objectives, policy instruments, and the targets of each National Program. Each leader was nominated and delegated by the Minister of the Council to represent the Council to formulate inter-ministerial consensus and to select agendas. The leaders, according to the name lists published on the official websites of the three National Programs<sup>28</sup>, were originally the senior scientists in universities, public research institutes and Academic Sinica. They played the role as the elected politicians and served in the National Programs on a part-time base. They held no formal positions within the government or the pharmaceutical or the agricultural sector.

Although pharmaceuticals and agriculture were two distinct sectors, under the coordination of the National Science Council, the agendas of the three National Programs were set by almost the same process. Each of the two

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<sup>28</sup> See the name lists for the leaders of the three National Programs.

pharmaceutical National Programs established a Steering Committee and a Consulting Committee. The agricultural National Program established a Steering Committee and a Project Committee. The two Committees in each of the National Programs had similar functions. As described by the leader of the National Research Program for Genetic Medicine (Intex4), the Steering Committee played the role to give the general advice to leaders, and the leaders should transform these general advice into concrete policy objectives and policy instruments. In addition, the Consulting Committee or the Project Committee played the roles to help leaders to review the detailed policy proposals and to give leaders advises for the details of these policy proposals. In principle, the leaders should follow these advises of the Consulting Committee or the Project Committee to make detailed agendas. The interactions between the leaders and the members in these two Committees in the stage of agenda-setting are described below.

#### 6.4.2.1.2 The agenda-setting of the two pharmaceutical National Programs

The Steering Committee and the Consulting Committee of the National Research Program for Genetic Medicine were influential to the decisions of the leaders. The Steering Committee was chaired by the Minister of the National Science Council and recruited 19 members, including 9 government officials, 7 academics and 3 pharmaceutical representatives. According to the name list published on the official website of the National Program<sup>29</sup>, the 9 government officials included the two vice-Ministers of the National Science Council, the vice-Minister of the Ministry of Economic Affairs and the vice-Minister of the Department of Health. The 7 academics were the principals of the universities participated in the National Program, and the 3 pharmaceutical representatives included the CEOs of three new

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<sup>29</sup> See the name list for the Steering Committees of the National Research Program for Genetic Medicine: <http://nrpgm.sinica.edu.tw/members.php?team=3&#t>.

bio-pharmaceutical companies. According to the description of the leader of the National Program (Intex4), the government officials and academics were recommended by the ministries and participating universities, and the pharmaceutical representatives were recommended by the leaders. The 3 CEOs of the pharmaceutical companies were invited by the leaders because of the affiliation of their business or because of their long-standing connections with the National Program. For example, as explained by the leader (Intex4), the CEO of AbGenomics was invited because of the company's outstanding performance in the development of new immune bio-pharmaceuticals. The CEO of Taigen (Intcomph1) also explained that she was invited because she was the ex-leader of the National Science and Technology Program for Biotechnology and Pharmaceuticals. Moreover, the Consulting Committee of the National Program recruited 13 scientists who served in the universities or the research institutions in the United States. All the scientists were invited by the leaders. As explained by the leader (Intex4), the Consulting Committee was responsible for reviewing the detailed agendas of the National Program, such as the funding for the research projects. Since almost all the Taiwanese scientists doing genetic research applied for the research funding of the National Program, the leaders invited the American scientists who didn't apply for any funding to neutrally review the research projects.

The Steering Committee and the Consulting Committee of the National Science and Technology Program for Biotechnology and Pharmaceuticals were also influential to the decisions of the leaders. The Steering Committee of the National Program was also chaired by the Minister of the National Science Council and was composed of 14 members, including 7 government officials, 5 academics and 2 pharmaceutical representatives. The 7 government officials included the vice-Ministers of the National Science Council, the Ministry of Economic Affairs, and the Department of Health.

The 5 academics were recommended by universities and research institutions participated in the National Program. Only the 2 pharmaceutical representatives, as described by the CEO of Taigen (Intcomph1), were invited by the leaders of the National Program. The pharmaceutical representatives included the CEO of one new bio-pharmaceutical company, Taigen, and the CEO of one larger company of genetic medicines, Genovate. The main reason for the 2 pharmaceutical representatives to be invited was their long standing access to the National Program. The CEO of Taigen was the ex-leader of the National Program. According to statement on the official website of Genovate<sup>30</sup>, the company was very experienced in applying for the funding from the government. Moreover, the Consulting Committee of the National Program recruited 35 members, including 31 academics and 4 pharmaceutical representatives. The 31 academics were from the universities and research organizations participated in the National Program, and the 4 pharmaceutical representatives included a new bio-pharmaceutical company and 2 larger companies of generic medicines. All the members were invited by the leaders (Intcomph2). There was no company of Chinese herbal medicines involved in the two Committees.

The Steering Committee and the Consulting Committee of each National Programs in fact played two key roles: forming the inter-ministerial consensus and involving the external stakeholders. Each of the key roles is discussed below.

The two Committees played a key role in the formulation of the inter-ministerial consensus. The Steering Committees of the two National Programs were both chaired by the Minister of the National Science Council and involved the vice-Ministers of the Ministry of Economic Affairs and the

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<sup>30</sup> See the statement on the official website of Genovate:  
[www.genovate-bio.com/chinese/index.htm](http://www.genovate-bio.com/chinese/index.htm).

Department of Health. The Steering Committees in fact secured the inter-ministerial consensus that the three ministries should make the policy objectives of the 15 % Mid-term Plans of the three ministries to be horizontally consistent with each other under the framework of the National Programs and be vertically consistent with the general policy objectives of the Promotion Plan. The Steering Committees also secured the inter-ministerial consensus for the appropriateness of the National Programs that the inter-ministerial resources should be invested in the bio-pharmaceutical research and the results of the research should be transferred to the pharmaceutical SMEs. However, there is no evidence showing that there was inter-ministerial consensus for the consistencies and appropriateness between the National Programs and the Law. Indeed, while the general advices were given by the Steering Committees to the leaders, the general advice already contained the inter-ministerial consensus. As long as the leaders followed general advise, they were able to make the concrete policy objectives and policy instruments of the National Program not only consistently coordinate the 15 % Mid-term Plans of the three ministries but also be appropriate to the development of pharmaceutical NSTIS through clustering the network between universities and local pharmaceutical companies. However, the members of the Consulting Committees of the two National Programs were all invited by the leaders who represented the National Science Council. In other words, the detailed agendas of the National Programs were dominantly decided by the National Science Council. No representative from the Ministry of Economic Affairs and the Department of Health were involved, and there was indeed no inter-ministerial consensus formed for the detailed agendas of the National Programs, including the targets of the National Programs. Once the detailed agendas were implemented by different ministries, it showed that the originally intended effects of the two National Programs were very difficult to achieve. We will further discuss the issue in section 6.4.2.3.

The two Committees also played a key role in the involvement of external stakeholders, including academics and pharmaceutical companies. The interactions of the external stakeholders within each of the two Committees are introduced in the following paragraphs.

In the Steering Committees of the two National Programs, the academic representatives were recommended by the academic institutions which participated in the National Programs, but the pharmaceutical representatives were recommended by the leaders rather than the pharmaceutical associations. Since all participating universities had their own representatives, the academic representatives were able to represent the general interests of universities in the National Programs. Yet, the pharmaceutical representatives, as individual companies, were unable to speak for the general interests of the pharmaceutical sector. Moreover, the Committee included much more academics than pharmaceutical representatives. As described by the CEO of Taigen (Intcomph1), the pharmaceutical representatives had no influence on the agendas of the two National Programs at all, and the decisions of the Steering Committees were entirely guided by the academics. The leader of the National Research Program for Genetic Medicine (Intex4) shared the same opinion. For example, he once decided to listen to the suggestions of the pharmaceutical representatives and announced that the mice used by the National Program should be purchased from pharmaceutical companies. Yet, because the universities insisted to produce mice by themselves in order to save their research funding, the leaders finally agreed with the universities and no longer purchased mice from pharmaceutical companies. While the Steering Committees were set up to give general advice to the leaders, these advises only revealed the general interests of academics. In fact, the interests of the pharmaceutical sector, no matter the interests of individual companies or the



general interests of the pharmaceutical sector, were easily diminished in the Steering Committees. The National Program intended to cluster the networks between the universities and pharmaceutical companies which were important for the development of modern biotechnology. Yet, the way for the National Programs to involve the interests of pharmaceutical sector was unable to help the elected politicians to understand the dynamics of pharmaceutical sector and to formulate the agendas which were able to appropriately encourage the majority of pharmaceutical companies to cluster the network with the universities and involve in the innovation of bio-pharmaceuticals. Although both academics and pharmaceutical representatives were able to present their interests to all the elected politicians and positively contributed to the consistencies of National Programs, the involvement of these external stakeholders was incapable of positively increasing the appropriateness of the agendas of the National Programs.

Moreover, all the external stakeholders involved in Consulting Committees of the two National Programs were recommended by the leaders. The Consulting Committee of the National Research Program for Genetic Medicine included all American scientists. With limited understanding to the scientific community and pharmaceutical ecology of Taiwan, these scientists were difficult to help leaders to make the detailed policy proposals of the National Program to be appropriate to the pharmaceutical NSTIS in Taiwan. Furthermore, the Consulting Committee of the National Science and Technology Program for Biotechnology and Pharmaceuticals included both local scientists and pharmaceutical representatives. However, just as the Steering Committee, the number of the local scientists was much more than pharmaceutical representatives. As the external stakeholders recommended by the leaders, both the academics and the pharmaceutical companies were unable to represent the general interests of the local

scientific community or the pharmaceutical sector and helped the leaders to understand the dynamics of the pharmaceutical sector. Since there were much more academics than pharmaceutical companies, these academics easily guided the detailed agendas, including the targets of the National Program, to incline to the partial interests within the local scientific community. Indeed, as described by the leaders of the National Research Program for Genetic Medicine (Intex4), the National Program decided to fund the generic research of cancers, infectious diseases and highly heritable diseases, because some Taiwanese scholars had relatively outstanding research in these diseases. The leaders of the National Science and Technology Program for Biotechnology and Pharmaceuticals (Intex5) also decided to fund the research of new herbaceous pharmaceuticals, new chemical pharmaceuticals and new pharmaceutical protein intermediaries which aimed at the four selected diseases, because these diseases were common among Taiwanese citizens or because some Taiwanese scholars had more strength in doing related research for the diseases. In other words, the detailed targets were strongly guided according to the strength of particular groups of academics rather than pharmaceutical companies. Besides, the common diseases of the Taiwanese citizens, the targets selected by the strengths of the small group of scientists in fact were very difficult to incentivize pharmaceutical companies to cooperate with academics and involve in the innovation of bio-pharmaceuticals. Once the detailed agendas were implemented, the National Programs would neither appropriately match the general interests of the scientific community nor the pharmaceutical sector, but particular group of scientists only. We will further discuss the issue in section 6.4.2.3.

Even though the general interests of the pharmaceutical sector were not suitably involved in the agendas of the National Programs, none of the eight pharmaceutical associations motivated their members to lobby the Ministers

or the leaders. As described by the CEO of Sunten (Intcomph2), from the perspectives of pharmaceutical companies, the two National Programs were just one of the possible channels for the pharmaceutical companies to be funded to transfer biotechnology. As long as the pharmaceutical companies were able to get R&D funding through other policies, such as the Mid-term Plan of the Ministry of Economic Affairs, the pharmaceutical companies did not have incentives to lobby the elected politicians of the two National Programs.

The leaders of each National Programs, as described by the leader of the National Research Program for Genetic Medicine (Intex4), decided the concrete policy objectives, the policy instruments and the details of targets of the National Programs according to the advises of the Steering Committee and the Consulting Committee of each National Program. With the inter-ministerial consensus and the mechanisms to involve the interests of the external stakeholders, the policy objectives of the two National Programs were vertically consistent with the general policy objectives of the Promotion Plan. This meant that the policy objectives and the policy instruments of the 15% Mid-term Plans of the three ministries were horizontally consistent under the general framework. Moreover, the policy objectives to encourage the bio-pharmaceutical research in the universities and the technology transfers from the universities to pharmaceutical local SMEs were also appropriate. However, because of the shortage of the inter-ministerial consensus and the absence of the suitable involvement of pharmaceutical companies in the detailed agendas, once being implemented, the two National Programs were not consistently implemented by different ministries and were very difficult to generate appropriate supports to the pharmaceutical NSTIS. We will further discuss the issue in Chapter 7.

#### 6.4.1.1.3 The agenda-setting of the agricultural National Program

The decisions of the leaders of the National Program were deeply influenced by the Steering Committee and the Project Committee. The Steering Committee was chaired by the Minister of the National Science Council and recruited 9 government officials, including vice-Ministers of the National Science Council, the Ministry of Economic Affairs, and the Council of Agriculture. The Project Committee which reviewed the detailed agendas of the National Program was co-chaired by the vice-Minister of the National Science Council and the vice-Minister of the Council of Agriculture and was composed of 9 government officials, 3 academics and 3 agricultural representatives. The 9 government officials included the heads of the implementation bodies under the three ministries, such as the Director of the Bureau of Industrial Development under the Ministry of Economic Affairs. The 3 academics were recommended by the National Science Council and included the heads of universities and the research organizations participating in the National Program. Moreover, the 3 agricultural representatives included the CEOs of one larger seed company and one company of aquaculture, and one ex-CEO of larger feeding company. The agricultural representatives were recommended by the Council of Agriculture because of the affiliation of their business with the National Program. As described by one of the agricultural representatives (Intcomag4), he was invited because of the company's outstanding performance in the innovation of seeds. The other representative (Intcomag3) explained that he was invited because of his long-term international experiences in the agricultural sector. No companies of food, pesticide and fertilizers were recruited.

The Steering Committee and the Project Committee played the roles to formulate horizontal inter-ministerial coordination and to involve external stakeholders. Since the structure and the purpose of the two Committees

were very similar to and only the composition of the two Committees was different from the ones of the two pharmaceutical National Programs, in the following paragraphs, we only focus on the differences of the two Committees.

The two Committees played the significant role in forming inter-ministerial consensus. The Steering Committee was chaired by the Minister of the National Science Council and involved the vice-Ministers of the three participating ministries, i.e. the National Science Council, the Ministry of Economic Affairs and the Council of Agriculture. The Steering Committee not only secured the inter-ministerial consensus for the consistencies of the National Program but also secured the inter-ministerial consensus for the appropriateness of the National Programs. The inter-ministerial resources should be invested in the bio-agricultural research which had the potential to be developed to be the high value-added agricultural products. Through technology transfer, the universities and agricultural companies were encouraged to establish the network which was important of the development of modern biotechnology. Moreover, since the vice-Ministers of the National Science Council and the Council of Agriculture were also involved in the Project Committee, the inter-ministerial consensus formed in the Steering Committee was able to be further secured in the detailed agendas of the National Program, including the targeted products. As described by the leader of the National Program (Intex6), many targeted products selected by the National Program were decided through the mutual agreements between different ministries. The agricultural products which were export-oriented, such as orchids and groupers, were especially selected. However, besides the coordination of the Mid-term Plans, there was no sufficient inter-ministerial consensus formed for the regulation policies related to the National Program. As described by one of the agricultural representatives (Intcomag3), although the vice-Ministers of the National

Science Council and the Council of Agriculture have once tried to set up the regulations of GMO in the meetings of the Project Committee, there was no actual inter-ministerial consensus formed for the regulation of GMO. The vice-Ministers at best agreed to fund the research of non-edible GMO and allowed the trade of non-edible GMO in the domestic market without any regulation. Also there was no inter-ministerial consensus formed for the amendments of the Management Act. In other words, there was no inter-ministerial consensus for the consistencies and appropriateness between the National Program and other interrelated agricultural regulations. While the general advice and the advice for the detailed agendas of the National Programs were given by the Steering Committee and the Project Committee to the leaders, the advice was instrumental for the inter-ministerial consensus. As long as the leaders followed this advice, they were able to make the concrete policy objectives and policy instruments of the National Program not only consistently coordinated the 15 % Mid-term Plans of the three ministries but also appropriately match the development of agricultural NSTIS. In addition, once the detailed agendas of the National Program, such as the targets of the National Program, were implemented by different ministries, these details were able to be consistently implemented by each ministry. Yet, because there was no inter-ministerial consensus for the consistencies and appropriateness between the National Program and interrelated regulation policies, the implementation of the National Program was not consistent with other regulation policies; and once being implemented together, the appropriateness of the National Program and regulation policies were limited and did not support adequately the development of agricultural NSTIS.

The two Committees also played a significant role in involving external stakeholders. Since the Steering Committee involved no external stakeholders, the external stakeholders were unable to influence the policy

objectives and policy instruments. However, it was the Project Committee which played the most important roles in involving the external stakeholders. The numbers of academics and agricultural representatives in the Project Committee were almost the same, and the two kinds of external stakeholders were usually able to achieve the consensus for the development of agricultural NSTIS. As described by one agricultural representative (Intcomag3), he usually achieved the consensus with academics easily. Since the consensus of both kinds of representatives were able to be presented to all elected politicians of the National Program, such as the leaders and the vice-Ministers of the three ministries, the involvement of these external stakeholders positively contributed to the consistencies of the agendas of the National Program. Nevertheless, both the academic and the agricultural representatives were recommended by the government officials as individual scientists and individual companies. As individuals recommended by the government, they were in fact unable to represent the general interests of the scientific community or the general interests of the agricultural sector. They were also unable to let the elected politicians fully understand the dynamics of the agricultural NSTIS and increased the appropriateness of the National Program. They at best presented the partial interests within the scientific community and the agricultural sector to the elected politicians. For example, one of the agricultural representatives (Intcomag4) explained that he once suggested the vice-Ministers that the National Program should increase the funding for the research of seeds of fruits and vegetables. Such suggestion was involved in the detailed agendas of the policy proposal of the National Program.

The leaders of the National Program, as described by one of the leaders (Intex6), followed the advice of the Steering Committee and the Project Committee and decided the concrete policy objectives, policy instruments and the details of policy proposals. Since the agendas of the National

Program were designed through the inter-ministerial consensus, the policy objectives of the National Program were vertically consistent with the general policy objectives of the Promotion Plan, and the National Program was able to make the policy objectives and the policy instruments of the 15% Mid-term Plans of the three ministries horizontally consistent with each other. Moreover, the policy objectives which encouraged the bio-agricultural research within the universities and encouraged the technological diffusion from the universities to agricultural companies were also appropriate. In addition, since the inter-ministerial consensus for the detailed agendas of the National Program was achieved, the National Program was expected to be consistently and appropriately implemented by different ministries. Yet, because of the absence of the suitable involvement of external stakeholders, the representatives of the external stakeholders were unable to increase the appropriateness of the National Program. Once the details of the National Program were implemented, even though the general direction of the National Program was still appropriate, the appropriateness was unavoidably limited as the interests of particular groups of scientists and agricultural companies captured the National Program.

#### 6.4.2.1.4 Brief conclusion of the section 6.4.2.1.1

The agendas of the two pharmaceutical National Programs and the agricultural National Program were set up by similar process. However, because of the different extents of the inter-ministerial consensus and the involvement of external stakeholders, the consistencies and appropriateness of the three National Programs were also different. The agricultural National Program which were made under higher inter-ministerial consensus for the policy objectives and detailed agendas was expected to have more appropriateness to the development of the agricultural NSTIS than the two pharmaceutical National Programs towards the pharmaceutical NSTIS.



#### 6.4.2.2 The stage of deciding

The stage of deciding of the National Programs was the stage for the congressmen of the opposition party, Kuomintang, to authorize the policy proposals of the National Programs to be formal policies. According to our discussion in section 3.2.1.1, the decision making stage in the Taiwanese polity is deeply influenced by two independent variables, the divided government and the involvement of external stakeholders. In this section, we would especially focus on the influence of the two independent variables on the consistencies and appropriateness of the three National Programs.

The congressmen of the opposition party, according to a congressman of Kuomintang (Intleg1), had different policy preferences and priorities from the ruling party and had high incentives to change the contents of the National Programs; yet, there were three reasons which reduced the oversight of the congressmen. First, biotechnology was too technical to congressmen. Once the policy proposals of the National Programs were full of professional terms, congressmen were unable to understand, to monitor the policy proposals and to judge the consistencies and the appropriateness of these policy proposals. Second, the congress itself didn't provide sufficient resources, including financial and human resources, to support the congressmen to understand the National Programs. The congressmen of the opposition party in fact needed to rely on the information given by the four ministries to review the policy proposals. According to our interviewee, the Ministers of the four ministries then used to give the congressmen insufficient information and easily escaped from the oversight of the congress. Third, the congressmen should face the pressures from their districts. The majority of voters of the opposition party supported economic development, and the development of biotechnology was considered to be

an important part of the economic development. With the pressure from the voters, the congressmen of the opposition party hesitated to change the policy contents and cut the budgets of the National Programs which aimed to support the growth of biotechnology and related sectors. One further congressman of Kuomintang (Intleg2) shared the same opinion that since his voters had limited opposition to the development of biotechnology, he had no incentives to cut but authorized the majority of the budgets of the National Programs.

The external stakeholders, especially the pharmaceutical and agricultural companies, interacted with the congressmen of the opposition party through the participation of congressional public hearings. As described by the CEO of R&D of Taiwan Liposome Company (Intcomph3), the company once participated in the public hearings to explain the problems of the implementation of the Law of Pharmaceutical Affairs. One of the agricultural representatives in the National Science and Technology Program for Bio agriculture also once participated in the public hearings to express the general interests of the agricultural companies (Intcomag3). According to his experiences, the public hearing was an effective mechanism to express the interests of the agricultural companies to the congressmen. However, both the individual companies and interests groups were involved in the public hearings. From our perspective, these companies and interest groups did not necessarily present the general interests of the pharmaceutical or the agricultural sector to the congressmen but in many cases the interests of particular companies and small groups of companies only. Therefore, the external stakeholders involved in the congressional public hearings were in most of the cases unable to help the congressmen to understand the dynamics of the modern biotechnology, pharmaceutical and the agricultural sectors in Taiwan and authorized the National Programs towards the direction which was appropriate to the

development of the two NSTIS.

However, according to the experiences of the congressman of the opposition party (Intleg1), the involvement of the companies of pharmaceuticals or the agriculture was not influential to the judgment of the congressmen towards the National Programs. Therefore, the involvement of the companies had limited impacts on the deciding process of the National Programs. Since the policy proposals of the three National Programs were decided separately, we introduce the deciding process of each National Program below.

The policy proposals of the National Research Program for Genetic Medicine were smoothly authorized by the congress; all policy objectives, the policy instruments and the details of the policy proposals remained while transformed to be formal policies. As described by the leader of the National Research Program for Genomic Medicine (Intex4), the congressmen of the opposition party only monitored the expenditure and the outputs of the National Program, such as the number of technology transfer. As long as the leaders successfully persuaded the congressmen that the development of the genetic research took long time, and it was normal that the National Program would not be able to produce obvious outputs in a short-term, the congressmen authorized all the budgets of the National Program. The congressman of Kuomintang (Intleg1) also stated that the National Program was too specialized for the congressmen. Since the congressmen of the opposition party had difficulties in judging the consistencies and appropriateness of the National Program, all the budgets of the National Program were approved.

However, the policy proposals of the National Science and Technology Program for Biotechnology and Pharmaceuticals were highly criticized by the congressmen; even though the policy objectives remained the same,

details of the policy instruments were changed while being transformed into be formal policies. As described by the leader of the National Program (Intex5), the policy proposals of the National Program were seriously criticized by the congressmen because it was hard to see the National Program's substantial contribution to the pharmaceutical sector in a short time. As shown in the Committee Record of the Legislative Yuan<sup>31</sup>, 20% of the budgets derived from the Mid-term Plan of the Department of Health were suspended, while the budgets derived from the Mid-term Plan of the National Science Council were all approved. Even though the policy objectives remained consistent and appropriate, the policy instruments were changed. Once the policy instruments of different ministries were implemented, it was expected that the National Science Council would still fund the basic bio-pharmaceutical research in the universities according to the original plan, but the Department of Health would have difficulties to fund the research of clinical trials because of unsatisfied budgets. Indeed, the congressmen broke the consistencies of the policy instruments of the National Program. It was then very difficult for different ministries to consistently implement the National Program. Moreover, since the ministries did not achieve a consensus for the National Program with the congressmen, the policy instruments were changed without the consideration of the appropriateness. The budgets of the Department of Health cut by the congressmen in fact reduce the efforts of the National Program which tended to establish the network between different actors.

In contrast, the policy proposals of the National Science and Technology Program for Bio-Agriculture were smoothly authorized by the congressmen of the opposition party; neither the policy objectives and policy instruments nor the details of the policy proposals were changed while being

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<sup>31</sup> See the Committee Record of Legislative Yuan:  
[http://lci.ly.gov.tw/doc/communique%5Cfinal%5Cword%5C98%5C37%5CLCIDP\\_983701\\_00047.doc..](http://lci.ly.gov.tw/doc/communique%5Cfinal%5Cword%5C98%5C37%5CLCIDP_983701_00047.doc..)

transformed into formal policies. As described by the leader of the National Program (Intex6), since many congressmen of the opposition party were elected by agricultural counties, these congressmen easily understood the importance of bio-agriculture. Some congressmen of the opposition party even suggested the leaders of the National Program to do more research related to their counties.

While the three National Programs were decided by the congressmen of the opposition party, only the policy contents of one National Program, the National Science and Technology Program for Biotechnology and Pharmaceuticals, was changed by the congressmen, and the contents of the other two National Programs remained the same. Once being changed, the formal policies of the National Science and Technology Program for Biotechnology and Pharmaceuticals became difficult to be consistently implemented and appropriate to match the development of pharmaceutical NSTIS. It was the divided government which shaped the inconsistencies and inappropriateness of the National Program.

#### 6.4.2.3 The stage of the Implementation

##### 6.4.2.3.1 Introduction

The stage of implementation of the three National Programs was the stage for the administrators to implement the policy contents and to realize the policy objectives of the National Programs. In order to coordinate the implementation of different implementation bodies under the National Programs, the National Science Council newly established and supervised the Office of each National Program. The administrators of each Office, according to the official websites of the three National Programs<sup>32</sup>, were led

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<sup>32</sup> See the Office of the three National Programs.

by the leaders of each National Program. These Offices were especially established by the National Science Council to implement the National Programs and should represent the National Science Council to coordinate the implementation of the implementation bodies of other ministries. However, these Offices were horizontal to other implementation bodies without higher authority or more resources. As we have described in section 3.3.3, the stage of implementation is deeply influenced by three independent variables: the vertical coordination, the horizontal inter-departmental coordination and the involvement of external stakeholders. All of these three variables would influence the consistencies and appropriateness of RTDI policies. In this section, we especially focus on the influence of the three independent variables on the consistencies and appropriateness of the three National Programs.

#### 6.4.2.3.2 The implementation of the two pharmaceutical National Programs

The Office of each pharmaceutical National Program played essential roles to coordinate the implementation bodies under the Ministry of Economic Affairs and the Department of Health. The Office of the National Research Program for Genetic Medicine was under the National Science Council and was responsible for coordinating the implementation of the Bureau of Industrial Development under the Ministry of Economic Affairs and the National Health Research Institute under the Department of Health (see Figure 6.2). As also shown in Figure 6.2, the Office of the National Science and Technology Program for Biotechnology and Pharmaceuticals was responsible for coordinating the implementation of the Department of Industrial Technology under the Ministry of Economic Affairs and the National Health Research Institute under the Department of Health. However, both the two Offices encountered three problems of implementation that impinged upon inter-departmental coordination,

vertical coordination and the involvement of external stakeholders in the technology transfer.

The two Offices encountered the problem for the horizontal inter-departmental coordination. Since the stage of agenda-setting, there was no inter-ministerial consensus formed for the detailed agendas of the two National Programs, such as the targets of the National Programs. As described by the leader of the National Research Program for Genetic Medicine (Intex4), it was very difficult to coordinate the implementation bodies of different ministries. For instance, the Bureau of Industrial Development under the Ministry of Economic Affairs was very reluctant to be involved in the National Program. From the perspective of the Bureau, the National Program which targeted the genetic research was very difficult to generate local pharmaceutical SMEs profits in a short term. Since the mission of the Bureau was to support local pharmaceutical SMEs to generate short-term profits, after several years of coordination, the Bureau decided to withdraw the majority of its funding from the National Program. The Office which had no higher authority than the Bureau in fact was unable to forbid the Bureau to withdraw the resources. Moreover, the Office of the National Science and Technology Program for Biotechnology and Pharmaceuticals also encountered very similar problem for horizontal inter-ministerial coordination. As described by the leader of the National Program (Intex5), the Department of Industrial Technology under the Ministry of Economic Affairs was very reluctant to implement the National Program. The National Program which targeted the development of new pharmaceuticals took long time to generate profits; yet, the Department explained that its mission was to help the local pharmaceutical SMEs to create values in a short-term. Therefore, the Department tended to fund the innovation of Me-Too pharmaceuticals rather than the new pharmaceuticals. After four years collaboration, the Department also drew back the majority

of its resources from the National Program.

In addition, the problem of vertical coordination of the two National Programs even increased the difficulties of implementation. As described by the officer of the Office of the National Science and Technology Program for Biotechnology and Pharmaceuticals (Intad5), once the Ministers of the three ministries delegated power to the implementation bodies, they no longer monitored the implementation of the two National Programs. In other words, the Ministers and the vice-Ministers involved in the Steering Committees of the two National Programs didn't monitor the implementation of the National Programs. Even though the leaders, as elected politicians, were delegated by the Minister of the National Science Council to coordinate and to monitor the implementation of the National Programs from top-down, in practice, it was almost impossible for the leaders to improve the vertical coordination of the National Programs. As described by the leader of the National Research Program for Genetic Medicine (Intex4), the budgets of the National Program were contributed by different ministries, and the head of each implementation body was in fact the Minister of the ministry to which it belonged. The leaders who only represented the National Science Council were very difficult to supervise the implementation of the implementation bodies belonging to the other two ministries. The same opinion was shared by the leader of National Science and Technology Program for Biotechnology and Pharmaceuticals (Intex5). He once asked the two research organizations under the Department of Industrial Technology, the Ministry of Economic Affairs, to help universities to do fundamental biotechnological research, because their help would accelerate the development of new pharmaceuticals. Yet, the suggestion was rejected by the Department of Industrial Technology, the boss of the two research organizations. In other words, even though the leaders of the two National Programs discovered that the implementation of



the National Programs was distorted and was hard to realize the policy objectives of the National Programs, the leaders were unable to improve the vertical coordination and amend the distortion.

Moreover, the two National Programs also encountered great difficulties in involving external stakeholders in the technology transfer. As we have described in section 6.4.2.1.2, the detailed agendas of the two National Programs, such as the targeted diseases and products, were strongly guided by the partial interests among the scientific community, and the general interests of the pharmaceutical sector were largely excluded from these detailed agendas which were later authorized as formal policies. When these formal policies were implemented, as described by an academic involved in the National Program (Intac3), he was eager to transfer his innovation to pharmaceutical companies. Yet, as described by the officer of National Science and Technology Program for Biotechnology and Pharmaceuticals (Intad5), the majority of pharmaceutical companies were quite indifferent to the transfer of the biotechnologies from the universities funded by the National Program. The larger pharmaceutical companies which have not yet intended to invest in the innovation of new pharmaceuticals were not incentivized to transfer biotechnologies from universities funded by the National Programs. Only a small number of new bio- pharmaceutical companies and the companies of Chinese herbal medicines were more willing to transfer biotechnologies funded by the National Programs. As described by one new bio-pharmaceutical company (Intcomph3) and two companies of Chinese herbal medicines (Intcomph2, Intcomph4), they expected to discover the new components of new pharmaceuticals in an early stage. They transferred biotechnologies from the universities funded by the National Program because the targets of the National Programs coincidentally fit their business. However, in many cases, as described by the officer of the National Program (Intad5), many biotechnologies could

not be licensed out.

After the implementation bodies implemented the policies of the two National Programs, the two National Programs, as we have described in section 6.3.1.3, didn't achieve their policy objectives. At least in the short term, the two National Programs have very limited appropriate supports to the development of pharmaceutical NSTIS. The horizontal inter-departmental coordination, the vertical coordination, and the involvement of external stakeholders are the main reasons to explain the implementation failure of the two pharmaceutical National Programs.

#### 6.4.2.3.3 The implementation of the agricultural National Program

The Office of the National Science and Technology Program for Bio agriculture played essential roles to coordinate the implementation bodies under the Ministry of Economic Affairs (the Bureau of Industrial Development) and the Council of Agriculture (Technology Department) (see Figure 6.2). Nevertheless, the Office encountered similar problems as for coordination and involvement of external stakeholders. Since the context of the implementation of the National Programs was very similar to the two pharmaceutical National Programs, this section only focuses on the differences of the agricultural National Program.

First, the Office encountered the problem of horizontal inter-departmental coordination. As described by the leader of the National Program (Intex6), the implementation bodies under different ministries were very difficult to coordinate with each other. In the stage of agenda-setting, the three ministries have achieved the inter-ministerial consensus for the detailed agendas of the National Program and decided to coordinate the R&D funding derived from the 15% Mid-term Plans of the three ministries to

fund the targeted bio-agricultural research and agricultural products. Therefore, in the stage of implementation, the implementation bodies under different ministries had no problem to horizontally cooperate with each other in funding the innovation of bio-agricultural products. However, since there was no inter-ministerial consensus formed for the agricultural regulation in the stage of agenda-setting, the Bureau of Industrial Development and the Technology Department always competed for the leadership of regulations of the agricultural sector. For example, the Bureau of Industrial Development executed the 'Factory Rules' to regulate pesticide factories, and the Bureau of Animal and Plant Health Inspection and Quarantine of the Technology Department also executed 'Agro-pesticides Management Act' to regulate the same factories. While the Bureau of Industrial Development considered some of the factories not to be the pesticide factories and should only get one license from the Bureau, the Technology Department insisted that all factories related to pesticide should get the second license from the Department. Even though the inter-departmental competition already delayed the technology transfer, especially the technology transfer to the companies of bio-pesticides, the two bodies were still very difficult to coordinate with each other.

The Office also encountered the problem of the vertical coordination. As described by the leader of the National Program (Intex6), the Minister and the vice-Ministers of the three ministries had severe difficulties in monitoring the details for the implementation of the National Program. As long as the implementation bodies were able to persuade that the implementation was proper, the Minister and the vice-Ministers simply believed the agencies and no longer supervised the implementation. Even when the leaders discovered the direction of implementation was distorted and far from the policy objectives, the leaders who only represented the National Science Council was unable to fixed the distortion of the

implementation of the implementation bodies of the other two ministries from top-down.

The Office also encountered problems to involve the external stakeholders in the technology transfer. As described by the leader of the National Program (Intex6), the larger agricultural companies were very indifferent to transfer biotechnologies from the National Program, and it was the new small companies which were more willing to transfer the biotechnologies. In fact, none of the agricultural representatives transferred biotechnologies funded by the National Program. As described by one of the agricultural representatives (Intcomag4), as he already knew that the government was unable to solve the regulation problem of GMO, he hesitated to transfer biotechnologies of GM. The new agricultural company of bio-pesticide and agricultural trade company (Intcomag5, Intcomag6) transferred biotechnologies from the universities funded by the National Program because the targets of the National Program, as expressed by the Assistant Manager and the Vice president R&D of the two companies, coincidentally fitted to their business of bio-pesticide and GMO ornamental fish. However, as described by the leader of the National Program (Intex6), the National Program finally transferred the majority of technologies to small companies.

After being implemented, as we described in section 6.3.2.3, the National Program did not fully achieve its objectives. The inter-ministerial resources have been consistently invested in the targeted bio-agricultural research and products and have encouraged some academics and small agricultural companies to establish networks through technology transfer. Yet, because of the three problems of implementation, the policy had only limited participation and mobilization.

#### 6.4.2.3.4 A brief conclusion of the section

After being implemented, the agricultural National Program was more effective than the two pharmaceutical National Programs. The agricultural National Program which had higher extent of horizontal inter-departmental coordination in the stage of implementation offered more appropriate supports to the agricultural NSTIS than the two pharmaceutical NSTIS to the pharmaceutical NSTIS.

#### 6.4.2.4 The stage of the evaluation

The stage of evaluation, according to our discussion in section 3.3.5, is the stage to examine and to access the effect of the three National Programs on the pharmaceutical or agricultural NSTIS. As we have assumed in section 3.3.5, if the evaluation of the three National Programs has been done properly and truly reflected the response of the external stakeholders, the National Program would contribute to the consistencies and appropriateness of new agendas of the National Programs in the new cycle of the policy-making process. However, the National Programs were not evaluated under the ideal conditions.

The evaluations of the National Programs which were done by the Office of each National Program only showed the quantitative data of the economic index of each National Program without further assessments. The evaluation only displayed the numbers of papers published, postgraduate students trained, patents produced, technology transfers and spring-offs<sup>33</sup>. There was no external evaluation mechanism. Furthermore, the policy effect of the three National Programs on the development of NSTIS was totally ignored. As we have described in section 6.2., one of the main purposes of the

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<sup>33</sup> See the rules of evaluation of National Science Council

National Programs was to better integrate the R&D resources of the four ministries. However, as discussed in section 6.4.2.3.2 and section 6.4.2.3.3, only the agricultural National Program has integrated the resources of different ministries in the stage of implementation, and the two pharmaceutical National Programs didn't because the implementation bodies of the Ministry of Economic Affairs withdrew the majority of their resources from the two National Programs. Moreover, as shown in section 6.3.1.3 and section 6.3.2.3, the two pharmaceutical National Programs were not effective, and only the agricultural National Program better achieved their goals on the agricultural NSTIS. However, the different levels of effects of the three National Programs on different sectors were never discussed by the evaluation reports of the National Programs.

Because of the un-proper mechanism of the evaluation, the Taiwanese government as a whole in fact learned very little from the experiences of the National Programs. Thus, the same problems that appeared in the first cycle of policy-making process may be repeated. Moreover, the policy of the National Programs may never really achieve the policy objectives to a meaningful extent.

#### 6.4.3 Regulation policies

##### 6.4.2.1 The stage of agenda-setting

The stage of the agenda-setting of the Law and the Management Act was the stage for the Ministers and the high level management of the regulatory bodies to decide the agendas of these two policies. As we have described in section 3.3.1, the stage of agenda-setting is deeply influenced by two independent variables: the horizontal inter-ministerial coordination and the involvement of external stakeholders. In this section, we will discuss the

nature of the two independent variables and their influence on the consistencies and the appropriateness of two regulation policies.

#### 6.4.3.1.1 The agenda-setting of the Law of Pharmaceutical Affairs

The Director-General and the high level managers of the Bureau of Pharmaceutical Affairs under the Department of Health (see Figure 6.2) were the most essential elected politicians to decide the agendas of the Law. As described by one of the high level managers of the Food and Drug Administration (the new name of the Bureau of Pharmaceutical Affairs) (Intad8). Although the Minister of the Department of Health was institutionally the highest level of elected politicians to set up the agendas of the bills of the Law and the affiliated administrative rules, in the majority of cases, the Minister only gave the general managerial direction to the Bureau and fully delegated the Director-General and other high level management of the Bureau to decide the detailed agendas of the bills and the administrative rules. While the bills should be approved by the Minister before sending to the Legislative Yuan for further legislation, the administrative rules should only be decided by the Director-General of the Bureau.

All the agendas of the Law were set up without inter-ministerial consensus. As described by the Minister of the Department of Health (Intex3), the Minister of the Department set up the Platform for Communication between the Department and the Ministry of Economic Affairs in order to form the inter-ministerial consensus for the agendas of the policy objectives and the policy instruments of the Law and its affiliated administrative rules. Yet, according to the description of a high level manager of the Food and Drug Administration (Intad8), there was in fact no general concrete inter-ministerial consensus formed through the Platform. Besides the

Platform, as we have described in section 6.4.2.1.2, the agenda-setting process of the National Programs did neither lead to sufficient consistency between the Law and the National Programs nor the appropriateness of the Law. Indeed, while the Minister of the Department of Health gave the general directions for the agendas of the Law, these general directions were given without inter-ministerial consensus. As described by the Minister (Intex3), he has once requested the Bureau to set up the agendas of the Law and its affiliated administrative rules not only to control the safeties of medicines but also to appropriately match the development of pharmaceutical NSTIS, such as using the regulation of the Law to encourage the pharmaceutical companies to involve in the innovation of new pharmaceuticals and new bio-pharmaceuticals and cluster network with academics through technology transfer. This general direction was in fact vertically consistent with the general policy objectives of the Promotion Plan and horizontally consistent with other interrelated policies which aimed to support the growth of the pharmaceutical sector, including the National Programs. However, because of the shortage of inter-ministerial consensus, the Bureau was not informed to consider the policies of other ministries while it set up the agendas of the Law and the affiliated administrative rules. We will further discuss the issue in section 6.4.3.3.

It was indeed the involvement of external stakeholders which deeply influenced the Bureau in the selection of the agendas of the Law and its affiliated administrative rules. Since the involvement of the pharmaceutical associations and which of the medical device companies were very different, in the following paragraphs, we introduce the involvement of pharmaceutical associations first and introduce the involvement of the medical device companies afterwards.

The pharmaceutical associations were heavily involved in the



agenda-setting process of the bills of the Law. During 2000 to 2008, the Law was extensively amended in order to add new clauses for pharmaceutical data exclusivity to encourage the innovation of new medicines through the policy instruments of protection. To initiate the agendas for the amendments of the Law, the Bureau invited the representatives recommended by 6 pharmaceutical associations, i.e. 5 pharmaceutical associations composed of local SMEs and 1 pharmaceutical association composed of MNCs (Bureau, 2005). From the perspective of the MNCs, the protection for the pharmaceutical data exclusivity should be as long as possible. Since the government of the United States allowed 5 years protection and the governments of EU countries allowed 7 years protection, the representative of MNCs asked the Taiwanese government to give pharmaceutical data 7 years protection. However, from the perspective of local SMEs, the protection for pharmaceutical data should be as short as possible. The representatives of local SMEs strongly opposed the 7 years protection because the high protection would seriously delay their manufacturing activities of genetic medicines or the innovation of Me-too medicines. In fact, it was very difficult for the representative of MNCs and the representatives of SMEs to achieve a consensus. Therefore, the Bureau decided to compromise the interests of both MNCs and SMEs and set up the agendas that the Taiwanese government would give pharmaceutical data 5 years protection. Yet, MNCs were quite unsatisfied about such agendas. They turned to lobby the government of the United States to stress the Minister of the Department of Health. The government of the United States informed the Minister, if the Taiwanese government expected to sign the FTA with the United States, the Taiwanese government must accept the 7 years protection. After several years of negotiation, the Minister finally released the bill that the Taiwanese government would give 5 years protection to the pharmaceutical data of new medicines as the balance between the local SMEs and MNCs. Besides, the Taiwanese government

also gave 3 years protection to the data of Me-too medicines in order to response to the government of the United States and the interests of MNCs (Yang, 2004). In other words, while the bill was released by the Minister, the policy purpose which intended to encourage both MNCs and SMEs to innovate new pharmaceuticals was appropriate. The policy instrument of protection which was decided with the full knowledge of the pharmaceutical ecology and balanced the different interests of MNCs and SMEs in order to support the general interests of the pharmaceutical sector was also appropriate but relatively inclined to the interests of MNCs. We will further discuss the bill in the next section.

The pharmaceutical associations were also heavily involved in the agenda-setting process of the affiliated administrative rules of the Law which decided the details of the policy instruments of the Law, such as the detailed process of license. As described by the high level manager of the Food and Drug Administration (Intad8), in order to smoothly implement the administrative rules, the Bureau tended to involve the interests of the pharmaceutical associations since the stage of agenda-setting. For example, as pointed out by the manager of Bayer Taiwan (Intcomph5), through the association of the MNCs, the company suggested the Bureau to reduce the administrative procedures for importing new patented pharmaceuticals. Such suggestion was adopted by the Bureau. To expand the market in EU, in 2007, Taiwan Pharmaceutical Manufacturers' Association suggested the Bureau to adopt EU standard, the 'Pharmaceutical Inspection Cooperation Scheme' (PIC/S), as part of the administrative rules of 'Good Manufacturing Practice'. The Bureau also adopted the suggestion of the Association and involved PIC/S in the agendas for the amendments of 'Good Manufacturing Practice' (MOEA News, 2007).

However, compared with the intensive involvement of pharmaceutical

association, the medical device companies were quite indifferent to the agenda-setting of the Law. No clause of the Law which was related to medical devices has been significantly amended during 2000 to 2008. While the policy purpose and the policy instruments of pharmaceutical clauses of the Law were extensively amended to positively support the development of the pharmaceutical sector, the policy purpose of the clauses relating to medical devices remained to merely control the safeties of medical devices and did not intend to positively support the development of medical device sector through all kinds of policy instruments. However, the only association of the medical device sector hardly activated its members to lobby the high level management of the Bureau or the Minister of the Department of Health. As described by the Director of the R&D Division of Medical Device SME B (Intcommd2), the companies of medical devices competed with each other severely not only in the domestic but also in the foreign markets. It was very difficult for the companies of medical devices to consolidate with each other and lobby the elected politicians.

While the agendas of the Law and affiliated administrative rules were set up, the purpose and instruments of these new agendas, according to the discussions above, was appropriate to the development of pharmaceutical NSTIS but inconsistent with other interrelated policies. In fact, these agendas were set up without inter-ministerial consensus and extensive involvement of pharmaceutical associations. Without sufficient inter-ministerial consensus, only the policy purpose of the new clauses loosely followed the general policy objectives of the Promotion Plan, while the policy instruments of the bills of the Law were not horizontally complementary to other interrelated policies. Moreover, because of lacking inter-ministerial consensus for the appropriateness of the Law, once being implemented, the effect of the Law may not be complementary with other interrelated policies, such as the National Programs. In addition, since both

the interests of the pharmaceutical MNCs and SMEs were involved in the agenda-setting process, they were able to represent the general interests of the pharmaceutical sector to the Bureau. Through the involvement of the pharmaceutical associations the policy goals and instruments of the Law became more appropriate, as all the agendas tended to encourage the innovation of new pharmaceuticals were decided with fully knowledge of the general interests of the pharmaceutical sector. Therefore, the new agendas were able to match the knowledge dynamics of the pharmaceutical sector, and the policy purpose was expected to be achieved. However, since the pharmaceutical associations were only able to be involved in the agenda-setting of the Law rather than the National Programs, the involvement of the pharmaceutical associations was not able to contribute to the consistencies between the Law and the National Programs. Furthermore, the medical device companies which were not involved in the agenda-setting of the Law were unable to contribute to the consistencies and appropriateness of the Law.

#### 6.4.3.1.2 The agenda-setting of the Agro-pesticides Management Act

The Director-General and other high level managers of the Bureau of Animal and Plant Health Inspection under the Council of Agriculture (see Figure 6.2) were the most important elected politicians to decide the agendas for the bills of the Management Act. As described by one of the high level managers of the Bureau of Animal and Plant Health Inspection and Quarantine and the Agriculture (Intad6), the Minister of the Council of Agriculture only gave the general directions to the Bureau, and it was the high level managers of the Bureau to decide all the agendas of the Management Act. As we have described in section 6.4.2.2, there was no inter-ministerial consensus formed as to what should be the most appropriate objectives and instruments of the Management Act and as to the

consistencies of the policy objectives and the policy instruments between the Management Act and the National Program. Rather, it was indeed the involvement of external stakeholders that mainly influenced the selection of the agendas of the Act.

The Bureau held regular public hearings to involve the interests of agricultural companies, especially the pesticide companies. However, the companies participated in these public hearings were not recommended by the agricultural associations but were involved as individual companies. As individual companies, they were in fact unable to represent the general interests of agricultural sector. As described by the high level manager of the Bureau (Intad6), since some companies suggested that the Management Act which adopted the policy instruments to regulate the manufacturing machines of bio-pesticides in detail seriously reduced the flexibility of these companies, the Bureau accepted the suggestions and then set up the agendas for the amendments of the policy instruments of the Management Act to delete the detailed regulations for the manufacturing machines.

Next to the pesticide companies, the congressmen of the opposition party also played significant roles in the agenda-setting process of the Management Act. Yet, the congressmen merely pushed the Bureau to amend policy instruments of the Management Act to stricter control the safeties of the pesticides rather than to appropriately encourage the innovation of bio-pesticide. As described by the high level manager of the Bureau (Intad6), since the poisonous pesticide was frequently misused for commit suicide, in 2007, under the suggestion of the congressmen, the Bureau initiated the new agendas for the amendments of the Management Act and revealed the new policy instruments that only the farmers were qualified to buy the poisonous pesticides.

While the new agendas of the policy instruments of the Management Act were selected by the Bureau, these new agendas strengthened the policy objective of the Management Act which tended to control the food safeties. These agendas were selected without inter-ministerial consensus and with unsuitable involvement of external stakeholders. Because of lacking inter-ministerial consensus, the policy objective of the Management Act which was solely decided by the Council of Agriculture was not vertically consistent with the general policy objectives of the Promotion Plan, the policy objective and the policy instruments of the Management Act which didn't tend to encourage the innovation of bio-pesticide was in fact inappropriate to the development of agricultural sector and horizontally inconsistent with other interrelated policies, such as the National Program which tended to encourage the innovation of bio-agricultural products. Furthermore, without the suitable involvement, the participation of the pesticide companies in the public hearing was very difficult to positively increase to the consistencies between the Management Act and the National Program, as well as the appropriateness of the Management Act.

#### 6.4.3.2 The stage of deciding

The stage of deciding of regulation policies was the stage for the congressmen of the opposition party to legislate the bills to be laws and to monitor the decisions of administrative rules. Since we have assumed in section 3.3.1 that the stage of deciding is deeply influence by two independent variables, the divided government and the involvement of external stakeholders, in this section, we emphasize the influence of the two independent variables on the consistencies and appropriateness of the Law and the Management Act.

The congressmen of the opposition party played important roles in the

legislation of Law and monitoring the decisions of affiliated administrative rules of the Law. For the bills of pharmaceutical data exclusivity, the congressmen changed the bills before legislation. As we have described in section 6.4.3.1, while the Minister of the Department of Health decided the policy instrument of data exclusivity, the bill of the policy instrument of protection relatively inclined to the interests of the MNCs. The pharmaceutical associations of local SMEs which were unsatisfied about the bill turned to lobby the congressmen of the opposition party, and the MNCs also lobbied the congressmen in order to secure their interests. According to the meeting record of the Legislative Yuan<sup>34</sup>, the congressmen tended to further balance the interests of MNCs and local SMEs. While the new formally legislated clauses still gave 5 years protection to the data of new medicines, the 3 years protection for the data of Me-too medicines was deleted. Moreover, for the administrative rules, as described by the high level manager of the Food and Drug Administration (Intad8), the administrative rules should only be authorized by the Bureau, and the congressmen hardly reviewed the details of these administrative rules. For instance, the pharmaceutical PIC/S standards should only be approved by the Bureau.

The congressmen of the opposition party also played important roles in the legislation of the Management Act. As described by the high level manager of the Bureau of Animal and Plant Health Inspection and Quarantine (Intad6), since it was the congressmen who suggested to amend the policy instrument of the Management Act and to strictly control the status of the buyers of the poisonous pesticide, the congressmen of the opposition party smoothly legislated the bill to be law.

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<sup>34</sup> See the meeting record of the Legislative Yuan:  
<http://lis.ly.gov.tw/ttscgi/lgimg?@940604;0271;0292>

While the congressmen of the opposition party legislated the bills of the Law and the Management Act to be laws, according to the discussions above, the policy purpose and the policy instruments of the new clauses of the Law remained appropriate and consistent with the general policy objectives of the Promotion Plan and with policy objectives of other interrelated policies, such as the National Programs; the policy objectives and the policy instruments of the Management Act remained inappropriate and inconsistent with the National Program. In the case of the Law, even though the congressmen of the opposition party were unable to form the consensus with the Minister of the Department of Health, it was the same blocks of interest groups which lobbied both the executive and the legislative branches bridged the policy preferences of the two branches. Because the bills of the Law was legislated with the full knowledge of the dynamics of the pharmaceutical sector, once the bills were legislated to be laws, the new clauses of the Law were able to further appropriately match the pharmaceutical NSTIS. In the case of the Management Act, since the policy preference of the congressmen of the opposition party was involved in the agendas of the Management Act, the congressmen consistently authorized the bills to be laws. Yet, even if the executive branch and the legislative branch have established high consensus, this consensus was established upon without the suitable involvement of the external stakeholders (especially the agricultural companies of pesticide) and without the clear understanding on the dynamics of modern biotechnology and the agricultural sector. The consensus was in fact unable to positively increase the appropriateness of the agricultural sector. We will further discuss the roles of the congressmen in the divided government in Chapter 7.

#### 6.4.3.3 The stage of implementation

The stage of implementation of the Law and the Management Act was the



stage for the administrators of the regulatory bodies to implement the clauses of the laws and administrative rules. The implementation body of the Law was the Bureau of Pharmaceutical Affairs, and the implementation body of the Management Act was the Bureau of Animal and Plant Health Inspection and Quarantine. Since we assume in section 3.3.3 that the stage of implementation is deeply influenced by three independent variables, the vertical coordination, the horizontal inter-departmental coordination and the involvement of external stakeholders, in this section, we will focus on the influence of these three variables on the consistencies and appropriateness of the Law and the Management Act. In the following paragraphs, we introduce the implementation of the Law and its affiliated administrative rules first and introduce the implementation of the Management Act afterwards.

The Bureau of the Pharmaceutical Affairs had no horizontal inter-departmental coordination in the implementation of policy instruments of the Law and the administrative rules. According to the description of the high level manager of the Bureau (Intad8), the Bureau understood that many pharmaceutical companies which got R&D funding through the two pharmaceutical National Programs or the Mid-term Plan of the Ministry of Economic Affairs to transfer biotechnologies frequently failed to get licenses from the Bureau for further clinical trials. Yet, besides dealing with such issues case by case, the Bureau had not further plan to establish new institutions to coordinate with other interrelated departments or to revise its regulations.

The problem of the vertical coordination even deepened the difficulties of the implementation of the Law and the affiliated administrative rules. Once the Minister of the Department of Health gave the general direction to the Bureau, according to the description of the high level manager of the Bureau,

the Minister of the Department of Health seldom supervised the implementation of the Law and administrative rules. The general direction given by the Minister was to coordinate the Law under the framework of the Promotion Plan and make policy purpose and the policy instruments of the new clauses not only consistent with the general policy objectives and other interrelated policies but also positively support the development of the pharmaceutical sector. However, the implementation directed by the Bureau was towards the direction which was neither consistent nor appropriate. For example, according to the experiences of Taiwan Liposome Company and Pharmaceutical SME A (Intcomph3 and Intcomph4), even if the new clauses of reviewing the licenses of new medicines were legislated, the Bureau were very conservative to license the companies to do clinical trials. Yet, even though the implementation was distorted, the Minister was unable to fix the distortion from top-down immediately.

The companies of pharmaceuticals and medical devices were involved in the stage of implementation as individual companies. For the pharmaceutical companies, according to the descriptions of the pharmaceutical companies we have interviewed (Intcomph3, Intcomph4, Intcomph5), even though some of them have participated in the stage of agenda-setting through the pharmaceutical associations, they were involved in the stage of implementation as individual companies. Unless these individual companies were able to persuade the pharmaceutical associations to take actions, they were difficult to get positive response from the Bureau. Moreover, for the medical device companies, the companies were only able to involve in the stage of implementation through suggesting the administrators of the Bureau individually. Yet, they frequently got rejections. For example, Medical Device SME C (Intcommd3) has once suggested the Bureau to increase the staffs to review the licenses of the medical devices. Such suggestion was rejected by the Bureau.

The Bureau of Animal and Plant Health Inspection and Quarantine which implemented the policy instruments of the Management Act also established no horizontal inter-departmental coordination with other interrelated implementation bodies. According to the description of the high level manager of the Bureau (Intad6), the high level management of the Bureau has discovered that lots of the agricultural companies of bio-pesticides which were funded by the National Program to transfer single ingredients for fermentation were not able to get the license of manufacturing bio-pesticides. The reason was that these companies of bio-pesticides were unable to provide the Bureau sufficient documents of toxicology. From the Bureau's perspective, if the research organizations or the universities provided the documents of toxicology to the companies while they transferred biotechnologies, the companies should be easier to get the licenses. Yet, besides communicating with the research organizations under the Council of Agriculture., the Bureau had no plan to coordinate with the implementation bodies of other ministries, such as the implementation bodies of the National Science Council or the Ministry of Economic Affairs.

The problem for vertical coordination increased the difficulties for the implementation of the Management Act. As we have described in section 6.4.3.1.2, the vertical coordination between the Minister of the Council of Agriculture and the Bureau was in fact very limited. The policy objective of the Management Act was not coordinated under the framework of the Promotion Plan, and there was no inter-ministerial consensus to coordinate the policy objectives and the policy instruments of the Management Act to be horizontally consistent with other policies, like the National Program. Once being implemented, the implementation of the Management Act was towards the direction which was neither vertically consistent with the general policy objectives of the Promotion Plan nor horizontally consistent

with the National Program. Furthermore, there was no inter-ministerial consensus for the appropriateness of the Management Act. After being implemented, the Management Act was difficult to appropriately match the development of agricultural sector.

Moreover, the agricultural companies were only able to be involved in the implementation of the Management Act as individual companies. As described by the Assistant Manager of Advanced Green Biotechnology (Intcomag5), there was no association formed by the companies of bio-pesticides. As individual companies, the interests of these companies were difficult to be accepted by the Bureau. The point of view was shared by the high level management (Intad6). For example, some companies once suggested the Bureau to set up the agendas to initiate a new law especially to regulate the bio-pesticide. Such suggestion was rejected by the Bureau. In short, as individual companies, the companies of pesticides were unable to represent the general interests of the agricultural sector to the Bureau and increase the Bureau's understanding to the dynamics of the agricultural sector. Therefore, these companies were unable to increase the appropriateness of the Management Act. In addition, since these companies only explained their situations to the Bureau, they were not able to contribute to the consistencies between the Management Act and the National Program.

To sum up, the policy objectives of the Law and the Management Act were inconsistent and inappropriate, because they hampered the establishment of the network between different actors; and only the purpose of the new clauses of the Law was vertically consistent with the Promotion Plan and horizontally consistent with other interrelated policies. However, once being implemented, as we have discussed in section 6.3.1.3 and section 6.3.2.3, both policies were not complementary with the National Program. The two

policies were in fact difficult to appropriately match the development of the three biotechnology related NSTIS. The vertical coordination, horizontal coordination and involvement of external stakeholders, were the key variables which shaped the stage.

#### 6.4.4 Brief conclusion of section 6.4

As we have already shown in Figure 6.3, the political institutions of the two policies changed from stage to stage. The change of the political institutions will be further discussed in Chapter 7 while we compare the political institutions with our conceptual framework shown in Figure 3.1. In addition, on the basis of our analysis above, the consistencies and appropriateness of the two policies also change through the stages. Indeed, the two policies were decided by totally different processes. Since the actors involved in the National Programs had very limited connections to those involved in the regulation policies, it is not only that the policy objectives of the two policies were not consistent with each other, but once being implemented, the policies also were not entirely complementary. In addition the two policies towards the three biotechnology NSTIS differed.

Through analyzing the policy-making process of the National Programs and the regulation policies, we clearly recognize the reasons why the policy objectives and the policy instruments of the two policies were not consistent with each other, as well as the reasons why the two policies together were unable to generate appropriate supports. As we have discussed in section 6.3, the two policies generated limited appropriate supports to the biotechnology related NSTIS in Taiwan. Since the stage of agenda-setting, the elected politicians didn't coordinate the agendas of the two policies, and the involvement of external stakeholders was not able to positively contribute to the appropriateness and consistencies of the two policies. While the

congressmen decided the two policies, the congressmen of the opposition party were unable to positively coordinate the two policies to be consistent and appropriate. Moreover, in the stage of implementation, even though some of the administrators of implementation bodies noticed the inconsistencies and inappropriateness of the two policies, they were unable to implement the two policies towards the direction which was consistent and appropriate. As long as there was no mechanism to evaluate the appropriateness of the two policies, the Taiwanese government as a whole was very difficult to improve the variables which influenced the consistencies and appropriateness of the two policies. We will further discuss the dynamics of policy-making process in Chapter 7.

## **6.5 Conclusion**

In this Chapter, using the empirical cases of Taiwan, we not only discuss the consistencies and the appropriateness of the National Programs but also explore the dynamics of the policy-making process. In Chapter 3, we only set up a single conceptual framework all RTDI policies. Yet, through analyzing the empirical cases, we discover that indeed there are many processes of policy-making within one political system; furthermore, one political system produces different policies towards different NSTIS because of the different interactions between different actors. The conceptual framework and the empirical discoveries are the main topic of Chapter 7.

## **Chapter 7 Analysis of the research questions, the conceptual framework and the empirical cases**

### **7.1 Introduction**

The purpose of this chapter is to provide in-depth analysis for our research questions and the conceptual framework through discussing the empirical cases of Taiwan. As we have described in Chapter 3, our four research questions and the conceptual framework are established upon four independent variables and two dependent variables, the consistencies and the appropriateness of RTDI policies. In addition, in Chapter 6 we have described in detail the policy - making process of the National Programs and the regulation policies (focusing on the Law and the Management Act), through the lens of our conceptual framework. However, as we have mentioned in the conclusion of Chapter 6, we set up one conceptual framework for the policy - making process of all RTDI policies within one political system, but as shown by the empirical cases, there were indeed many policy - making processes within one political system. The analysis for the variety and the multiplicity of the cases and the stages are the core of this chapter and we will not only answer the research questions, but also further develop the conceptual framework on the basis of the empirical cases.

The chapter is structured as follows. Section 7.2 reflects the four research questions. On the basis of the empirical cases we will analyze the influence of the four independent variables on the consistencies and appropriateness of the RTDI policies. Section 7.3 re-explores the conceptual framework by the empirical cases. In Chapter 3, as we have shown in Figure 3.1, we have divided the RTDI policy - making process into four stages and we assume each stage is influenced by different independent variables. Nevertheless, on

the basis of the empirical cases, in this section we will add the new analysis in our conceptual framework and deepen the understanding towards the RTDI policy - making process. The contribution and the limitation of the conceptual framework will be also discussed in the section. Section 7.4 is the conclusion of the chapter.

## **7.2 The analysis of the research questions and the empirical cases**

### **7.2.1 The influence of the divided government on the consistencies and appropriateness of RTDI policies**

Our first research question established in section 3.2.1.1 asks: **how does a divided government under the presidential polity influence the consistencies and appropriateness of the RTDI policies?** The divided government, according to the definition of Elgie (2001:3), refers to the situation that ‘the president’s party fails to control a majority in at least one house of the legislature. As we describe in section 3.2.1, the literature of comparative politics extensively contributes to our first research question. As described by Smith et al (2006), the congress which is controlled by the opposition party most often has different policy priorities and preferences from the president’s ones. Samuels (2007) also speculates that under the divided government the president’s policies are very difficult to get approvals of the congress and once the dead - lock between the president and the congress happens, the presidential polity provides no institutional solution to solve the problems of the dead - lock. Moreover, according to the descriptions of Weatherford (1994), Cox and McCubbins (2000) and Pfiffner (1994), under the situation of the divided government the consistencies of policies are very difficult to be maintained because the congressmen of the opposition party are likely to break the consistencies of these policies through the legislative process. The only way for the president



to maintain the consistencies of the policies, from the perspectives of these scholars, is to employ his / her leadership to persuade the congressmen to authorize the policy proposals released in the name of the president. However, since no existing literature provides sufficient linkage between the divided government and the consistencies and appropriateness of RTDI policies, on the basis of the existing literature, in section 3.2.1.1, we have assumed that a divided government is very difficult to make consistent and appropriate RTDI policies. The congressmen of the opposition party who possess different policy priorities and preferences from the president's ones may break the consistencies of the RTDI policies. Moreover, as long as the congressmen of the opposition party are likely to have difficulties to form a consensus for the appropriateness of the RTDI policies with the president, the divided government as a whole is very difficult to make appropriate RTDI policies to support the development of the NSTIS. Nevertheless, our assumptions made in section 3.2.1.1 are not fully demonstrated by the empirical cases of the National Programs and the regulation policies discussed in section 6.4.

Both cases, the National Programs and regulation policies, show that the divided government is capable to make consistent and appropriate RTDI policies. In fact, in the case of the National Programs, the congressmen of the opposition party only changed a part of the contents of the National Science and Technology Program for Biotechnology and Pharmaceuticals and broke the consistencies and the appropriateness of the National Program. For the other two National Programs, as we have described in section 6.4.2.2, once the elected politicians have decided the policy proposals of the two National Programs to be consistent and appropriate, the congressmen of the opposition party approved the policy proposals and didn't change the consistencies and appropriateness of the two National Programs. In addition, in the case of the regulation policies the congressmen of the opposition

party authorized the bills of the new clauses of the Law with only one change, and indeed the change, as we have described in section 6.4.3.2, made the new clauses of the Law to be more appropriate to the development of the pharmaceutical NSTIS. The congressmen even authorized the bills of the new clauses of the Management Act without change. Yet, the new clauses of the Management Act authorized by the congressmen, as we describe in section 6.4.3.2, were inappropriate to the development of agricultural NSTIS. In fact, according to the empirical cases of the National Programs and the regulation policies, we consider that the congressmen of the opposition party under the divided government did influence the consistencies and appropriateness of RTDI policies. Yet, the congressmen, in the majority of cases, only had slight influence (such as one of the National Program and the Law) or no influence (two of the National Programs and the Management Act). In addition, even if the congressmen made some changes to the RTDI policies, the changes made by the congressmen are either positive (such as the Law) or negative (such as National Science and Technology Program for Biotechnology and Pharmaceuticals) to the consistencies and appropriateness of the RTDI policies. The influence of the congressmen on the consistencies and appropriateness of RTDI policies is actually very complex. On the basis of the discussions about the two empirical cases we recognize that there are three factors which effect on the influence of the congressmen of the opposition party on the consistencies and appropriateness of the RTDI policies. Each of the factors is introduced below.

First of all, the congressmen have limited knowledge about the contents of RTDI policies, and their oversight to the proposals of RTDI policies is reduced because of the shortage of knowledge. As we have described in section 6.4.2.2, in the case of the National Programs, the congressmen of the opposition party had different policy priorities and preferences from the

president's ones and had incentives to change the contents of policy proposals of the National Programs. This is consistent with the literature on divided government. However, as it is shown in section 6.4.2.2, it was the limitation of knowledge which reduced the insights and leverage of the congressmen. As long as the policy proposals of the National Programs were full of professional terms of biotechnology, it was very difficult for the congressmen to monitor and criticize the policy proposals. Besides, the congress itself didn't provide sufficient support to the knowledge of the congressmen. Even as the congressmen of the opposition party had high incentive to change the policy proposals provided in the name of the president, they were unable to change the contents of policy proposals as much as they tended to. In other words, as we observe from the case of the National Programs, even though the congressmen of the opposition party do have incentives to change the policy proposals of RTDI policies, because of the shortage of knowledge, the congressmen are only able to make few changes before they approve the RTDI policy proposals.

Second, the extent to which the elected politicians can persuade and form the consensus with the congressmen deeply influenced the judgments of the congressmen towards the consistencies and appropriateness of the RTDI policy proposals. While the existing literature, such as Weatherford (1994), Cox and McCubbins (2000) and Pfiffner (1994), describe that it is the president who needs to employ his/her leadership to persuade the congressmen of the opposition party in order to get approvals of policies, we find that it is in fact the elected politicians, rather than the president, who need to form the consensus with the congress. As we have shown in section 6.4.2.2, there were two National Programs directed towards the pharmaceutical sector, but the congressmen had quite a different judgment from the policy proposals of the two National Programs. The congressmen smoothly authorized the policy proposals of the National Research Program

for Genetic Medicine and maintained the consistencies and appropriateness of the National Program, because the leaders successfully persuaded the congressmen that the development of generic research took long time. Yet, the congressmen suspended a part of the budgets of the National Science and Technology Program for Biotechnology and Pharmaceuticals and broke the consistencies and appropriateness of the National Program, because the leaders of the National Program were unable to successfully persuade the congress. Moreover, in the case of the Management Act, as we have described in section 6.4.3.1.2, it was also the high level managers of the Bureau of Animal and Plant Health Inspection and Quarantine, as elected politicians, to form the consensus with the congressmen. As long as the policy priorities and preference of the congressmen were included in the bills in the stage of agenda - setting, in the stage of deciding, the congressmen authorized the bills to be laws without changes. Yet, as we have described in section 6.4.3.1.2, even if the new clauses of the Management Act were legislated, these new clauses merely strengthened the policy objective of the Management Act which was neither consistent with other interrelated policies, such as the National Program, nor appropriate to the development of agricultural NSTIS. Indeed, the congressmen didn't play the role to check for the consistencies and appropriateness across policies. The two pharmaceutical National Programs and the Management Act show three different processes for the divided government to shape the consistencies and appropriateness of RTDI policies. In the case of the National Research Program for Genetic Medicine, the elected politicians achieved the consensus with the congressmen which was based on the understanding towards the consistencies and appropriateness of the National Program, and the divided government made the National Program to be consistent and appropriate; on the contrary, even if the elected politicians formed the consensus with the congressmen in the case of the Management Act, since the consensus was not established upon the understanding

towards the consistencies and appropriateness, the divided government didn't make the Management Act to be consistent and appropriate. In addition, in the case of the National Science and Technology Program for Biotechnology and Pharmaceuticals, even though the elected politicians made the National Program to be consistent and appropriate, since there was no consensus formed for the National Program, the congressmen broke the consistencies and appropriateness of the National Program. In sum, from the empirical cases we find that it is the interactions between the elected politicians and the congressmen which influence the judgments of the congressmen towards the RTDI policies. Furthermore, only under the condition that the consensus between the elected politicians and the congressmen is established upon the understanding of the consistencies and appropriateness of RTDI policies, the divided government is able to make consistent and appropriate RTDI policies.

Third, the pressures from the voters and the involvement of external stakeholders facilitate the formation of the consensus between the congressmen and the elected politicians. In the case of the National Programs, as we have shown in section 6.4.2.2, voters preferred to support the development of biotechnology. The preference of the voters was similar to the policy preference of the president and the elected politicians who tended to promote policies, such as the National Programs, to support the development of biotechnology and related sectors. Therefore, the congressmen of the opposition party tended to approve the policy proposals of the National Programs. In addition, the congressmen formed different levels of consensus with the elected politicians to satisfy their voter's preferences. The congressmen had much stronger consensus with the elected politicians towards the agricultural National Program than the two pharmaceutical National Programs, because many congressmen of the opposition party were elected by agricultural counties. Therefore, all the

budgets of the agricultural National Program were smoothly authorized and parts of the budgets of one of the two pharmaceutical National Programs were suspended. Moreover, in the case of the Law, as we have described in section 6.4.3.2, even though the congressmen of the opposition party didn't achieve the consensus with the Minister of the Department of Health for the consistencies and the appropriateness of the Law, it was the involvement of the same groups of pharmaceutical associations to shape the consensus between the congressmen and the ministers. Since the pharmaceutical associations presented their policy preference to both the Minister and the congressmen, the policy preference of the Minister and the one of the congressmen of the opposition party were shaped to be similar to each other. While the congressmen of the opposition party authorized the bills of the new clauses of the Law to be laws, they only slightly changed the details of the bills, such as deleting the 3 year protection of the data exclusivity of Me-Too medicines. Since the policy purpose and the policy instruments of the new clauses were not changed, the congressmen in fact didn't change the vertical and horizontal consistencies of the Law. In addition, since the congressmen further balanced the interests of the local SMEs and MNCs, they in fact changed the new clauses of the Law to be more appropriate to the development of pharmaceutical NSTIS. In short, based on our discussion about the National Programs and the Law, we find that the pressure from the voters and the involvement of external stakeholders are able to shape policy preferences of the congressmen of the opposition party and the elected politicians to be similar to each other and facilitate the executive and legislative branches to form a consensus for the policy objectives and the policy instruments of RTDI policies.

On the basis of our empirical cases of the three National Programs and the regulation policies, we identify that the divided government is able to make RTDI policies to be consistent and appropriate. We agree with some existing

literature of comparative politics, such as Samuels (2007), Weatherford (1994), Cox and McCubbins (2000) and Pfiffner (1994), and extend the contributions of the literature to the field of RTDI policies. Under the divided government the congressmen of the opposition party have different policy priorities and preferences of RTDI policies which are different from the ones of the president. In some cases, the congressmen do have incentives to change the contents of RTDI policies. Yet, as we have found in the empirical case of the National Programs, because of the specialties of these policies the oversight of the congressmen was reduced by the shortage of knowledge. In addition, we don't agree with some literature of comparative politics, such as Weatherford (1994), which considers the employment of the president's leadership to be the only method to persuade the congressmen to authorize the policy proposals. On the basis of our empirical findings we recognize that in the field of RTDI policies, the two branches of the divided government are able to achieve consensus through the interactions between the elected politicians and the congressmen and through the involvement of the policy preferences of the voters and the external stakeholders.

In sum, we recognize that our assumption that the divided government is very difficult to make consistent and appropriate RTDI policies is too simplified. The oversight of the congressmen under the divided government is able to be reduced by the shortage of knowledge, and the persuasion of elected politicians and the involvement of voters' and the external stakeholders' preferences are able to facilitate the establishment of consensus between the two branches. Therefore, we conclude that as long as the elected politicians and the congressmen of the divided government are able to establish a consensus upon the understanding towards the consistencies and appropriateness of RTDI policies, the divided government is able to make consistent and appropriate RTDI policies. The consensus

between the two branches is different from sector to sector because of the different preferences of voters and the involvement of external stakeholders.

### 7.2.2 The influence of the horizontal coordination on the consistencies and appropriateness of RTDI policies

In section 3.2.1.2 we have established our second research question: **how does the horizontal coordination between actors influence the consistencies and appropriateness of RTDI policies?** The actors refer to both the elected politicians on the ministerial level and the administrators on the agency level. Our second research question, as described in section 3.2.1.2, is established upon the literature of public management. On the ministerial level, according to the description of Laver and Shepsle (1996), the departmental egoism of elected politicians, especially the ministers, is very difficult to avoid. Even though Six et al (2006) have described that the collaborative organizational relationships are the precondition to make policies consistent with each other, from the perspective of Braun (2008), in the field of RTDI policies, unless the benefit of coordination is higher than costs, the self - interested ministers have no incentive to achieve the inter - ministerial consensus for coordination. Moreover, on the agency level, as described by Elmore (1997), Six et al (2002) and Lindblom and Woodhouse (1993), it is very hard for administrators to achieve the consensus to horizontally coordinate with each other. In the field of RTDI policies, as described by Biegelbauer (2003), RTDI policies are complex and usually decided and implemented by multiple ministries. Therefore, the coordination is important. Yet, unless the administrators gain benefits or at least secure their benefits through coordination, as depicted by Braun (2008), they have no incentives for horizontal coordination. Indeed, on the basis of the existing literature we assume that if ministers are difficult to horizontally coordinate with each other, it is very difficult for the cabinet to make



vertically and horizontally consistent RTDI policies which appropriately match the development of NSTIS. We assume if ministers have difficulties to form inter - ministerial consensus, the general policy objectives are difficult to be formed and the RTDI policies promoted by different ministries would be difficult to be horizontally complementary to each other. Moreover, since the cabinet as a whole would have difficulties to form a unified judgment for the appropriateness of RTDI policies, the cabinet would have difficulties to promote a set of RTDI policies to match the development of a particular NSTIS. In addition, we assume if administrators have difficulties to horizontally coordinate with each other, RTDI policies will be implemented towards the directions which are neither vertically consistent with the general policy objectives of the whole government, nor horizontally consistent with the implementation of other interrelated policies. Once being implemented, the RTDI policies are very difficult to generate appropriate support to the development of a particular NSTIS. In fact, what we have assumed in section 3.2.1.2 is confirmed by the cases of National Programs and regulation policies.

The cases of the National Programs and regulation policies show that horizontal coordination deeply influences the consistencies and appropriateness of RTDI policies. In the case of National Programs, as we have described in section 6.4.2.1, the policy objectives and the policy instruments of the three National Programs were decided through the inter - ministerial consensus between ministers and were consistent and appropriate. Yet, all the three National Programs suffered the problem of poor horizontal inter - departmental coordination and were implemented towards the direction which was not consistent and was difficult to generate sufficient appropriate support to the pharmaceutical and agricultural NSTIS. Furthermore, in the case of regulation policies, as we have described in section 6.4.3.1, the policy objectives and the policy instruments of the Law

and the Management Act were set up without horizontal inter - ministerial consensus and were neither consistent with the National Programs, nor appropriate. Even though the policy purpose and policy instruments of the new clauses of the Law loosely followed the general policy objectives of the Promotion Plan and tended to generate appropriate support to the pharmaceutical NSTIS, without inter - ministerial consensus, the new clauses of the Law were not horizontally complementary with other interrelated policies, such as the National Programs. In addition, because there was no horizontal inter - departmental coordination, both the Law and the Management Act were implemented towards the direction which was not vertically consistent with the general policy objectives of the Promotion Plan and not horizontally consistent with other implementation bodies. After being implemented, the regulation policies were difficult to generate appropriateness on the development of pharmaceutical and agricultural NSTIS.

In summary, based on the two empirical cases we are able to confirm that the horizontal coordination does influence the consistencies and the appropriateness of RTDI policies. However, we further recognize that the horizontal coordination on the ministerial level and the horizontal coordination on the agency level have different influences on the RTDI policies. The influences of the horizontal coordination on each of the two levels are discussed below.

The horizontal inter - ministerial coordination has the influence on the consistencies and the appropriateness of the policy objectives and the policy instruments of RTDI policies. In the case of the National Programs, the policy objectives and the policy instruments of the National Programs were decided through inter - ministerial consensus. As we have described in section 6.4.2.1, the resources of the National Programs were contributed by

different ministries. Although the National Science Council played the role to coordinate other ministries to form the inter - ministerial consensus for the policy objectives and the policy instruments of the National Programs, in fact, none of the Ministers of the four ministries lost interests or lost their authorities because of the participation of the National Programs. The Steering Committees of the three National Programs which gave the general advices for the policy objectives and the policy instruments to the leaders were chaired by the Minister of the National Science Council but involved the vice - ministers of other ministries. Therefore all the ministries participating in the National Programs shared the authority to decide the policy objectives and policy instruments of the National Programs. Moreover, in the agricultural National Program, the Project Committee was co - chaired by the vice-Minister of the National Science Council and the vice-Minister of the Council of Agriculture. In other words, not only the policy objectives and the policy instruments, but the detailed agendas of the National Program were decided through inter - ministerial consensus. Indeed, inter - ministerial consensus of the National Programs was achieved under the institution in which no minister lost resources or lost the authority. Because the ministers achieved inter - ministerial consensus, as we have described in section 6.4.2.1, the policy objectives and policy instruments of the National Programs were consistent and appropriate. However, in the case of the regulation policies, the policy objectives and policy instruments of the Law and the Management Act were not decided through the inter - ministerial consensus. As we have described in section 6.2, the Department of Health was the single ministry to execute the Law and the affiliated administrative rules, and the Council of Agriculture was the single ministry to execute the Management Act. If the Minister of the Department of Health or the Minister of the Council of Agriculture coordinated with other ministers for the promotion of the Law or the Management Act, they may lose their authority to be the single ministry to execute the Law or the

Management Act. Under the condition that there was no benefit, such as increasing resources and authority for the horizontal coordination, we are not surprised that the two Ministers had no incentives to form inter - ministerial consensus for the Law and the Management Act. As we have shown in section 6.4.3.1, because of lacking inter - ministerial consensus, even if the policy purpose of the new clauses of the Law loosely followed the general policy objectives of the Promotion Plan, the policy objectives remained vertically inconsistent with the general policy objectives of the Promotion Plan and the policy objective and the policy instruments of the Law were not horizontally consistent with the two pharmaceutical National Programs. In addition, since the agendas of the Management Act were decided without inter - ministerial consensus, the policy objective and policy instruments of the Management Act were not vertically consistent with the general policy objectives of the Promotion Plan, were not horizontally complementary with the agricultural National Program and were unable to generate appropriate support to the development of agricultural NSTIS.

On the basis of the empirical cases of the National Programs and regulation policies, we agree and further extend the perspectives of the existing literature of public management. In the field of RTDI policies, as described by Laver and Shepsle (1996), the departmental egoism of ministers exists and is the most important underlying factor which makes the horizontal inter - ministerial coordination difficult. Even though the inter - ministerial coordination deeply influences the consistencies and appropriateness of the policy objectives and policy instruments of RTDI policies, just as described by Braun (2008), unless the ministers are able to perceive the benefits of coordination they have no incentive to decide the policy objectives and policy instruments of RTDI policies to be consistent and appropriate through inter - ministerial coordination.

Furthermore, the administrators' horizontal inter - departmental coordination influences the consistencies and the appropriateness of the implementation of RTDI policies. In fact, the National Programs were implemented without horizontal inter - departmental coordination. As we have shown in section 6.4.2.3, all three National Programs encountered the problem of horizontal inter - departmental coordination. In the cases of the two pharmaceutical National Programs, since the implementation bodies of the Ministry of Economic Affairs didn't consider their mission were fully respected by the National Programs and they were unable to gain obvious benefits through the participation of the National Programs, from our perspective, it is not surprising that the two implementation bodies were reluctant to be involved in the National Programs. Moreover, in the agricultural National Program, the implementation body of the Council of Agriculture and the implementation body of the Ministry of Economic Affairs had no problem to horizontally coordinate with each other in funding the bio - agricultural research because the missions of the two implementation bodies were similar to each other. Yet, the implementation bodies were very difficult to horizontally coordinate with each other to execute the agricultural regulations under the framework of the National Program. The Bureau of the Industrial Development was the single body to execute the 'Factory Rules', and the Bureau of Animal and Plant Health Inspection and Quarantine under the Technology Department was the only body to execute the Management Act. There was in fact no perceived benefit to incentivize the two implementation bodies to coordinate with each other. As a result, the direction of implementation of the National Programs was neither vertically consistent with the general policy objectives of the Promotion Plan, nor horizontally consistent with the implementation of other implementation bodies. After being implemented, the National Programs were difficult to generate appropriate support to the development of pharmaceutical and the

agricultural NSTIS. Moreover, in the case of the regulation policies, the Law and the Management Act were also implemented without horizontal inter - departmental coordination. As we have described in section 6.4.3.3, the Bureau of Pharmaceutical Affairs was the only implementation body of the Law and the affiliated administrative rules, and the Bureau of Animal and Plant Health Inspection and Quarantine was the only implementation body of the Management Act. According to our discussions above these two Bureaus indeed had no incentives to implement the Law and the Management Act through inter - departmental coordination, which may reduce their authority in the implementation of these regulation policies. As a result, the implementation of the Law and the Management Act was towards the direction which was not vertically consistent with the general policy objectives of the Promotion Plan, not horizontally consistent with the National Programs, and not to generate appropriate support to the pharmaceutical and the agricultural NSTIS.

On the basis of the empirical cases of the National Programs and regulation policies we agree and extend several points of the existing literature of public management. We assent to Elmore (1997) and Lindblom and Woodhouse (1993) that the administrators have their own departmental egoism, and further explain that in the field of RTDI policies the departmental egoism of the administrators is one of the most important reasons which make the horizontal inter - departmental coordination difficult. We also agree with Braun (2008) that unless the departmental routines of administrators are fully respected and administrators are able to at least secure their benefits in the coordination, they have no incentives to horizontally coordinate with each other to implement RTDI policies.

In sum, according to empirical analysis of the National Programs and the regulation policies, we recognize that the horizontal coordination, including

the horizontal coordination between the elected politicians and the coordination between the administrators, deeply influences the consistencies and appropriateness of RTDI policies – in both directions. Our conclusion not only confirms the opinions of Six et al (2006) that the collaborative organizational relationship is the precondition to make consistent policies, but also extends the perspectives of the existing literature of public management, such as Laver and Shepsle (1996), Elmore (1997), that in the field of RTDI policies the departmental egoism exists on both the ministerial level and the agency level and is one of the fundamental factors which make the horizontal coordination difficult. Moreover, the horizontal coordination on the ministerial level and on the agency level of actors has different influence on the consistencies and appropriateness of RTDI policies. While the horizontal inter - ministerial coordination influences the consistencies and appropriateness of the policy objectives and policy instruments of RTDI policies, the horizontal inter - departmental coordination influences the consistencies of implementation and the extent for the RTDI policies to generate appropriate support to the development of NSTIS.

### 7.2.3 The influence of the vertical coordination on the consistencies and appropriateness of RTDI policies.

As we have described in section 3.2.1.2 our third research question is: **how does the vertical coordination between the elected politicians and the administrators influence the consistencies and appropriateness of RTDI policies?** The scholars of public management have rich analyses for the vertical coordination within the government. As described by the Hogwood and Gunn (1997), administrators are very difficult to ‘perfectly’ implement the policies decided by the elected politicians. As also described by Lindblom and Woodhouse (1993), because of the limited time elected politicians have they are not able to supervise the implementation of the

majority of policies. Elmore (1997) also describes that even if the elected politicians have major changes in the policies, unless the elected politicians give sufficient incentives for the administrators to adjust and to implement these changes, the new policies would be implemented by old routines and suffer implementation failure. On the basis of the existing literature of public management, we assume that if the vertical coordination between the elected politicians and administrators is very difficult to achieve, even if the elected politicians have decided the policy objectives and policy instruments of every RTDI policy to be vertically consistent with the general policy objectives of the whole government and horizontally consistent with other interrelated policies. In addition, even though the elected politicians have decided that policy objectives and policy instruments appropriate, the implementation may be difficult to generate appropriate support to the development of NSTIS. Our empirical descriptions of the National Programs and regulation policies in section 6.4 confirm our assumptions of the vertical coordination established in section 3.2.1.2.

Both the National Programs and the regulation policies encountered the difficulties of vertical coordination which deeply influence the consistencies and appropriateness of the two policies. In the case of the National Programs, as we have described in section 6.4.2.3.1, the elected politicians, including the ministers and the leaders, have coordinated the policy objectives and the policy instruments of the National Programs to be consistent and appropriate. Yet, because of the problem of vertical coordination, even though the implementation bodies of different ministries didn't consistently implement the National Programs, none of the elected politicians were able to amend the distortion. During implementation, the National Programs didn't generate sufficient appropriate support for the development of pharmaceutical and agricultural NSTIS. Moreover, in the case of the regulation policies, both the Law and the Management Act were



implemented without vertical coordination. Even though the implementation of policies was far from the general directions given by the Minister of the Department of Health and the Minister of the Council of Agriculture, none of the Ministers fixed the distorted implementation of the two policies. After being implemented, the regulation policies did not generate the intended appropriateness on the development of the pharmaceutical and agricultural NSTIS. Indeed, according to the two empirical cases we recognize that the vertical coordination actually influences the consistencies and appropriateness of RTDI policies. Furthermore, as we have described in section 3.2.1.2, there are two possible factors which explain the difficulties of vertical coordination: the limitation of the elected politicians and the organizational inertia of the administrators. Since both factors are further demonstrated by the two empirical cases, we discuss each of the factors below.

First, the limitation of elected politicians to monitor the implementation is one of the factors which make the vertical coordination difficult. As described by Lindblom and Hoodhouse (1993), compared with the vast scope of the administrative activities, elected politicians only have limited time and energy to supervise the implementation of policies. In fact, both cases of the National Programs and the regulation policies demonstrated this. In the cases of the two pharmaceutical National Programs, as we have described in section 6.4.2.3, once the Minister and the vice - Ministers of the three ministries delegated power to the implementation bodies, they no longer monitored the implementation. The agricultural National Program was also implemented in the context that the minister and the vice-ministers simply believed the implementation bodies even if the implementation was distorted. Moreover, in the cases of the Law and the Management Act, once the Ministers delegated the regulatory bodies to set up the agendas and to implement these regulation policies, they no longer monitor the agendas and

the implementation. From our perspective, both the National Programs and the regulation policies were just a small part of the policies which were promoted by Ministers and vice - Ministers. In practice, each of the Ministers and vice - Ministers had too many policies to monitor and it was almost impossible for them to monitor the implementation of every single policy promoted under the ministry. Therefore, on the basis of the empirical cases of the National Programs and regulation policies, we agree with Lindblom and Hoodhouse (1993) that the limitations of the elected politicians, especially the ministers, to supervise the implementation is one of the fundamental problems which derives the difficulties of vertical coordination. However, according to the empirical case of the National Programs, we also find that the improvement of institutions is one of the possible ways to overcome the limitation of Ministers and therefore to improve the vertical coordination. As we have shown in section 6.4.2.3, in the case of all the three National Programs, the leaders of the National Programs, as elected politicians, have discovered that the implementation of the National Programs was distorted. Yet, since the leaders were only nominated by the Minister of the National Science Council and only represented the Council, they were unable to supervise the implementation of the implementation bodies of other ministries from top - down and had difficulties to fix the distortion of the implementation of the National Programs. From our perspective, it was the institutional design which hampered the improvement of vertical coordination. If the leaders were nominated by the Ministers of the three ministries, rather than the Minister of the National Science Council, the leaders should be able to improve the vertical coordination and maintain the consistencies and the appropriateness of the implementation of the National Programs. Therefore, we recognize that the limitation of the ministers to supervise implementation is one of the possible reasons which make the vertical coordination difficult, but we also consider that the improvement of institutions is one of the possible ways to

improve the vertical coordination.

Second, organizational inertia is another factor which derives the problem of vertical coordination. As we have defined in section 3.2.1.2 the organizational inertia refers to the situation that administrators get used to the administrative routines too much and avoid to accept new changes. As described by Elmore (1997), the elected politicians who introduce major changes in policies should give sufficient incentives for the administrators to implement these changes or the new policies would frequently suffer implementation failure. The perspective of Elmore is further demonstrated by the empirical cases of the National Programs. Indeed, the National Programs, as we have described in section 6.2, were the new policies which were on the top of the 15 % Mid-term Plans of the four ministries considered to be the old policies. The National Programs, as the new policies, were initiated in order to integrate the 15 % of the Mid-term Plans. Yet, the elected politicians, especially the Minister and vice-Ministers, didn't give the administrators sufficient incentives to adopt the new changes. The National Programs were then implemented by the old administrative routines of the Mid-term Plans which were implemented according to the priorities of each ministry, rather than the inter - ministerial consensus. The National Programs suffered implementation failure and didn't generate sufficient appropriate support to the development of pharmaceutical and agricultural NSTIS.

In sum, according to the empirical cases of the National Programs and the regulation policies, we consider that the vertical coordination between the elected politicians and the administrators has deep influence on the consistencies and appropriateness of RTDI policies. We agree with Hogwood and Gunn (1997) and extend their points that in the field of RTDI policies, 'perfectly' implementation of policies is indeed very difficult.

Moreover, we further recognize two factors which influence the vertical coordination of RTDI policies. Firstly, we agree with Lindblom and Woodhouse (1993) and extend their perspectives that in the field of RTDI policies, the limitation of the elected politicians, especially the elected politicians at ministerial level, is one of the reasons for the difficulties of vertical coordination. However, we also recognize that the improvement of institutions may be one of the possible methods to improve the limitations of the ministers and improve the vertical coordination. In addition, we agree with Elmore (1997) and further stretch his perspectives that in the field of RTDI policies organizational inertia is another reason of the problems of vertical coordination and implementation failure. In sum, we conclude that the vertical coordination does influence the consistencies and appropriateness of RTDI policies, especially the extent for the RTDI policies to be consistently and appropriately implemented. The improvements of the institutions for the supervision of the elected politicians and the organizational inertia of administrators are the key elements to improve the vertical coordination.

#### 7.2.4 The influence of the involvement of external stakeholders on the consistencies and appropriateness of RTDI policies

As we have asked in section 3.2.2 our fourth research question is: **how does the involvement of external stakeholders influence the consistencies and appropriateness of RTDI policies?** The external stakeholders include interest groups and academics. As we have described in section 3.2.2, our fourth research question is established upon the research of interest groups and scientists. The interest groups, as described by Chubb (1983), Feldmann (2002) and Scott and Cornelius (2004), participate in the policy - making process out of self - interests. According to the descriptions of Hrebener and Scott (1982) and Scott (1997), the capabilities of interest groups to influence

policies are different because of the unequal resources they hold. May et al (2005) and Steinmo and Watts (1995) also explain that the presidential polity yields interest groups enormous power because it allows them to effect on policies through lobbying the congress. As also described by Inzelt (2008) and Mogee (1988), the involvement of interest groups has both positive and negative impacts on the RTDI policies. Moreover, the academics, according to the descriptions of Tournon (1993), also participate in the policy - making process out of self - interests, and as described by Schooler (1971), the capabilities of academics to influence the policies are different because of their scientific field, their degree of specialization and so on. Rich (2005) also depicts that the presidential polity gives experts higher influences because the experts are able to influence policies from both sides, the president and the congress. According to the descriptions of Pollitt (2006) and Barker and Peters (1993), there are both positive and negative impacts of academics on the policies. Indeed, on the basis of the existing literature, in section 3.2.2, we assume that only the suitable involvements of external stakeholders, including interest groups and academics, have positive impacts on the consistencies and appropriateness of RTDI policies. The suitable involvement of external stakeholders, according to our definition in section 3.2.2, refers to the situation that the involved external stakeholders are able to present the general interests of the whole industry or the whole scientific community to the government and help the government to promote consistent and appropriate RTDI policies. If the interest groups or the academics are able to present the general interests of the whole industry or the whole scientific community to all actors inside the government, they would ensure that the RTDI policies are decided with full knowledge of the conditions of the industry and scientific community and the likelihood of the RTDI policies may increase. Therefore, the involvement of external stakeholders would positively contribute to the consistencies and appropriateness of the RTDI policies. What we have

assumed in section 3.2.2 is in general further demonstrated by the empirical cases of the National Programs and the regulation policies.

Both the National Programs and the regulation policies show that only a suitable involvement of external stakeholders is able to positively contribute to the consistencies and appropriateness of RTDI policies. In the case of the National Programs, as we have described in the section 6.4.2, only the general interests of the academics were suitably involved in the agendas of the two pharmaceutical National Programs, while the general interests of the pharmaceutical sector were not. Once being implemented, the majority of pharmaceutical companies were quite indifferent to the National Programs, and the two National Programs indeed generated very limited appropriate support to the pharmaceutical NSTIS. In the case of agriculture, the general interests of the agricultural academics and the agricultural companies were not suitably involved in the agricultural National Program, and thus they were unable to positively contribute to the consistencies and the appropriateness of the National Program. After being implemented, the agricultural National Program didn't generate sufficient appropriate support to the development of agricultural NSTIS.

Moreover, in the case of the Law, as long as the general interests of the pharmaceutical sector were suitably involved in the agendas of the Law, they positively contribute to the appropriateness of the new clauses of the Law. Nevertheless, since the agricultural companies, especially the companies of pesticides, were unable to suitably present their general interests to the actors inside the government, they were very difficult to help the government to make the Management Act consistent with the National Program and appropriate to match the development of agricultural NSTIS. Indeed, according to the empirical cases, we consider that the extent for the general interests of external stakeholders to be involved in the policy -

making process of RTDI policies influences the consistencies and appropriateness of RTDI policies. However, we find that there are four points that are able to extensively deepen the analysis of the influence of the involvement of external stakeholders on the consistencies and appropriateness of RTDI policies.

First of all, the organization of political system deeply influences the capabilities of external stakeholders to effect on the consistencies and the appropriateness of the RTDI policies. Various authors in the existing literature, such as Steinmo and Watts (1995), May et al (2005) and Rich (2005), have noticed that the organization of the political system is one of the factors which determine the capabilities of interest groups and the academics to influence policies. From their perspective, the presidential polity shapes the organization of the political system and gives the external stakeholders opportunity to influence policies through lobbying the congressmen. Such perspective is demonstrated by the case of the Law. As we have shown in section 6.4.3.1.2 and section 6.4.3.2, the pharmaceutical associations influenced the contents of the Law through lobbying both the elected politicians and the congressmen of the opposition party. However, the case of the National Programs shows that the presidential polity is not the only factor which shapes the organization of the political system. The political institution also shapes the organization of the political system and gives some external stakeholders more access than others. As we have shown in section 6.4.2.1, the influence of the academic representatives and the pharmaceutical or the agricultural representatives on the agendas of the National Programs was much higher than any other external stakeholders. The institutions of Steering Committees and the Consulting or the Project Committees gave these external stakeholders special status to influence the agendas of the National Programs. In other words, it was the political institution which shaped the capabilities of these external stakeholders to

influence the National Programs. According to the empirical cases of the National Programs and the Law, we recognize that it is not only the presidential polity, but the political institutions which shape the organizations of the political system and the influence of the external stakeholders on the contents of RTDI policies, as well as the consistencies and appropriateness of RTDI policies.

Second, the external stakeholders of the same sector have different participation in the different stages of the RTDI policy - making process, and in each stage, they have different influence on the consistencies and appropriateness of RTDI policies. While the existing literature, such as Inzelt (2008), Moguee (1988), Pollitt (2006), Tournon (1993) and Barker and Peters (1993), discuss the positive and negative influences of the external stakeholders on the RTDI policies, these authors haven't discussed that the positive and negative influence of the external stakeholders is continuously changing through the policy - making process. Indeed, as we have noticed in the empirical cases, not only the external stakeholders in the same sector had different modes of participation in the different stages of the RTDI policy - making process, but the impact of external stakeholders, either positive or negative, changes during the policy - making process. As we have shown in the cases of the two pharmaceutical National Programs in section 6.4.2.1.2, in the stage of agenda-setting, the academic representatives, as external stakeholders, have presented the general interests of the whole scientific community to all elected politicians and positively contributed to the consistencies and appropriateness of the National Programs. Yet, these academic representatives had no involvement in the stages of deciding and implementation and had no positive influence on the contents of the National Programs in the two stages. Moreover, in the case of the Law, the pharmaceutical associations were involved in the stages of agenda-setting and deciding, positively represented the general interests



of the pharmaceutical sector to both the elected politicians and the congressmen, and positively contributed to the appropriateness of the policy objectives and instruments of the new clauses of the Law. However, the pharmaceutical associations had no involvement in the stage of implementation. While the new clauses of the Law were implemented towards the direction which was not appropriate to the development of the pharmaceutical NSTIS, the pharmaceutical associations didn't present the general interests of the pharmaceutical sector to the administrators. After being implemented, the new clauses of the Law were very difficult to generate appropriate support to the pharmaceutical sector. In short, according to the cases of the National Programs and the Law we recognize that the influence of the external stakeholders changes from stage to stage because of their different modes of involvement in the different stages of RTDI policies. The more the external stakeholders are able to suitably involve in the different stages of the RTDI policy - making process, the more the involvement of the external stakeholders is able to have positive influence on the consistencies and appropriateness of RTDI policies.

Third, the external stakeholders of the same sector have different modes of participation in the different policies. While the existing literature, such as Chubb (1983), Feldmann (2002) and Scott and Cornelius (2004), depicts that the interest groups participate in the policy - making process out of self - interests, they don't discuss the reasons why the same sector has different participation in different policies. In fact, as we have shown through the cases of the two pharmaceutical National Programs and the Law, the pharmaceutical associations were quite indifferent to the National Programs but were very active in the policy - making process of the Law and its affiliated administrative rules. Moreover, the agricultural representatives who were active in the policy - making process of the National Program didn't participate in the policy - making of the Management Act. From our

point of view it is the different levels of awareness which influence the different participation of the same sector. The pharmaceutical associations didn't participate in the policy - making process of the National Programs because they didn't consider the importance of the National Programs; the agricultural representatives didn't participate in the policy - making process of the Management Act because they didn't recognize the interests of the Management Act. Yet, what are the underlying factors which influence the different levels of awareness of the companies of the same sector? We need more research in the future to fulfil the gap.

Fourth, the same policy has different involvements of external stakeholders from different sectors. While the existing literature, such as Goldstein (1999), Schooler (1971), Ricci (1993), Sabatier (1993) and Chubb (1983), discusses the involvement of external stakeholders in the policies, they usually focus on the interactions between the particular groups and the actors inside the government. Yet, the existing literature seldom discusses that the same policy which is promoted to different sectors may have different involvement of external stakeholders. As shown in the case of the Law, although the Law was promoted to both the pharmaceutical and the medical device sectors, the pharmaceutical associations were quite active in the policy - making process of the Law, while the medical device sector was quite indifferent to the Law. As a result, the Law was shaped to be more and more appropriate to the development of pharmaceutical sector, but remained un - appropriate to the medical device sector. From our point of view the same policy may have different appropriateness on the different sectors because of the different involvement of external stakeholders.

On the basis of the empirical cases we consider that the involvement of the external stakeholders does influence the consistencies and the appropriateness of RTDI policies, and only a suitable involvement of

external stakeholders has positive influence on the consistencies and appropriateness of RTDI policies. We agree with and extend the perspectives of the existing literature of interest groups and academics by four points. We find that in the field of RTDI policies, the capabilities of external stakeholders are deeply influenced by the organizations of political system which is shaped by both the polity and political institutions. We also find that the impacts of external stakeholders change in the different stages of policy - making process, and the external stakeholders who have positive influence on one stage do not necessarily have positive influence in another. In addition, the external stakeholders of the same sector have different participation in the different RTDI policies, and the same policy has different involvements of external stakeholders from different sectors. In sum, we consider that the suitable involvement of external stakeholders does influence the consistencies and appropriateness of RTDI policies, and the suitable involvement of external stakeholders is influenced by the organization of the political system, the modes of the participations of external stakeholders which are different because of the different sectors, different policies, different stages.

### **7.3 The analysis of the conceptual framework and the empirical cases**

In this section, we reconfirm and sharpen the conceptual framework by the analysis of our empirical cases. As we have shown in Figure 3.1 we have divided the RTDI policy - making process into four stages: agenda - setting, deciding, implementation and evaluation. In each stage we assume there are particular key actors who play the key roles in the stage, and each stage is influenced by particular independent variables. For example, we assume the key actors in the stage of agenda-setting are elected politicians and external stakeholders, and the stage is influenced by two independent variables, the horizontal inter - ministerial coordination and the involvement of external

stakeholders. However, as we have displayed in Figure 6.3, the dynamics of the policy - making process extend the analysis of the conceptual framework.

As shown in Figure 6.3 the policy - making process of the two policies is different, and the political institutions of the two policies change during the policy - making process. In the case of the National Programs, in the stage of agenda-setting, the National Science Council was the coordinator of other ministries, the academic representatives and the pharmaceutical or the agricultural representatives. In the stage of deciding, the Legislative Yuan played the central roles to authorize the policy proposals of the four ministries, and the academics and pharmaceutical or agricultural companies had limited influence on the congressmen. In the stage of implementation, the National Science Council was the coordinator of other ministries and interacted only with individual academics and pharmaceutical and agricultural companies. Moreover, in the case of the regulation policies, since the stage of agenda-setting, there was no coordinator of the Law and the Management Act. The Department of Health only interacted with the pharmaceutical associations; and the Council of Agriculture only interacted with individual agricultural companies. In the stage of deciding, it was the Legislative Yuan to play the central role to interact with the Department of Health, the Council of Agriculture and the pharmaceutical associations, and the agricultural companies played no roles in the stage. In the stage of implementation, the Department of Health only interacted with individual pharmaceutical companies, and the Council of Agriculture only interacted with individual agricultural companies.

The policy - making process of the two policies shown in Figure 6.3 sharpens our conceptual framework by two points. First of all, the actors involved in the different stages are not clearly distinguished. As shown in

Figure 3.1 we assume the congressmen of the opposition party only involve in the stage of deciding. Yet, Figure 6.3 shows that in the case of the Management Act the congressmen not only involved in the stage of deciding but also in the stage of agenda-setting. Second, the conceptual framework only assumes that the interactions between the actors inside the government and the external stakeholders would influence the consistencies and appropriateness of RTDI policies; yet, in Figure 6.3, it is shown in the empirical cases that not only the networks between the actors inside and outside the government, but the networks between the actors inside the government deeply influence the consistencies and appropriateness of RTDI policies. In short, what is happening in the reality is much more complex than the conceptual framework.

However, the empirical cases also demonstrate the value of the conceptual framework by two points. Firstly, as we have described in section 3.1, one of the theoretical blocks of the conceptual framework is the literature of comparative politics and the governance. The conceptual framework assumes that the government is the core of the political system and is embedded in the network of governance. The two empirical cases further confirm the assumptions of the conceptual framework. As shown in Figure 6.3, both the two cases show that the Taiwanese government is embedded in the network of governance which is composed of government and non - governmental actors, such as academics, companies and associations. The two policies were made through the interactions between the actors inside the government and actors outside the government. Inside the government, the political institutions change in the different stages of the policy - making process of the two policies, because the government itself is the core of a dynamic political system. Outside the government, the interactions between the government and non - governmental actors shape the RTDI policy - making process. Second, the conceptual framework assumes that the RTDI

policy - making process is under the context of NSTIS and the policy - making process influences the development of NSTIS. The assumption is reconfirmed by the empirical cases of the two policies. As shown in Figure 6.3, the Taiwanese government interacted with the external stakeholders outside the government and embedded in the network of governance in three biotechnology related NSTIS. The interactions, as we have mentioned in section 7.2.4, deeply influenced the consistencies and appropriateness of the two policies which further influenced the development of the three NSTIS.

In summary, the conceptual framework established in Chapter 3 outlines the framework for the analysis of the RTDI policy - making process and its impact on the content of policies. Although the conceptual framework itself, as a literature driven simplification to understand complex realities, does not – indeed cannot – perfectly reveal the dynamics and complexity of policy - making process, it helped us to identify the key actors, the different stages of the RTDI policy - making process, as well as the variables inside and outside the government which are able to influence the RTDI policy - making process.

## **7.4 Conclusion**

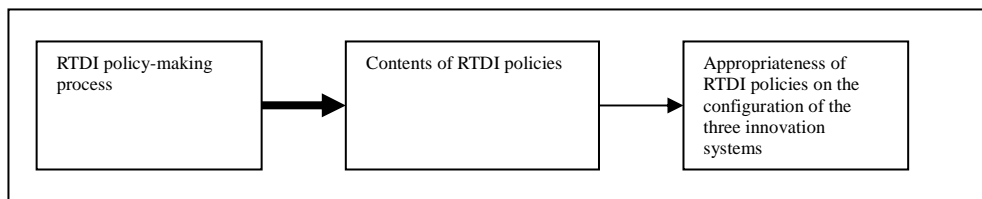
This chapter linked the conceptual framework and the empirical cases together. It not only analyzed the influence of each of the four independent variables on the consistencies and appropriateness of RTDI policies but also discussed the contributions of the conceptual framework to the empirical literature. Through opening the black - box of the RTDI policy – making process, we understand the influence of the four variables on the consistencies and appropriateness of the contents of RTDI policies and the influence of the contents of RTDI policies on the development of NSTIS. The key findings of this thesis, the main contributions of the thesis, and the

suggestions for the future research are discussed in the next chapter, Chapter 8.

## Chapter 8 Conclusion

### 8.1 Introduction

The chapter concludes with a summary of the key findings and the main contributions of the thesis, as well as suggestions for future research. The theme of the thesis, as we have described in Chapter 1, is to link three variables together: the RTDI policy - making process—the contents of RTDI policies—the appropriateness of RTDI policies on the development of configuration of the three innovation systems. The theme of the thesis is shown again in the dialogic box below.



The configuration of the three innovation systems, as we have defined in Chapter 2, is conceptualized as the *national, sectoral and technological innovation system* (NSTIS). Moreover, in order to open the black - box of the RTDI policy - making process, in Chapter 3 we establish the conceptual framework and set up the four research questions around the four independent variables which are likely to influence the RTDI policy - making process, as well as the contents and the appropriateness of RTDI policies. In Chapter 5 and Chapter 6, we then use the empirical experiences of the Taiwanese biotechnology and the three related sectors to demonstrate the concept of the NSTIS and on that basis, more importantly, to explore the conceptual framework of the RTDI policy - making process and its importance for the policy content. While we discuss the value and detect the gaps of the conceptual framework in Chapter 7, in this chapter we review the key findings and describe the main contributions of the thesis, as well as the limitations of the thesis, which need to be further overcome by future



research.

The chapter is structured as shown below. Section 8.2 summarizes the answers of the four research questions and the key findings of the whole thesis. Section 8.3 describes the main contributions of the thesis to the existing literature, i.e. the conceptual contributions and the empirical contributions. Section 8.4 detects the gaps of the thesis and gives suggestions for future research.

## **8.2 Key findings of the thesis**

In this section we review the key findings of the thesis and the answers to the four research questions and identify the influence of each of the four independent variables on the consistencies and appropriateness of RTDI policies, the two dependent variables. In addition, we also identify the findings from our conceptual framework which are able to contribute to our understanding towards the RTDI policy - making process. In the following paragraphs we will discuss the influence of each of the four independent variables first, and discuss the contribution of the conceptual framework afterwards.

The divided government under the presidential polity, as we have discussed in section 7.2.1, influences the consistencies and appropriateness of RTDI policies. In the field of RTDI policies the congressmen of the opposition party, under the divided government, have in fact limited oversight to the policy proposals of RTDI policies because of the shortage of knowledge. It is the persuasion of the elected politicians and the involvement of voters and external stakeholders to facilitate the establishment of the consensus between the elected politicians and the congressmen. Only under the condition that the consensus between the elected politicians and the

congressmen is achieved upon the understanding towards the consistencies and appropriateness, the divided government as a whole is able to make consistent and appropriate RTDI policies which match the development of NSTIS. However, since the level of consensus between the elected politicians and the congressmen differs across sectors, the divided government has different RTDI policies towards different sectors.

The horizontal coordination also influences the consistencies and the appropriateness of RTDI policies. As we have described in section 7.2.2 it is the departmental egoism which makes the horizontal coordination on both the ministerial level and the agency level difficult. While the horizontal coordination on the ministerial level influence the consistencies and appropriateness of the policy objectives and policy instruments of RTDI policies, the horizontal coordination on the agency level influences the consistencies and appropriateness of the implementation of RTDI policies. The government as a whole is able to make consistent and appropriate RTDI policies under the condition that the departmental egoism on both the ministerial level and the agency level is overcome and the horizontal coordination on both levels is achieved.

Moreover, as discussed in section 7.2.3 the vertical coordination between the elected politicians and the administrators also influences the consistencies and appropriateness of RTDI policies. The limitation of the elected politicians to supervise the implementation of the administrators and the organizational inertia of the administrators are the two main reasons which make the vertical coordination difficult. The government, as a whole, is able to promote consistent and appropriate RTDI policies under the condition that consistent and appropriate policy objectives and the policy instruments of RTDI policies decided by the elected politicians are able to be fully implemented by the administrators.

In addition, the involvement of external stakeholders, including academics and interest groups, is another variable which influences the consistencies and appropriateness of RTDI policies. As we have recognized in section 7.2.4 the involvement of external stakeholders in the RTDI policy - making process is dynamic. On one hand the external stakeholders of the same sector have different involvement in different RTDI policies, and on the other hand, same RTDI policy has different involvement of external stakeholders. Furthermore, the impact of the external stakeholders changes in the different stages of the RTDI policy - making process because of their different modes of involvement in the different stages. The stakeholders who have positive influence in the stage of agenda-setting do not necessarily have positive influence in the stage of implementation. Besides, the capabilities of external stakeholders to influence the RTDI policies are deeply influenced by the organizations of the political system. Indeed, it is the dynamic involvement of external stakeholders which shapes the RTDI policies of the same government different from sector to sector. We consider that only the suitable involvement of external stakeholders has positive contributions to the consistencies and appropriateness of RTDI policies. The government which is able to properly design the organization of the political system under the particular polity and to suitably involve the general interest of different external stakeholders through all the stages of the RTDI policy - making process is able to make consistent and appropriate RTDI policies to match the development of NSTIS.

Our conceptual framework provides the concept to analyze the policy - making process of RTDI policies which is influenced by multiple variables and involves multiple actors. Although, as we have described in section 7.3, the conceptual framework does not fully reveal the dynamics of the policy - making process, it makes one of the first attempts to open the black - box of

the RTDI policy - making process and provides the framework to discover the network of governance which shapes the RTDI policy - making process, formulates the contents of RTDI policies, and influences the appropriateness of RTDI policies and their appropriateness on the development of NSTIS. In other words, the conceptual framework enables us to link the three variable of the thesis together: RTDI policy - making process---the contents of RTDI policies---the appropriateness of RTDI policies on the development of NSTIS.

### **8.3 The main contributions of the thesis**

We set up two original and fundamental concepts in the thesis, the conceptual framework of the RTDI policy - making process and the concept of NSTIS. Moreover, we not only linked the two concepts together, but also applied the two concepts for the analysis of the Taiwanese biotechnology and related sectoral policies. The conceptual contributions and the empirical contributions of the thesis are discussed in detail below.

#### **8.3.1 The conceptual contributions**

We set up the conceptual framework of the RTDI policy - making process which opens the black-box of RTDI policy - making and the concept of NSTIS which defines the configuration of the three innovation systems. Through linking the two fundamental concepts together we actually initiate a new approach to understand and analyze the RTDI policies. There are three conceptual contributions of the two concepts established.

Above all, we build up the fundamental bridge between political science and the approaches of innovation systems. On one hand, as we have described in section 2.3, the literature of comparative politics, such as Almond et al

(1996) and Hague and Harrop (2008), never links their research to the research of RTDI policies and the approaches of innovation systems. Although some political scientists in the sub-discipline of public administration, such as the scholars of network governance approach (Jansen, 1991), the scholars of the public management (Braun, 2008), and the scholars of interest group and scientists research (Inzelt, 2008; Landers and Schgal, 2004; Tournon, 1993), apply the different approaches of public administration to the analysis of RTDI policies, they do not systematically link their research to the approaches of innovation systems. On the other hand the scholars of innovation systems do not systematically involve the research of political science in the research of innovation systems. Yet, through the conceptual framework of the RTDI policy - making process and the concept of NSTIS, we explore the linkage between the different sub - disciplines of political science and the approaches of innovation systems. We demonstrate that the research of political science is able to deepen the research of innovation systems.

Second, we link the different strands of the political science together for the analysis of RTDI policies. The conceptual framework of the RTDI policy - making process reveals that the government is not a unified entity, but the core of the political system, which is composed of institutions and actors. The government is embedded in the network of governance. RTDI policies are produced and shaped through the dynamic interactions between different actors inside and outside the government. Through uncovering the black-box of the policy - making process we clearly identify the polity and politics underlying the RTDI policies. A RTDI policy may be promoted because of the political incentives, such as departmental egoism of elected politicians, the pressures from voters or the lobbying activities of interest groups. Our conclusion echoes Flanagan et al (2010) that the rationale of RTDI policies in reality is decided through the interactions of multiple

actors at multiple levels. However, we have further explained the different modes of interaction between different actors in different stages of RTDI policies.

Furthermore, the new concept of NSTIS integrates the key concepts of the approaches of the three innovation systems and inspires the new perspective of the analysis of RTDI policies. We extend the nice picture of Makard and Truffer (2008) and further define the configuration of the three innovation systems as the national, sectoral and technological innovation systems (NSTIS). The concept of NSTIS inspires the new research for the dynamics of the knowledge base, the networks of actors, and the products of the configuration of the three innovation systems. Moreover, the concept of NSTIS also initiates the new perspective to understand the role of the governments and RTDI policies in the national development. As we have detected in section 2.2.1, the existing literature of the national innovation systems, such as Freeman (1987) and Nelson (1993), assumes that the role of the government in the national development is to promote RTDI policies to foster the development of the overall national innovation system. Yet, through the concept of the NSTIS, we understand that there are different NSTIS within the national border and the RTDI policies which concern the overall national development or fit one particular NSTIS do not necessarily fit the development of another. The new roles of the government are to sophisticatedly promote different RTDI policies which appropriately match the development of the different NSTIS. Instead of promoting one set of policies which fit the overall national innovation system, the new RTDI policies should be customized to deliberately match the different intersections of a particular sector and a particular technology within a particular national border. After being implemented, the RTDI policies should be evaluated by their appropriateness on the NSTIS rather than on the overall national innovation system. The government, under the context

of NSTIS, should thoroughly understand the uniqueness and the dynamics of a particular NSTIS before making policies. The establishment of consensus between the actors inside the government and between the government and external stakeholders is important to gain sufficient understanding towards the development of NSTIS. The RTDI policies copied from foreign countries or copied from another national sector and technology are very difficult to be effective and generate appropriate support.

In summary, through the conceptual framework of the RTDI policy - making process and the concept of NSTIS, we tend to provide new perspectives to understand the RTDI policies. We judge the roles of the government and RTDI policies from the perspective of NSTIS and provide the conceptual framework which shows the process to make consistent and appropriate RTDI policies to foster the development of the particular NSTIS. The understanding of the four variables which influence the RTDI policy-making process and the development of NSTIS would indeed help us to improve the consistencies and appropriateness of future RTDI policies. For example, while making policies, both elected politicians and administrators should pay attention to the possible difficulties of horizontal coordination and avoid the problems of horizontal coordination beforehand. In other words, our new perspective may contribute to the analysis of RTDI policies in the future.

### 8.3.2 The empirical contributions

The thesis also has two contributions to the empirical literature, which are the empirical contributions to the research of biotechnology and to the empirical research of Taiwan. Each of the empirical contributions is introduced below.

First, we analyze the development of biotechnology through the concept of NSTIS. On one hand, we explore the dynamic intersection between biotechnology and different sectors and echo the literature, such as Brink et al (2004) and Senker et al (2004), that modern biotechnology is adopted by several sectors and developed with plural sectors. On the other hand, we echo the existing literature, such as Senker et al (2000) and Geseisk (2000), which supports the view that governments' policies play important roles in shaping the development of biotechnology of the nation. However, we extend the analysis of existing literature. From the perspective of NSTIS, we consider that biotechnology policies need to be sensitive to the distinctive dynamics of different sectors. The biotechnology policies should be tailored from sector to sector because the policies that match the dynamics of one sector may not match another. Before the governments make the biotechnology policies, they should fully understand the dynamics of the different biotechnology related NSTIS of the country and coordinate policies to be consistent and appropriate through the policy - making process in order to match the development of a particular biotechnology related NSTIS.

In addition, we explore the case of Taiwan through the lens of NSTIS and RTDI policy - making process. As we have described in section 2.4.2, although the existing literature, such as Dogson et al (2008) and Wong (2005), provides some initial discussion about the development of biotechnology and the biotechnology policies in Taiwan, it considers the biotechnology in Taiwan as one sector. Through the perspective of NSTIS, we explore the dynamics of biotechnology and related sectors in the country. Taiwan in fact develops biotechnology and related sectors in very unique ways. Moreover, through the conceptual framework of RTDI policy - making process, we open the black-box of policy - making process and



further analyze the influence of the policy - making process on the consistencies and appropriateness of biotechnology and related sectoral policies in Taiwan. The insights into the case of Taiwan may inspire the research of the biotechnology development in the country and other East Asian countries in the future.

#### **8.4 Suggestions for future research**

This thesis has both the conceptual and empirical contributions of the existing literature. However, through the research carried out we also recognize some limitations of this thesis which need to be addressed by future research.

First of all, we only apply the conceptual framework of the RTDI policy - making process and the concept of NSTIS for the analysis of the Taiwanese biotechnology and related sectors and policies, and we adopt the qualitative method. In order to generalize the conceptual framework and the concept of NSTIS, we need more internationally comparative studies with broader methodologies to further explore the two closely related concepts.

Second, we are only able to analyze the influence of the RTDI policy - making process on the appropriateness of RTDI policies. Empirically we are only able to observe the appropriateness of the two cases in the period from 2000 to 2008. However, we are unable to analyze at this moment how the policy - making process of the two policies influences their effects and the effectiveness in the long-term. The influence of the RTDI policy - making process in the long-term needs research in the future to further explore it.

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